# **SWOG Specimen Tracking System**

## Instructions for Labs/Repositories

### Introduction

Nearly all clinical trials performed by the SWOG require the collection, transfer, and analysis of various kinds of biological specimens. Therefore, SWOG has developed a web-based tool called the Specimen Tracking System to assist with the tracking of specimens. Laboratories and repositories that receive specimens for SWOG studies are required to use this application to log the receipt of those specimens.

## **Vocabulary**

For the purposes of this document, and of the Specimen Tracking System, "specimen" refers to a material extracted from a patient such as tissue, blood, or marrow. A single "specimen" may have multiple units, which are indicated by "quantity". A specimen may also be "derived" which indicates that it has been cut, split, aliquotted, or otherwise been made from another specimen. Tests performed on specimens are referred to as "assays".

## **Features of the Specimen Tracking System**

The Specimen Tracking System is an interactive online application used by institution personnel who treat patients on SWOG studies, as well as the labs and repositories that receive those patients' specimens. The system allows labs and repositories to indicate the receipt of specimen shipments, to indicate if those specimens have been derived and/or shipped to other labs, and for selected studies, to enter the results of specimen assays.

Receiving labs/repositories use the system for the following purposes:

- To log receipt of specimens. This includes indicating the date and time of receipt and the condition of each specimen.
- To indicate when received specimens are derived.
- To assemble shipments to receiving labs/repositories.
- To enter assay results for specimens that determine real-time protocol decisions such as eligibility, stratification
  and treatment (selected studies only).
- To approve and sign assay result reports, where required (selected studies only).

Institutions who send specimens use the system for the following purposes:

• To identify ("log") individual specimens that will be sent (patient's SWOG ID number, date and time of collection, specimen type, etc.). In addition, study- and specimen-specific questions may be asked. These questions and answers are visible to the receiving lab/repository.

7/29/2014 Page 1 of 17

- To assemble shipments to receiving labs/repositories. This includes printing a packing list of all specimens in a shipment and address information for the receiving lab/repository. Look for this packing list in your shipments, as it will contain important information.
- To update answers to specimen consent questions as necessary. These answers are visible to the receiving lab/repository.
- To access reports of protocol decisions such as patient eligibility, stratification or treatment plan, based on assay results that have been entered by labs, when required for use in real-time protocol decision-making.

#### General features of the Specimen Tracking System:

- Specimens are all uniquely identified by a number generated by the Specimen Tracking System. In addition, specimens can be identified by local ID numbers (e.g., pathology numbers) and by accession numbers assigned by the receiving labs/repositories.
- Receiving labs/repositories can choose to receive automatic email notices when specimens are shipped, and the
  sending institutions can choose to receive automatic notices when shipments are received. Senders and receiving
  labs/repositories also receive automatic emails when specimens that have been shipped are not received within
  three days.
- The system has separate "Test" and "Production" versions. Users can access the "Test" version of the system in order to learn how it operates and practice using its capabilities. The "Production" version should only be used for real data.

# **Accessing the SWOG Specimen Tracking System**

The SWOG Specimen Tracking System can be accessed by any Internet Explorer browser at <a href="https://crawb.crab.org/SpecTrack/Logon.aspx">https://crawb.crab.org/SpecTrack/Logon.aspx</a>. Access for all users requires a SWOG Roster ID Number and password. To obtain a SWOG Roster ID and password, complete the "Laboratory Request for SWOG Roster ID" form, found on the "Administration" page within Specimen Tracking and fax it to the number on that form. The Membership Specialist at the Operations office will call that person with their SWOG Roster ID Number and initial password.

The form asks for your "lab number." This is the number assigned to your lab/repository by SWOG. If your lab is not yet registered with SWOG, or you do not know the number, please call the Operations Office at (210) 614-8808 to obtain this information.

If you have any questions about Roster ID Numbers or passwords, or registering your lab with SWOG, contact the Membership Specialist at (210) 614-8808.

## **Questions and Comments**

We welcome questions and comments! Please email us at <u>technicalquestion@crab.org</u>. Other ways to contact us are listed on the "Contact Us" page.

