Theradex Specimen Tracking System (STS) User Guide
Version 6 (November 2024)

THERADEX ONCOLOGY

Contents

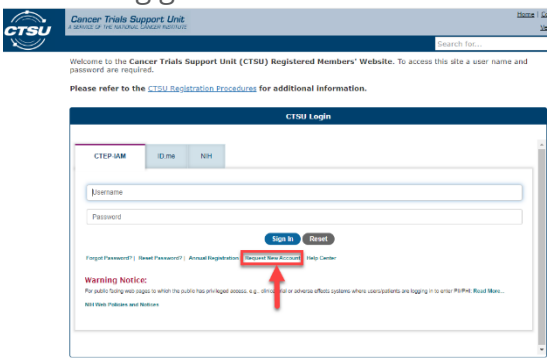
Access

Access to your study in Rave is overseen by CTSU and is granted based on the role assignment in the roster (and protocol DTL if applicable) for your site. You will need to contact your site's RSS or DTL administrator to request the addition of your name on the roster. Information on new Rave accounts is in the protocol (section 4 for protocols that use the newest CTEP template). Please contact the CTSU Help Desk for more assistance CTSUContact@Westat.com

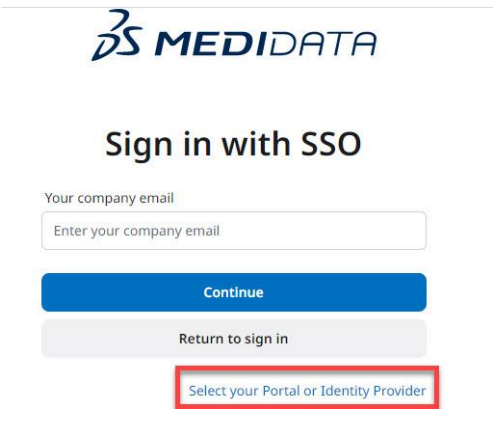
The Theradex Specimen Tracking System is integrated within a study in Rave. Contact your RSS or DTL site administrator or CTSU to ensure you are on the site roster for your study with the role of **Rave Clinical Research Associate** (CRA) for each protocol you need to enter data. For protocols that require a DTL: A staff member who is on the roster as Rave CRA but not on the DTL will only receive an invitation of Read Only. Once they are on the DTL, CTSU will send the Rave CRA invitation.

CTEP-IAM and Rave Account Setup

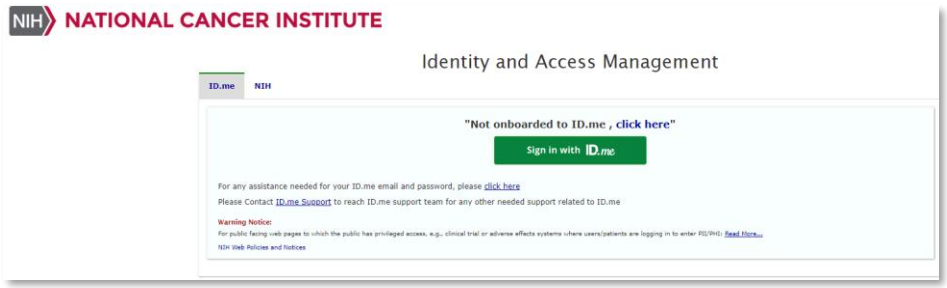
All individuals are required to have an active CTEP-IAM account prior to being granted access to Rave. To create a CTEP-IAM account, proceed as follows:



1. Go to the following URL: https://www.ctsu.org/public/default_login.aspx
2. Under the buttons, click **Request New Account**. This will take you to the CTEP-IAM page.
3. Follow the prompts to enter the required identifying information for your account. Choose the Associate Plus application
4. You will receive an authorization email in **24-48 hours**.
5. After receiving the CTEP-IAM authorization (which may take up to 48 hours), *documentation must be uploaded to the CTEP Registration and Credential Repository (RCR) to complete your registration*.
6. After these steps are completed, go to the following URL: https://login.imedidata.com/login
7. Click on **Sign in with SSO**
8. Click on **Select your Portal or Identity Provider**

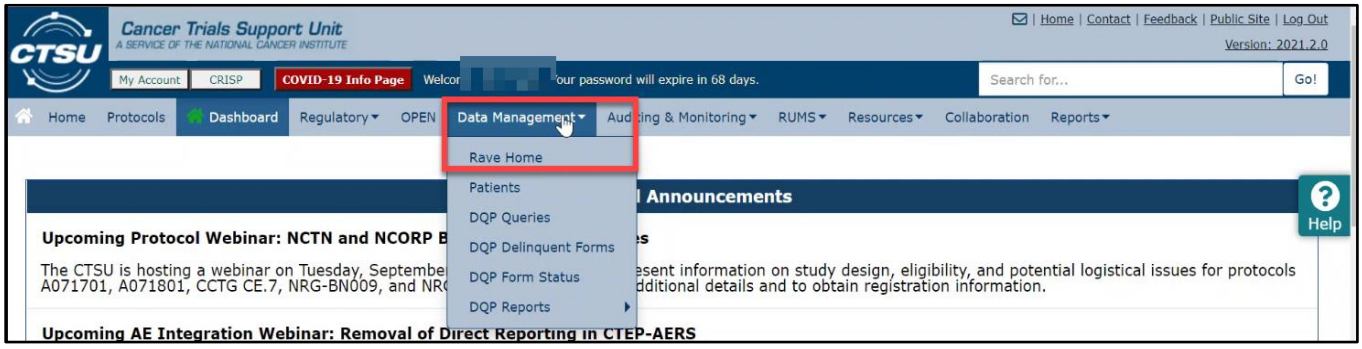


9. From the menu, choose **CTEP-IAM IdP**.
10. Click **Select**
11. At the NCI Identity and Access Management (IAM) screen, enter your **ID.me** credentials.



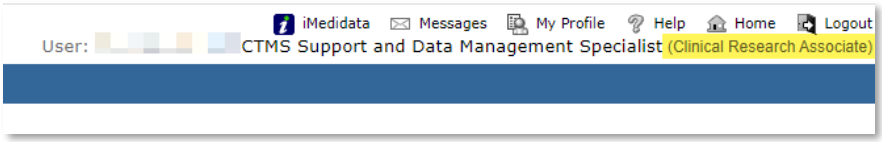
Logging in through CTSU

1. Go to the following URL: https://www.ctsu.org/Public/Default.aspx
2. Click **Log in.**
3. At the NCI Identity and Access Management (IAM) screen, enter your **ID.me** credentials.
4. Click **I agree and logon**.
5. Go to the **Data Management** menu.
6. Click **Rave Home**.



Current role in Rave

After logging in to Rave and select your study. If you only have the **Clinical Research Associate** role you will see it next to your name in the top right hand corner of the website after selecting the study.



If your role is Read Only, you will not be able to enter or edit data. The CTSU Help Desk will be able to advise you further on why you do not have Clinical Research Associate access.