7/29/2014 Page 2 of 17

# Using the SWOG Specimen Tracking System

# **Logging On**

To access the system, go to this address in your Internet Explorer web browser

#### https://crawb.crab.org/SpecTrack/Logon.aspx

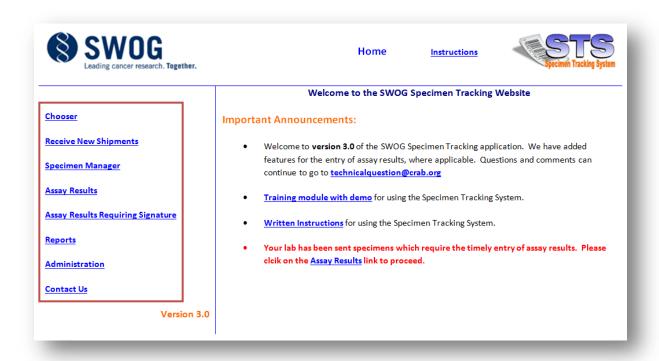
Please note that the Specimen Tracking System only supports an Internet Explorer (IE) web browser.

- 1. Enter your assigned SWOG Roster ID Number and Password.
- 2. If you are using the system for practice, be sure to click on the "Test Application" button. This will redirect you to the logon page for the test system. You may logon using the same username and password.
- 3. If you have more than one role in SWOG, e.g., if you work in a lab/repository and are a CRA, or if you are associated with more than one lab or repository, you will be asked to identify the institution or lab/repository for which you are using the system. If you are only associated with a single lab/repository, you will skip this step.

## **Home Page**

The Home page includes general announcements, links to instructions and demos, and alerts when specimens require assay result entry, or require an approval signature.

From the Home page, you will see a navigation bar on the left-hand side.

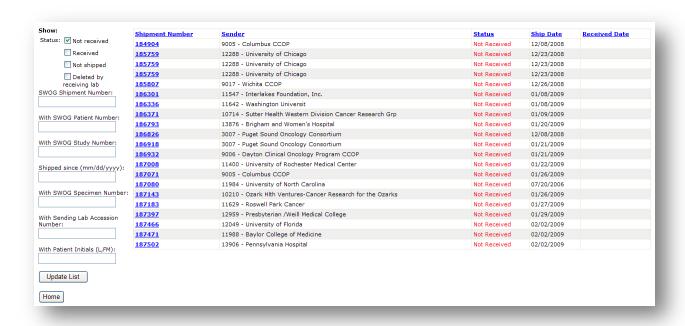


7/29/2014 Page 3 of 17

All of your work within the Specimen Tracking System will be done from one or more of these navigation bar links. All labs and repositories receiving shipments for SWOG studies will use the "Receive New Shipments" page. Selected labs and repsitories will use other pages.

## **Receive New Shipments**

When you click on "Receive New Shipments", you will be taken to a page similar to this:



This page lists all shipments that have been sent to your lab/repository. By default, only shipments that have not been received are shown. Use the parameters in the left-hand column to find the shipment you want to receive.

#### Tips:

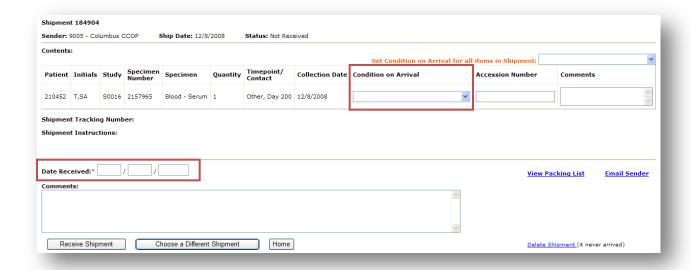
- If you have a barcode scanner, you can use it to input any of the parameter values. Make sure the cursor is in the correct box, and then scan.
- You may sort the list by clicking on the column headers.

When you find the correct shipment, click on the **Shipment Number**.

On the next page, select a **Condition on Arrival** for each specimen and **Date Received** for the shipment. **Condition on Arrival** refers to the general usability of the specimens as they arrived. This does **not** refer to the expected histological significance, or other attributes that may become clear after assays are run.

Optionally, you may enter accession numbers, specimen comments or shipment comments. Click the **Receive Shipment** button when you are done to save your work.

7/29/2014 Page 4 of 17



#### Tips:

- If there are many specimens in the shipment, and most or all have the same condition, use the "Set Condition on Arrival for all items in Shipment" drop-down box to prefill the condition for all the specimens in the shipment.
- Click the "View Packing List" link to view the packing list for this shipment, in case one was not included by the sender. This will include helpful information about the intended use of the specimen.
- Click the "Email Sender" link to start an email to the person who logged the specimen, if there are questions.
- If Condition on Arrival cannot be completed upon receipt of shipment, it should be completed as soon as the information is available.
- All shipments sent to your lab can be accessed through the "Receive New Shipment" link (on the Home page) at
  any time. You can always make changes to shipments you've already received, just make sure to click the Save
  Changes button.
- If you log the receipt of a shipment in error, you can remove the Date Received, but only while the specimens in that shipment remain un-derived and in your control (not shipped to another lab).
- If you never received the shipment, and you never expect to, you may delete the shipment by clicking the "Delete Shipment" link. These are still accessible by selecting the Deleted checkbox on the parameters page, and may be un-deleted if necessary.

7/29/2014 Page 5 of 17

## **Specimen Manager**

The Specimen Manager page is your primary portal to view and act on individual specimens. This includes

- viewing specimen-specific data
- editing local accession numbers
- deriving specimens
- shipping specimens to another lab/repository.

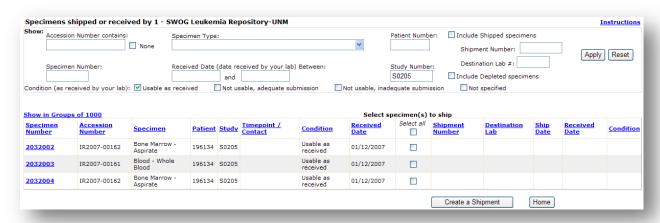
What you can see and do depends on the location of the specimen. You may *view* any specimen that was received by your lab/repository, even if it has since been depleted or shipped somewhere else. However, you may only *act on* specimens that are physically at your lab/repository. This means you cannot edit, derive, or ship a specimen unless it has been received by you and has not been shipped anywhere else or depleted.

#### Specimen Manager Display

Specimen Manager lists all specimens "received" by your lab/repository. "Received" means that a Date Received was entered and saved in the Receive New Shipments page. Specimen Manager will not list any specimens that were received with a condition of "Missing".

A Lookup Tool at the top of the page can be used to enter and apply filter criteria to the list. Specimen Manager will only show "Usable as received" by default. To see other specimens, select those Condition boxes. Note that derived specimens will have a null condition by default and will not show up unless "Not specified" is selected.

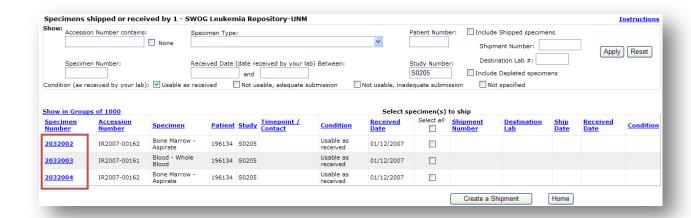
The list will display in groups of 200 by default. To see 1000 specimens at a time, click the "Show in Groups of 1000" link. The list may also be sorted by clicking on the column headers.



#### View or Act On an Individual Specimen

Each Specimen Number in the list is a hyperlink to the Specimen Page for that specimen. From the Specimen Page, you may view specimen-specific data, add or edit accession numbers, and derive the specimen. See Specimen Page below for more details.

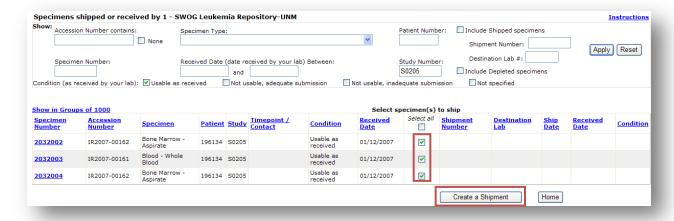
7/29/2014 Page 6 of 17



#### **Using Specimen Manager to Assemble a Shipment**

A specimen is available to ship if it is currently residing at your lab/repository and is not depleted. Any specimen that is available to ship will have a checkbox visible in the row for that specimen. Use the Lookup Tool to find the specimen(s) you wish to ship, check the boxes for those specimens, and click the "Create a Shipment" button at the bottom of the page. This will assign a Shipment Number to the shipment and take you to the Ship a Shipment page. See Ship a Shipment below for the next steps.