If your role is **Clinical Research Associate** and you are working on an older study (10300 and lower), contact STS support as we may need to add the **CRA Specimen Tracking** role to your account

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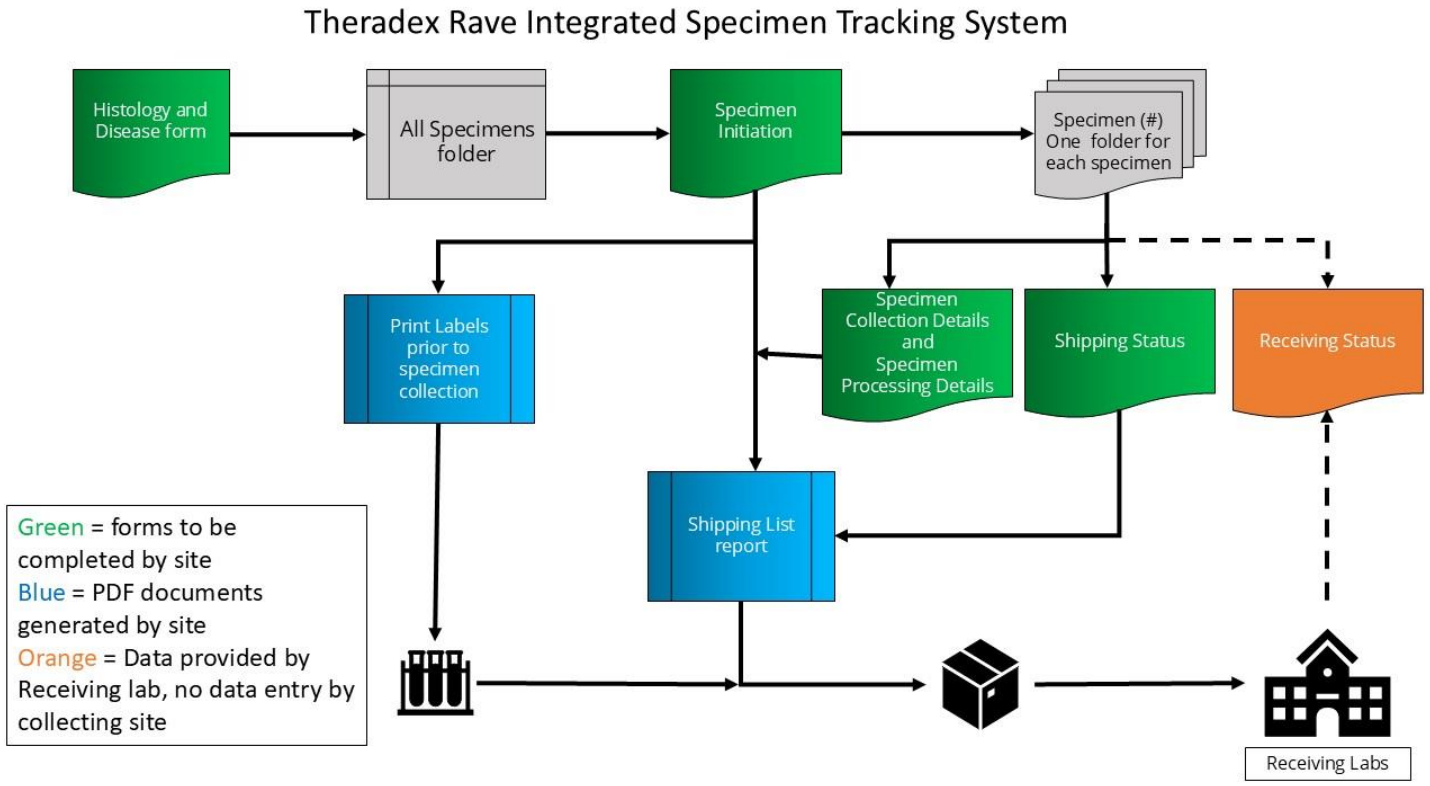
Specimen Tracking System Overview

The specimen tracking system was initially designed in conjunction with the Biopathology Center at Nationwide Children's Hospital. In earlier protocols they were known as the ETCTN Biorepository. Currently they have an NCI contract as the EET Biobank (Early-Phase and Experimental Clinical Trials Biospecimen Bank).

The Specimen Tracking System is made up of several parts. It is important to complete all the specimen tracking forms for every specimen collected from a participant. The system's programming depends on completion of the **Histology & Disease** form found in the Enrollment folder. Be sure this form is completed before entering specimen data. The remaining forms are located in the **All Specimens** folder.

Important – If the **Histology & Disease** form is not completed, the other forms/steps of STS will not function properly



Summary of STS data entry

All steps must be completed prior to shipping the specimen. Hand delivery of specimens within the same institution is considered shipping and completion of all steps is required.

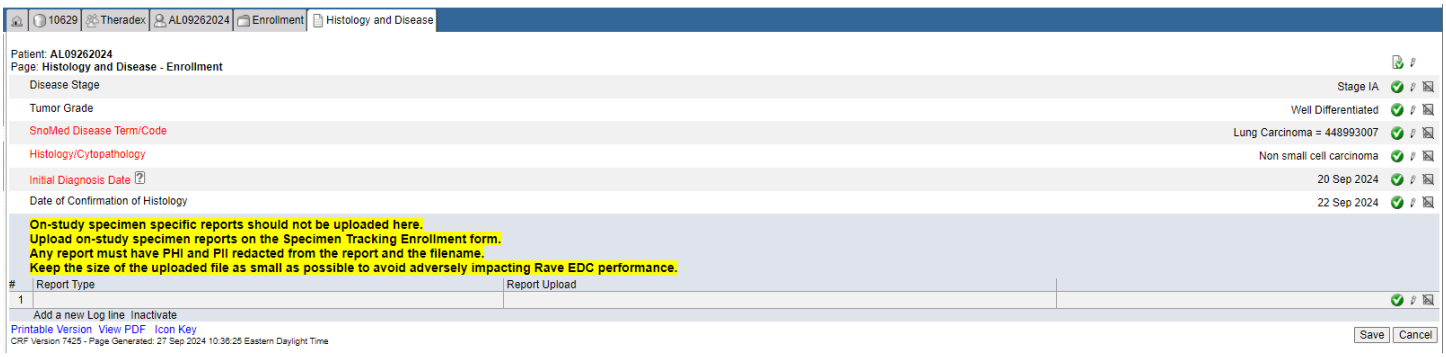
1. Go to **Enrollment** folder and complete the Histology & Disease form.
2. If patient has changed their consent for specimens to be collected and/or stored, update the Consent form.
3. Go to the All Specimens folder.
4. Complete the log line in the Specimen Initiation form for each specimen collected.
5. Complete the Print Labels form. Labels will be sent to the user's email address.
6. Open the **Specimen (#)** folder within the All Specimens folder. The number corresponds to the log line in the Specimen Initiation form. The date and specimen type are also present to help in selection.
7. On the **day of collection**, complete the Specimen Collection Details form.
8. If the specimen is processed, complete the Specimen Processing Details form.
9. When **ready to ship**, complete the Shipping Status form for each individual specimen.
10. Print the Shipping List report to send with the specimens (see page 19). Put the shipping list report and hard copies of relevant pathology reports in the box with the specimens.