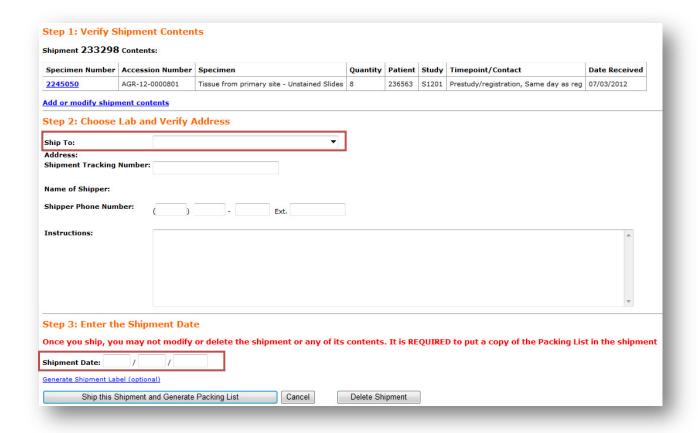
Note that specimens on this page refer to the full quanity that applies to each specimen. If some quantity less than that needs to be shipped, the specimen will need to be derived first.



#### Ship a Shipment

After you select specimens for shipment in the Specimen Manager page (see above), there are three steps to indicate that the shipment has been mailed. All three steps appear in the same page.

7/29/2014 Page 7 of 17



#### **Step 1: Verify Shipment Contents**

Make sure the specimens listed are the ones that will be included in the shipment. If you have any changes, click Add or Modify Shipment Contents. This will return you to the Specimen Manager page to select and deselect the correct specimens.



#### Step 2: Choose Lab and Verify Address

Select the receiving lab from the drop-down list. This will display the address(es) for that lab. If there is more than one address, select the one that is most appropriate. You may optionally add the Shipment Tracking Number and/or Instructions for the receiving lab as well.

7/29/2014 Page 8 of 17



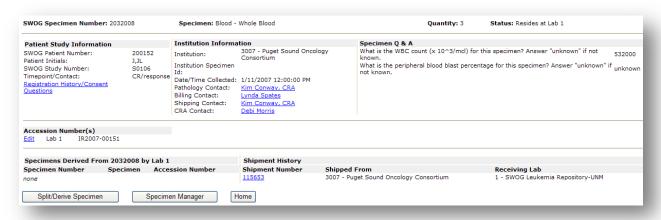
#### Step 3: Enter the Shipment Date

Finally, enter a Date Shipped and click the "Ship this Shipment and Generate Packing List" button. Note that you once you have clicked this button, the shipment and its specimens are considered "in-transit" and no longer in your possession. You will not be able to make changes to the specimens or the shipment after this step is completed. If desired, a Shipment Label is available for use.



#### Specimen Page

Clicking a specimen number on the Specimen Manager page will lead you to the Specimen Page for that specimen. This page will display information about the specimen as is available and appropriate.



7/29/2014 Page 9 of 17

#### **Header Information**

The top of this page will display the SWOG Specimen Number, the Specimen Type, the Quantity and the Status of the specimen.

- The SWOG Specimen Number is the number assigned by the Specimen Tracking system when the specimen was first logged or derived.
- The Specimen Type and Quantity was assigned by the user who logged or derived the specimen.
- The Status indicates the current location of the specimen (according to the SWOG database). A specimen may be in-transit, residing at a particular lab, or depleted.

If the specimen was derived from another within Specimen Tracking, a link to the Parent Specimen will also appear in the header section.

| SWOG Specimen Number: 2032008 | Specimen: Blood - Whole Blood | Quantity: 3 | Status: Resides at Lab 1 |
|-------------------------------|-------------------------------|-------------|--------------------------|
|                               |                               |             |                          |

#### **Patient Study Information**

The Patient Study Information section will display details about the patient and study registrations, including the SWOG Patient Number, Patient Initials, SWOG Study Number, Timepoint/Contact, and a link to the patient's registration history and specimen consent questions and answers.

- The SWOG Patient Number is the unique identifier assigned to the patient by SWOG.
- The SWOG Study Number was entered by the user when the specimen was first logged. Derived specimens will assume the Study Number of the parent specimen.
- The Timepoint/Contact was chosen by the user when the specimen was first logged. This will be a timepoint like
  "Prestudy" or "Response" for therapeutic studies, and the contact number for SELECT. This information does not
  display for derived specimens.
- The Registration History/Consent Questions link will display a page with that information. This information does not display for derived specimens.

| Patient Study Information   |  |
|---|--|
| SWOG Patient Number: Patient Initials: SWOG Study Number: Timepoint/Contact: Registration History/Consent Questions | 200152<br>J,JL<br>S0106<br>CR/response |

7/29/2014 Page 10 of 17

#### **Institution Information**

The Institution Information Section will display details about the institution that the specimen originated from. This section does not apply to specimens which are derived.

- The Institution Specimen ID is the local specimen number (i.e. pathology number) and is optionally entered by the user logging the specimen.
- The Date/Time Collected is when the specimen was collected from the patient. Time is optional and will default to Noon (12:00pm) if not entered by the user logging the specimen.
- The Pathology, Billing, and Shipping contacts are all optionally entered by the user logging the specimen. If present, these hyperlinks will lead to the person's phone number and/or email address as available.
- The CRA Contact is a link to the person who logged the specimen.

#### Institution Information

Institution: 3007 - Puget Sound Oncology

Consortium

Institution Specimen

Id:

Date/Time Collected: 1/11/2007 12:00:00 PM Pathology Contact: Kim Conway, CRA

Billing Contact: Lynda Spates
Shipping Contact: Kim Conway, CRA
CRA Contact: Debi Morris

#### Specimen Q&A

The Specimen Q&A section will display specimen-specific questions as defined by the study set-up, and answers to those questions as entered when the specimen was logged. Specimen Q&A will only appear for those specimens where it applies.

## Specimen Q & A

What is the WBC count (x 10^3/mcl) for this specimen? Answer "unknown" if not known.

What is the peripheral blood blast percentage for this specimen? Answer "unknown" if unknown not known.

7/29/2014 Page 11 of 17

#### Accession Number(s)

The Accession Number(s) section will display your lab's accession number, and the accession number(s) of the lab it came from and the lab it was shipped to, as they apply. To add or edit the accession number for your own lab, click "Edit", type in the number, then "Save" to save.

| Access      | ion Nun | nber(s)      |  |
|-------------|---------|--------------|--|
| <u>Edit</u> | Lab 1   | IR2007-00151 |  |

#### Derived Specimen(s)

The Derived Specimen(s) section will display any specimens that have been derived from this specimen. Each derived specimen will have been assigned its own Specimen Number, which will be a link to that specimen's Specimen Page. The Specimen Type, and Accession Number are also shown. To derive new specimens, click the "Split/Derive Specimen" button. See Split/Derive a Specimen below for the next steps.

| Specimens Derived From 2032008 by Lab 1 |                         |                  |  |
|---|-------------------------|------------------|--|
| Specimen Number                         | Specimen                | Accession Number |  |
| 2055936                                 | Blood - Buffy coat -70C | IR2007-00151-1   |  |

#### **Shipment History**

The Shipment History section will display information about where the specimen came from, and where it was shipped to. The Shipment Number hyperlink will display the shipment page for that specimen. If the Receiving Lab is not your own, it will be a hyperlink to information about that lab.

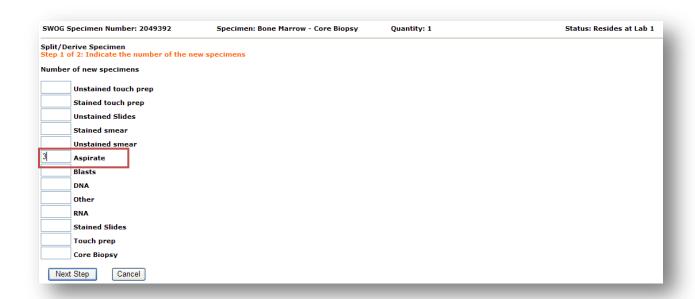
| Shipment History |  |                                  |
|------------------|--|----------------------------------|
| Shipment Number  | Shipped From                           | Receiving Lab                    |
| 115653           | 3007 - Puget Sound Oncology Consortium | 1 - SWOG Leukemia Repository-UNM |