Enrollment folder - Histology & Disease form

In the **Enrollment** folder, confirm the **Histology & Disease** form has been completed for the participant.

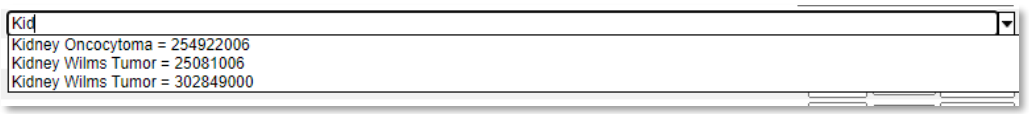
This is the first step in specimen tracking and **ALWAYS** needs to be completed before entering specimen data. Fields in red are required fields.

If all of the information is not known, at minimum, complete the SnoMed field (see information below). The remaining required fields, if blank, will trigger a query after saving but you can proceed to enter specimens and return to finish this form later.



Enter the **Disease Stage** and **Tumor Grade**, if known and applicable. Not all diseases are staged or graded.

Enter the **SnoMed Disease Term/Code**. Start typing in the box and the options will narrow based on what you type.



The SNOMED Disease Term/Code list is a combination of several sources. Some terms may be duplicated, select the first instance in the list.

In the **Histology/Cytopathology** field, briefly transcribe the findings in the pathology report which the patient's diagnosis is taken.

Initial Diagnosis Date is the date of the procedure, pathology report or evaluation used to determine the diagnosis.

In the bottom of the form, the supporting documentation can be uploaded. Use the Edit pencil to open the first row. Select the Report Type. Use the file browser to select the PDF in the Report Upload field. Use Add a New Log line to add any additional documents.

Notes on report uploads:

- The EET Biobank requires a Pathology report for tissue specimens.
- The upload of pathology and other reports depends on the protocol, however if the only samples collected are blood samples, these reports are generally not needed.
- Pathology reports that correspond to samples entered in the Specimen Tracking Enrollment form (i.e., collected on study) are uploaded on that form.
- **Any report must have PHI and PPI redacted from within the report and removed from the filename. Patients' initials are considered PHI, please see list below for other relevant data points.**
- The participant ID and UPID displayed must be included in the report.
- An extra specimen label is an easy way to add IDs onto the report before scanning.

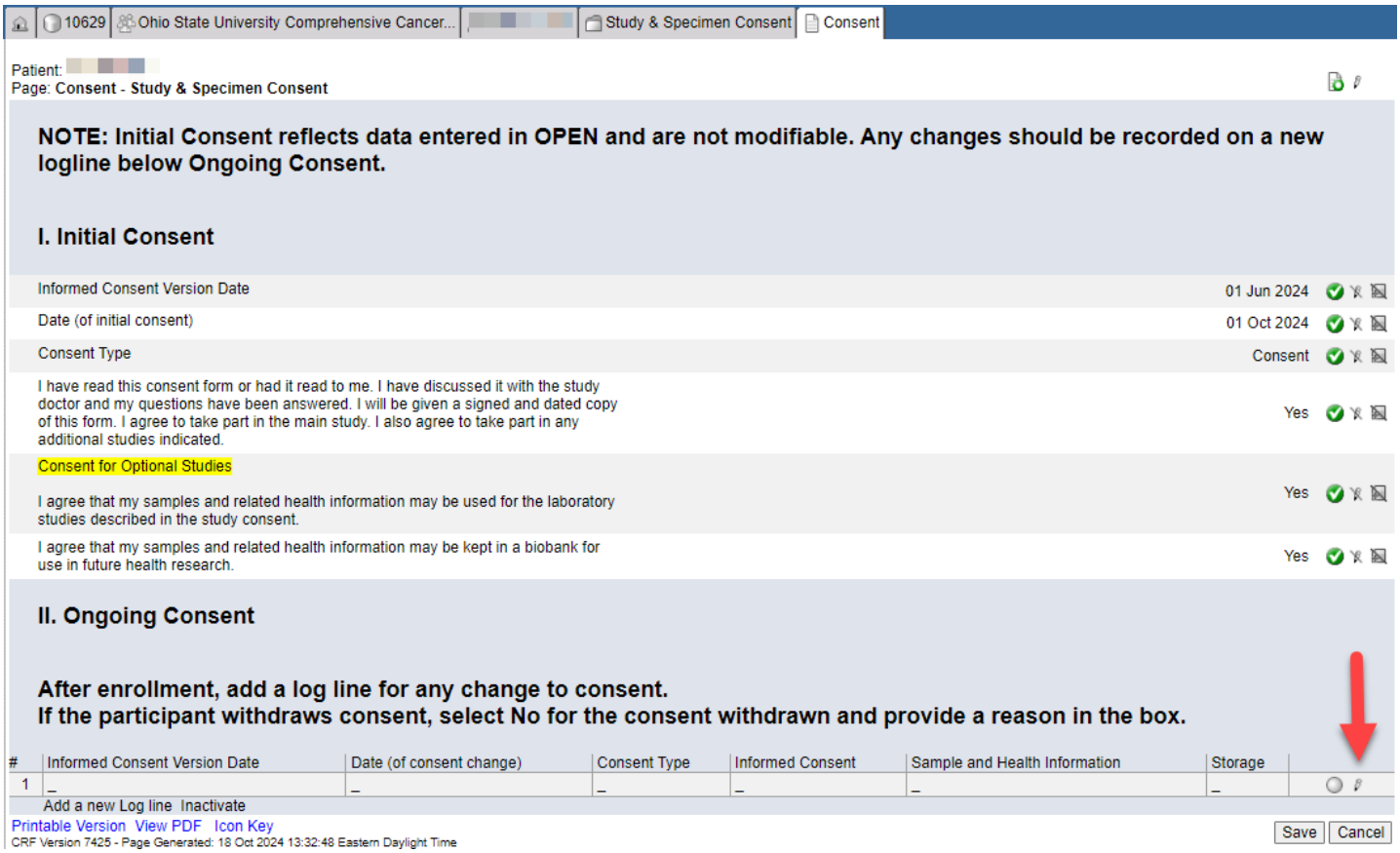
Examples of PHI/PPI

- Names and initials
- Geographic subdivisions smaller than a state (e.g., street address, city, county, etc.).
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URLs
- Biometric identifiers, including finger or voice prints
- Full face photographic images and any comparable images
- Internet Protocol address numbers
- Any other unique identifying number characteristic or code (e.g., DNA)

Consent form

The consent to collect, test, and store specimens is recorded in the combined Consent form in the Study & Specimen Consent folder. This form auto-populates with consent data that is entered in OPEN during registration. The auto populated data cannot be edited. Changes to consent are recorded in the log at the bottom of the form.

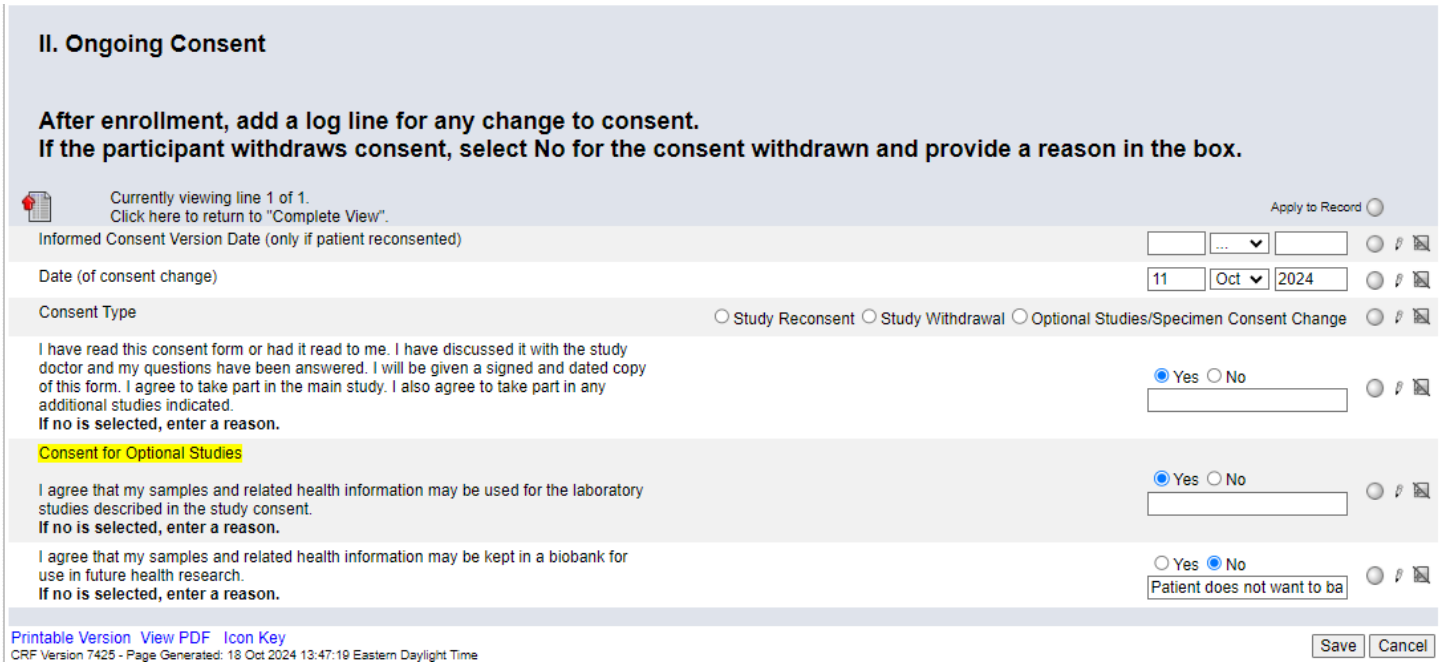
The questions which appear under **Consent for Optional Studies** are specific to each study and may differ from the screen shot below. The steps to complete the form, remain the same.



Informed Consent Version Date: The date of the IC document presented to the participant and which the patient signed.
Date (of initial consent): Date the participant signed the IC document.
Consent Type:
I have read this consent form … : Affirmative statement from IC document. Participant response captured in OPEN.
Samples for laboratory studies … : Participant affirms to have specimens collected and analyzed as described in the IC document.
Samples for future research … : Participant affirms to allow specimens to be stored and used in future research.

Change in consent

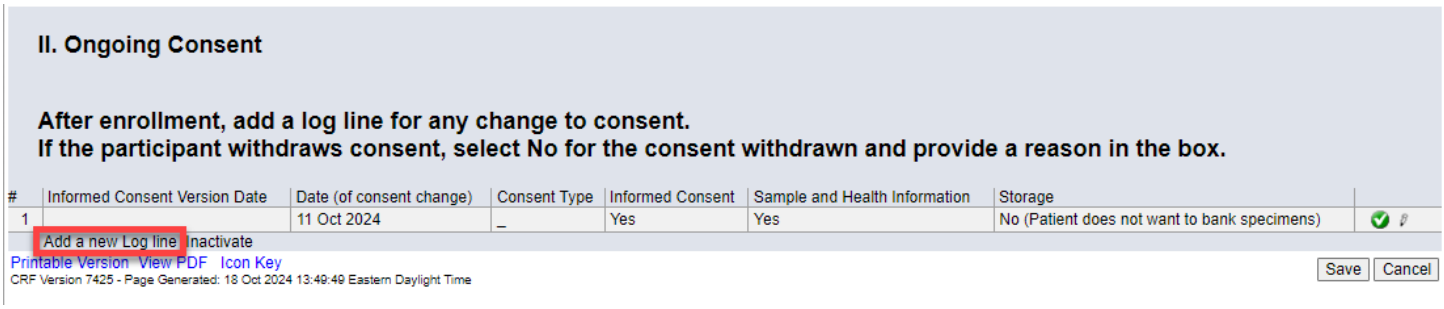
If the Patient changes their consent (including withdrawal from study) or if the patient is reconsented, use the **Edit** pencil (red arrow) to expand the log line to record this information.



For Study Reconsent, enter the version date of the IC document and the date of consent.

For Study Withdrawal, enter the date of consent change and select the Study Withdrawal radio button. To the right of the consent statement, select No and enter the participant's reason to withdrawal from the study. Be sure to respond to the remaining questions in the Consent for Optional Studies section.

For Optional Studies, enter the Date (of consent change), select the Optional Studies radio button, and complete the questions after Consent for Optional Studies. For No, please enter the participant's reason for withdrawal of consent for lab testing and/or storage.