#### Split/Derive a Specimen

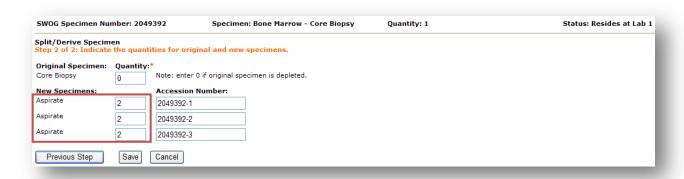
After clicking the Split/Derive Specimen button on the parent specimen Specimen page (see Derived Specimens above), you will be taken through a 2-step process to derive the specimen. In the example below, the user takes a Bone Marrow – Core Biopsy specimen and derives it in to 3 Aspirates of 2 tubes each.

In **Step 1 of 2**, indicate the number of new specimens created and click Next Step. The derived specimen types offered will depend on the parent specimen type.

7/29/2014 Page 12 of 17



In **Step 2 of 2**, the derived specimen type will be repeated for each number of new specimens being created. In this example, three times. Indicate the revised quantity for the parent specimen (0 if now depleted), the quanity for each new specimen, and click Save. Accession numbers may be added at this point as well.



After clicking Save, you will be redirected to the parent Specimen Page, which will now display the derived specimens. You may access the Specimen Page for each of these derived specimens by clicking on those hyperlinks. These specimens will also now appear in the Specimen Manager page.



7/29/2014 Page 13 of 17

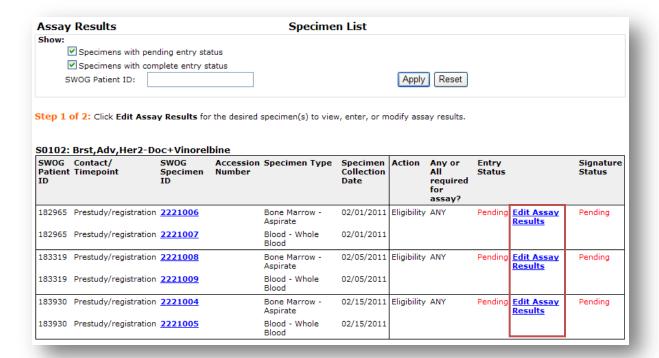
## **Assay Results**

The SWOG Specimen Tracking System allows lab personnel to enter assay results for specific protocols that require results for a real-time protocol decision such as eligibility, stratification or treatment. When assay results have been entered, the appropriate Statistical Center and Institution staff will be automatically notified that they can access reports describing the protocol decisions based on those results. For assay results that require an approval signature, the system provides a means to capture an electronic signature, and the resulting protocol decisions will not be communicated until the signature is obtained.

Only specimens that have been logged by the institution (with or without being shipped) will be listed. A filter allows you to show specimens based on entry status and/or SWOG Patient ID. By default, all specimens with pending entry status will display.

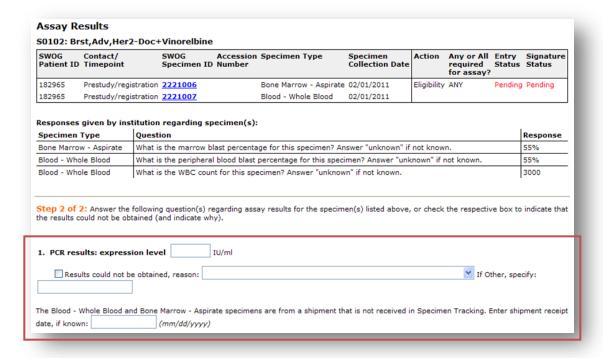
#### For each set of specimens:

- "Action" refers to the type of decision that is based on the assay result.
- "Any or All required for assay" refers to sets of more than one specimen. If "ANY", the decision can be made based on the assay result of any of the logged specimens. But, if "ALL", then all specimens need to be logged for the assay result to be entered.
- "Entry Status" = Pending if assay results need to be entered, and Complete if assay results have been entered.
- "Signature Status" = Pending if the assay results have not been signed off yet, Complete if they have been signed off, and Not applicable if the results do not require a signature. Results cannot be signed until they have been entered. See the Assay Results Requiring Signature report.