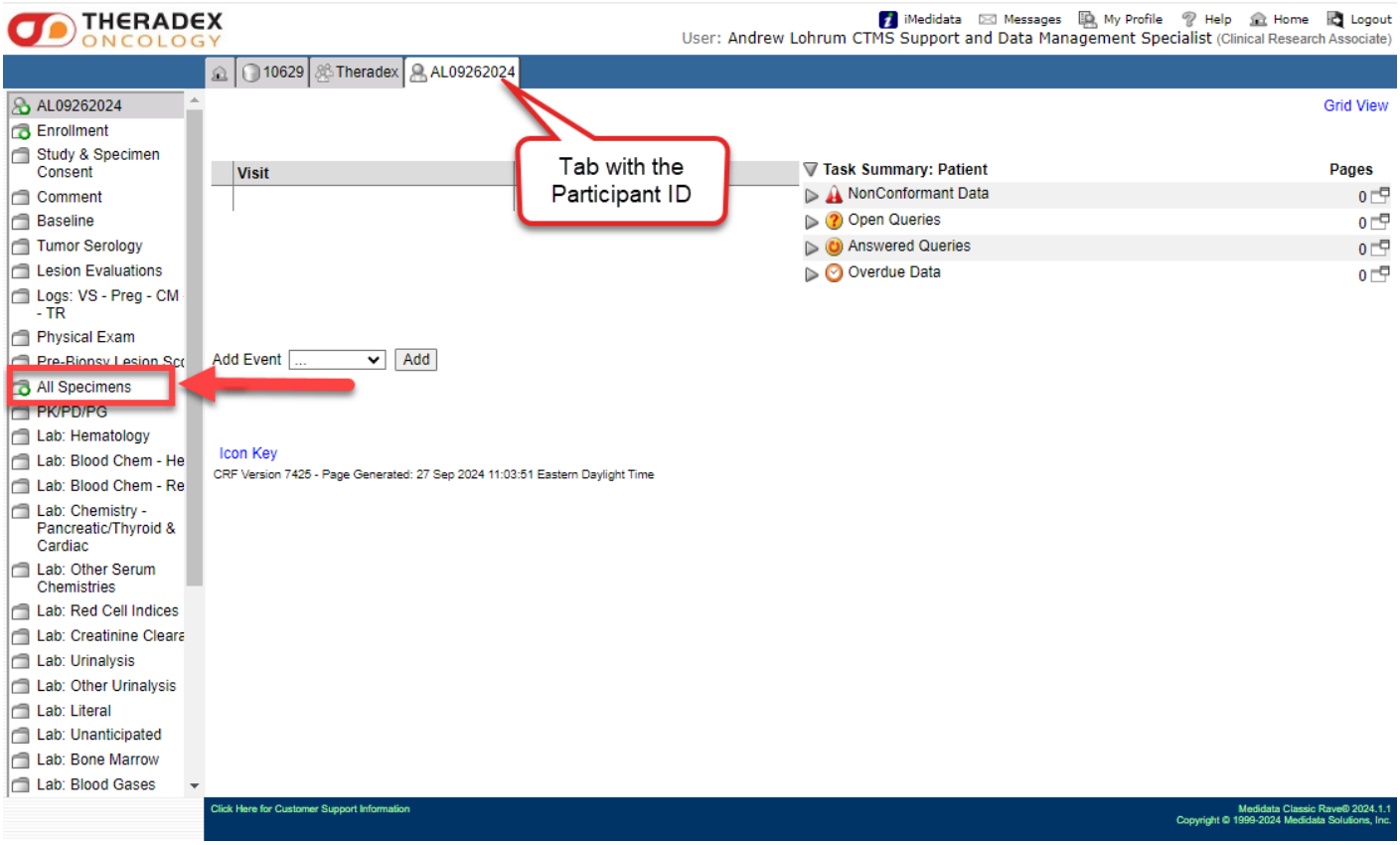


Any further changes in consent can be documented by using **Add a new Log Line** at the bottom of the form. For any erroneous entries, use the **Inactivate** function.

All Specimens folder

Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

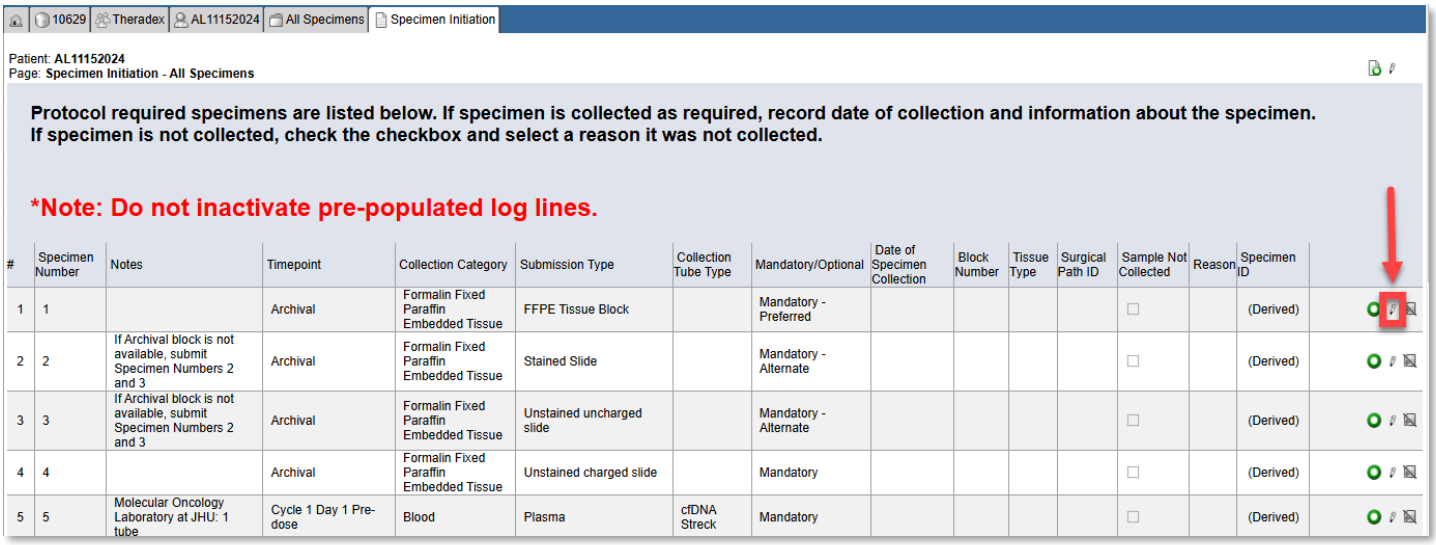
Return to the participant level by clicking the tab with the participant ID and open the **All Specimens** folder.



Specimen Initiation form

Ensure the Histology and Disease form in the Enrollment folder is complete before proceeding with any data entry.

The Specimen Initiation form contains a list of all expected specimens based on the Summary Table for Specimen Collection in the protocol. Each specimen is listed by **Timepoint** in ascending order and labeled as either **Mandatory** or **Optional**. If there are alternative specimens accepted by the study, these will be labeled as preferred or alternate based on their designation in the protocol. Collection details, shipping destinations, or other instructions are present in the **Notes** field for each specimen.



#	Specimen Number	Notes	Timepoint	Collection Category	Submission Type	Collection Tube Type	Mandatory/Optional	Date of Specimen Collection	Block Number	Tissue Type	Surgical Path ID	Sample Not Collected	Reason	Specimen ID
1	1		Archival	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block		Mandatory - Preferred					☐		(Derived)
2	2	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Stained Slide		Mandatory - Alternate					☐		(Derived)
3	3	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained uncharged slide		Mandatory - Alternate					☐		(Derived)
4	4		Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained charged slide		Mandatory					☐		(Derived)
5	5	Molecular Oncology Laboratory at JHU: 1 tube	Cycle 1 Day 1 Pre-dose	Blood	Plasma	cfDNA Streck	Mandatory					☐		(Derived)

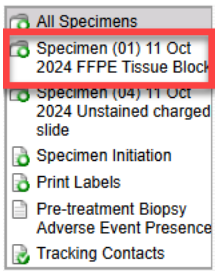
For Tissue specimens:

1. Click the **Edit** pencil to open the row for editing.
2. Enter the **Date of Specimen Collection**. This date is when the specimen collection occurred and must match the date on the specimen label.
3. Enter the **Block Number** from the corresponding pathology report. Alphanumeric entries are supported.
4. Select the **Tissue Type** from the drop-down menu.
5. Enter the **Surgical Path ID** from the corresponding pathology report, if available.
6. Click **Save**.

For non-Tissue specimens (i.e. blood, urine, CSF)

1. Click the **Edit** pencil to open the row for editing.
2. Enter the **Date of Specimen Collection**. This date is when the specimen collection occurred and must match the date on the specimen label.
3. Click **Save**. After saving, the **Specimen ID** will be displayed in the last column.

#	Specimen Number	Notes	Timepoint	Collection Category	Submission Type	Collection Tube Type	Mandatory/Optional	Date of Specimen Collection	Block Number	Tissue Type	Surgical Path ID	Sample Not Collected	Reason	Specimen ID
1	1		Archival	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block		Mandatory - Preferred	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-1 (Derived)
2	2	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Stained Slide		Mandatory - Alternate					☑	Not Required	(Derived)
3	3	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained uncharged slide		Mandatory - Alternate					☑	Not Required	(Derived)
4	4		Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained charged slide		Mandatory	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-4 (Derived)



After saving, the **Specimen ID** will be displayed in the last column of the form. A folder will appear in the folder panel on the left labeled with the Specimen number, collection date and specimen type. The Specimen Collection Details, Specimen Processing Details, and Shipping Status forms for the specimen are located in these folders. These forms need to be completed prior to shipment.

Samples Not Collected

Use this checkbox to mark any sample that was not collected, then select a Reason in the drop-down menu in the next column.

- For **Mandatory – Preferred** specimens, this will **automatically** check when the Alternate specimen is collected.
- For **Mandatory – Alternate** specimens, this will **automatically** check when the Preferred specimen is collected.

Reasons

Use this menu in conjunction with the Samples Not Collected Checkbox. Select the best fitting reason to explain why the sample was not obtained.

- For **Mandatory – Preferred** specimens, this will **automatically** be selected with 'Protocol Specified Alternate Submitted' when the Alternate specimen is collected.
- For **Mandatory – Alternate** specimens, this will **automatically** be selected with 'Not Required' when the Preferred specimen is collected.

Specimen collection issues

Protocol Specified Alternate Submitted

The protocol may list alternative specimen types that can be submitted if the required specimen is not available (pertains mostly to tissue specimens). The requested specimen is listed as Mandatory – Preferred and the alternative specimens are Mandatory – Alternate in the Specimen Initiation form.

Time Point	Specimen	Send Specimens To:
Archival		
	• Formalin-fixed paraffin-embedded (FFPE) tumor rich tissue block[1] (Mandatory) If a block is not available, then submit: • 20 unstained charged slides (5 µm)	EET Biobank

For this example, when the collection date and tissue specific fields are entered for the slide specimens, the FFPE block is automatically updated. The Not Collected checkmark is active and Protocol Specified Alternate Submitted is chosen from the Reason menu.

#	Specimen Number	Notes	Timepoint	Collection Category	Submission Type	Collection Tube Type	Mandatory/Optional	Date of Specimen Collection	Block Number	Tissue Type	Surgical Path ID	Sample Not Collected	Reason	Specimen ID
1	1		Archival	Formalin Fixed Paraffin Embedded Tissue	FFPE Tissue Block		Mandatory - Preferred					☑	Protocol Specified Alternate Collected	(Derived)
2	2	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Stained Slide		Mandatory - Alternate	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-2 (Derived)
3	3	If Archival block is not available, submit Specimen Numbers 2 and 3	Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained uncharged slide		Mandatory - Alternate	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-3 (Derived)
4	4		Archival	Formalin Fixed Paraffin Embedded Tissue	Unstained charged slide		Mandatory	11 Oct 2024	1A	Primary	SP1993285	☐		10629-GL14P4-4 (Derived)

Not Collected: Specimen was not obtained.

Collection Delayed: Use as a temporary selection when the collection of this specimen is expected at a later time than others collected at the same time point. When the sample is eventually collected, this reason should be removed, and the Sample not Collected checkbox unchecked. If the collection timepoint has elapsed, this reason needs to be changed to Not Collected

Patient Refused: Patient refused this sample collection. If the patient has changed their consent for all future collections, document this in the medical record and on the Consent form.

Less than Complete Specimen Collection: The quantity of sample was not sufficient for processing and submission.

Local Testing: The specimen will be tested locally and not entered into the STS.

Treatment Delayed\held\withdrawn: The specimen is treatment related and not necessary as the patient's treatment has been delayed or withdrawn.

Not Required: This reason is automatically selected for any Mandatory – Alternate specimen when the preferred specimen is collected. Do not manually apply this to any Mandatory specimen without checking with the study team and data management first.

Patient enrolled in a different treatment Arm, Cohort or Subgroup: The patient's treatment has changed, and the specimen is no longer necessary.

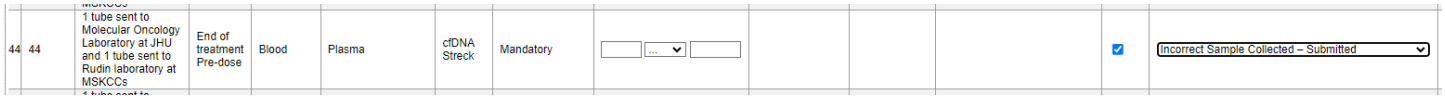
Not Feasible: Specimen collection was attempted but was not able to be obtained or other external factors prevented specimen collection. Do not use this selection if a patient refuses to be drawn.

Incorrect Sample Collected – Destroyed: An error was made in specimen collection or processing (i.e., wrong tube type, tissue processed incorrectly, etc.) and the decision is made by the **PI in consultation with the Biobank** to destroy the sample or return it to the site.

Incorrect Sample Collected – Submitted: An error was made in specimen collection or processing, but the decision is made by the **PI in consultation with the Biobank** to keep the sample for analysis. The protocol defined sample is marked Not Collected, and this reason should be selected. Then a separate entry needs to be made in Specimen Initiation for unexpected sample.

In the example below, the protocol requires a blood collection in a cfDNA Streck tube to be processed for Plasma and then shipped to the repository. There was a mix up at the lab and whole blood was shipped. The study team has decided to keep the sample.