7/29/2014 Page 14 of 17

For **Step 1 of 2**: Click the "Edit Assay Results" link to enter results for that specimen(s). This page will list the selected specimen(s), answers provided by the treating institution to any specimen-specific questions, and the assay results data to be collected.



For **Step 2 of 2**: Enter the requested assay result data. If the assay could not be performed for some reason, please check the "Results could not be obtained" check box, and select the most applicable reason. This will satisfy the entry requirement, unless the reason is "Specimen(s) not received yet".

The above screen shot depicts an example in which the shipment with the listed specimens has not yet been logged as received by the lab. For your convenience, you may enter the shipment receipt date here, rather than going back to the Receive New Shipments page.

Assay results can always be changed after they are entered. Just re-click the "Edit Assay Results" link, make your changes, and click the **Save Changes** button.

| tep 2 of 2: Answer the following question(s) regarding assay results for the specimen(s) listed above, or check the respective box to indicate that the results could no e obtained (and indicate why).  Responses successfully saved 2/24/2011 11:16:10 AM by Angela Smith.   | it |
|--|----|
| . WBC 10000 g/DL   |    |
| Results could not be obtained, reason:   | ]  |
| 2. Histology Other   |    |
| Results Adenocarcinoma Other If Other, specify:  | ]  |
| Small cell Squamous cell Squam |    |
| Save Changes Cancel Home   |    |

7/29/2014 Page 15 of 17

## **Assay Results Requiring Signature**

The Assay Results Requiring Signature report lists specimens that have had assay results entered and require an approval signature before the institution is notified of the results. If assay results had been changed, the history of the changes will also be listed.

Only users with authorization to sign this report will see the Electronic Signature field. Each patient listed will have a separate field to enter the electronic signature, or for convenience, a single electronic signature can be applied at the bottom of the report to cover all results listed.

To obtain an electronic signature, complete the "Electronic Signature Authorization Form", found on the "Administration" page within Specimen Tracking and fax it to the number on that form. The Membership Specialist at the Operations office will call that person with their electronic signature.

Once signed, the results will no longer appear on this report, but will still be visible in the Assay Results page. If any changes are made to the result after signature, a new signature will be required (even if the interpreted result does not change).



# **Reports**

The Reports Page offers two reports: Assay Results Requiring Signature, and Patient/Participant Information.

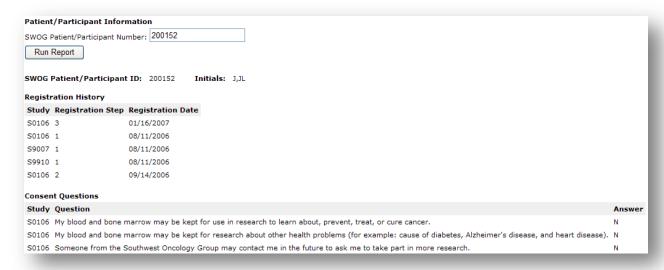
**Assay Results Requiring Signature** 

See above.

**Patient/Participant Information** 

7/29/2014 Page 16 of 17

Type in a SWOG Patient Number, and this Patient/Participant Information report will display the registration history and specimen consent questions and answers, as available.



### Administration

Click on the "Administration" link, then the "Setup Email Notification" link to setup automatic email notification when an institution or lab/repository has sent you a shipment, or when assay results are ready for signature. You may list multiple addresses in either box, separated by a semi-colon.

If you do not want to receive notifications when shipments are sent, simply leave the first box blank. The second box must contain at least one valid email address.

| Email addresses for Lab 93 - SWOG ALL/CLL/CML Repo  | ository-FHCRC               |  |  |
|---|-----------------------------|--|--|
| This page is used to maintain email addresses that receive automatic notifications from the Specimen Tracking System.   |                             |  |  |
| 1. Notify these email addresses when an institution indicates that a shipme lab/repository named above:                 | ent has been shipped to the |  |  |
| labstaff1@lab.com; labstaff2@lab.com  |                             |  |  |
| Separate multiple emails with a semi-colon (;)  |                             |  |  |
| 2. Notify these email addresses when the lab/repository named above has require an approval signature:  labguru@lab.com | entered assay results that  |  |  |
| Separate multiple emails with a semi-colon (;). At least one email address is required.                                 |                             |  |  |

7/29/2014 Page 17 of 17