1. Go to the log line entry in **Specimen Initiation** for the that was incorrectly processed.
2. Click on the **Sample Not Collected** checkbox.
3. Select **Incorrect Sample Collected – Submitted** in the **Reason** dropdown.
4. Click **Save**.



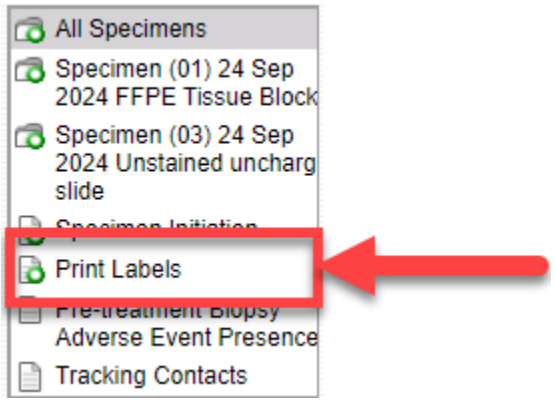
Proceed to make an entry for the sample as it was collected/processed:

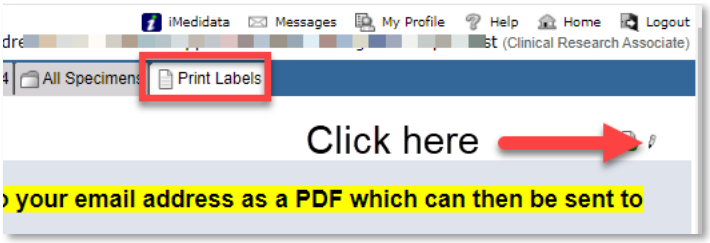
1. Go to the bottom of the **Specimen Initiation** form, click **Add a New Log line**.
2. Set the **Protocol Timepoint, Specimen Category,** and **Specimen Type** fields.

3. Proceed to enter the **Collection Date** and the tissue sample fields if applicable.
4. Click **Save**.
5. After saving a Specimen (#) folder will populate with the remaining forms and the specimen will be available in Print Labels.

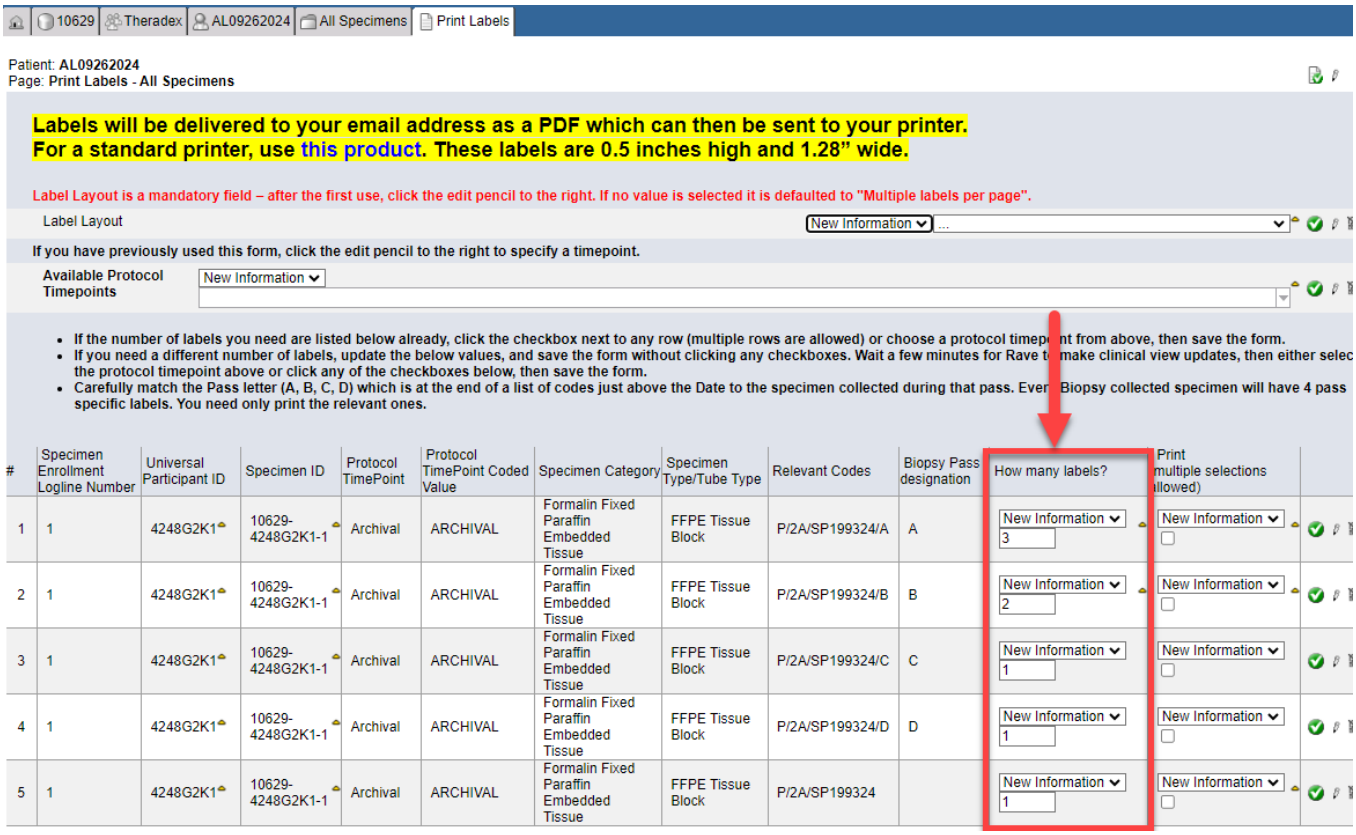
Print Labels

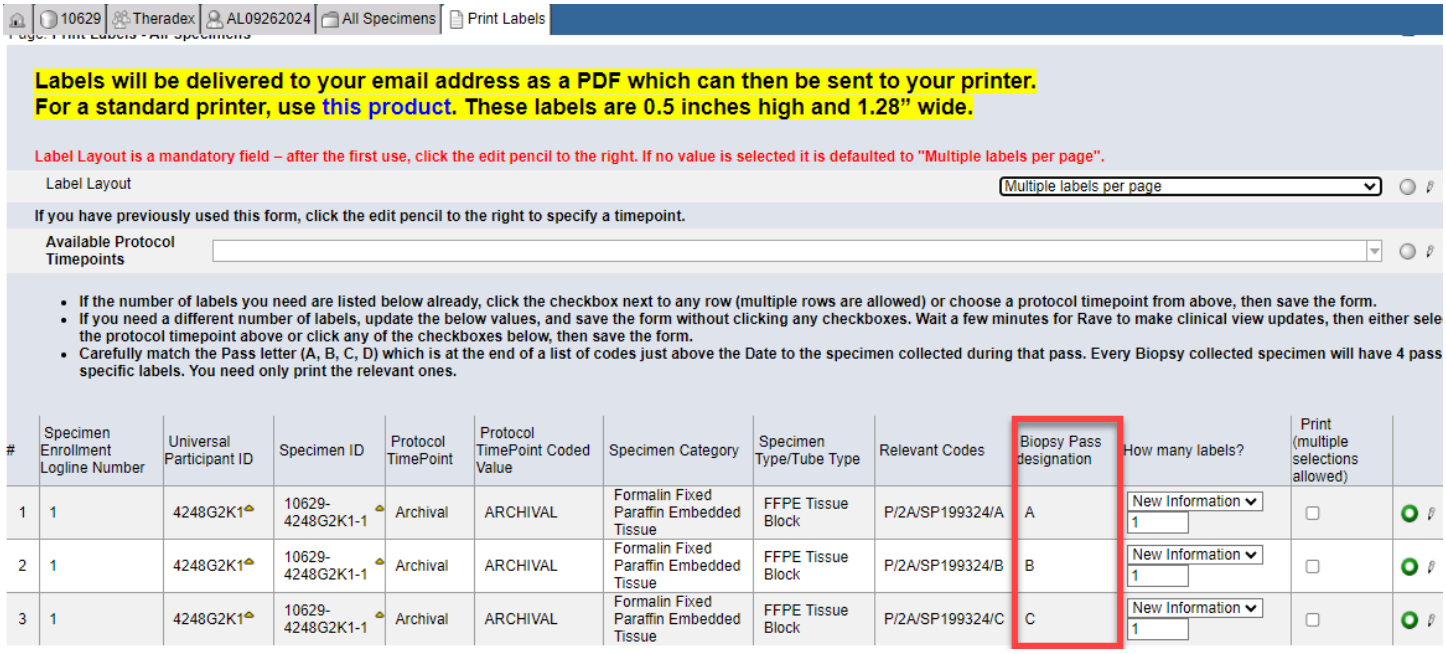
In the **All Specimens** folder, click on **Print Labels** to open the form.





1. At the top right of the form, click on the pencil to edit.
2. The quantity of labels defaults to 1, if more than 1 is needed edit the number in the **How many labels?** field.
3. Click **Save**. **After updating, wait a few minutes for Rave to register the update.**





For **tissue** specimens, five separate labels will automatically be created in the form. These will be labeled for four separate biopsy passes A, B, C, D and one unlabeled. If the sample has less than four passes, the extra labels can either be discarded or use the Print checkbox (see below) to only print the passes needed.

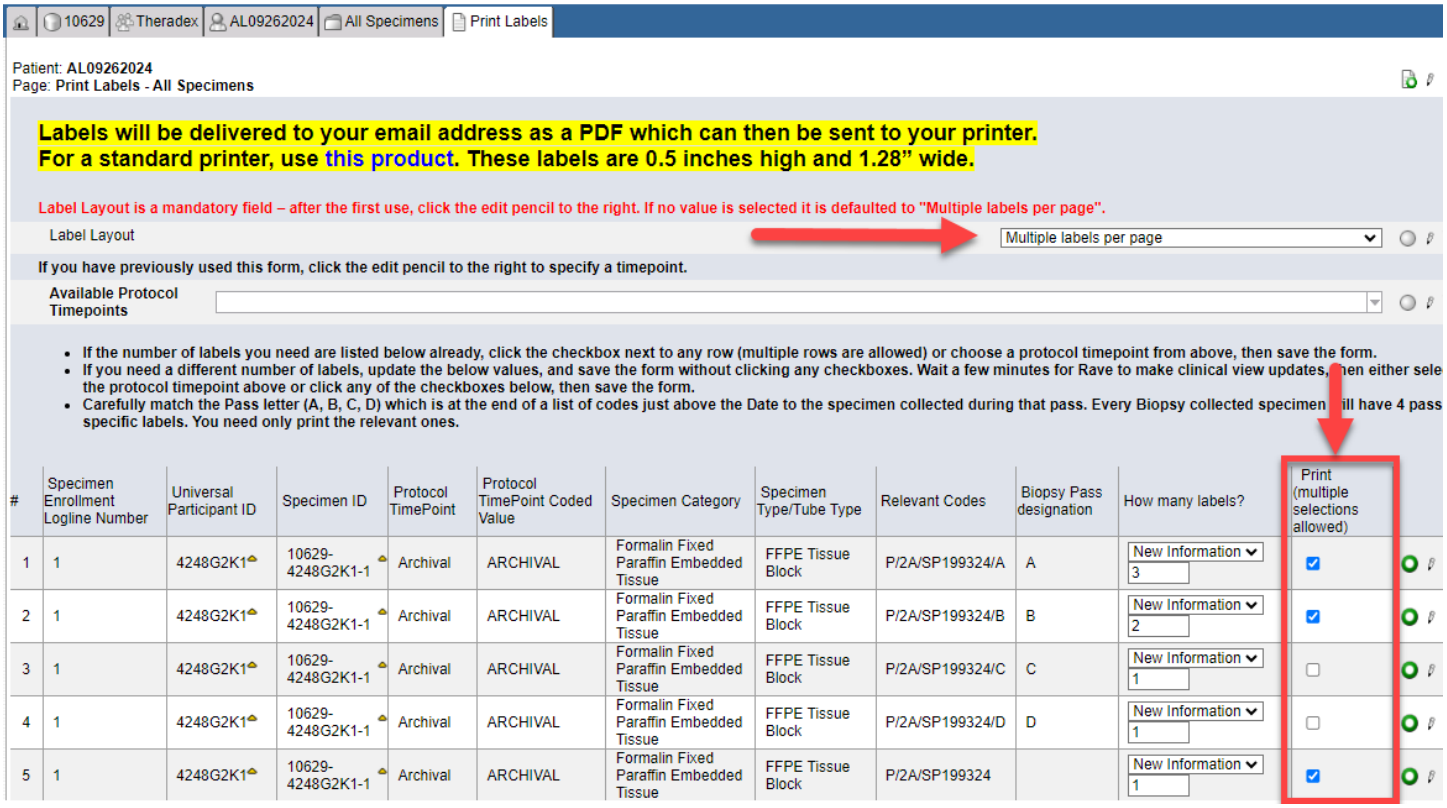
There are two ways to print labels – **CHOOSE ONE METHOD ONLY**.

- Printing labels by manual selection – the user can select individual Specimen IDs by clicking the checkbox under the column Print.

--OR--

- Printing labels by Available Protocol Timepoints.

Printing labels by manual selection



1. Select the **Label Layout:**
    a. **Multiple labels per page** (default) — for standard laser printers
    b. **One label per page** — for special purpose thermal label printers
2. **Skip over** Available Protocol Timepoints
3. Click the **Print** checkbox for each specimen needed (multiple selections allowed).
4. Click **Save** button.

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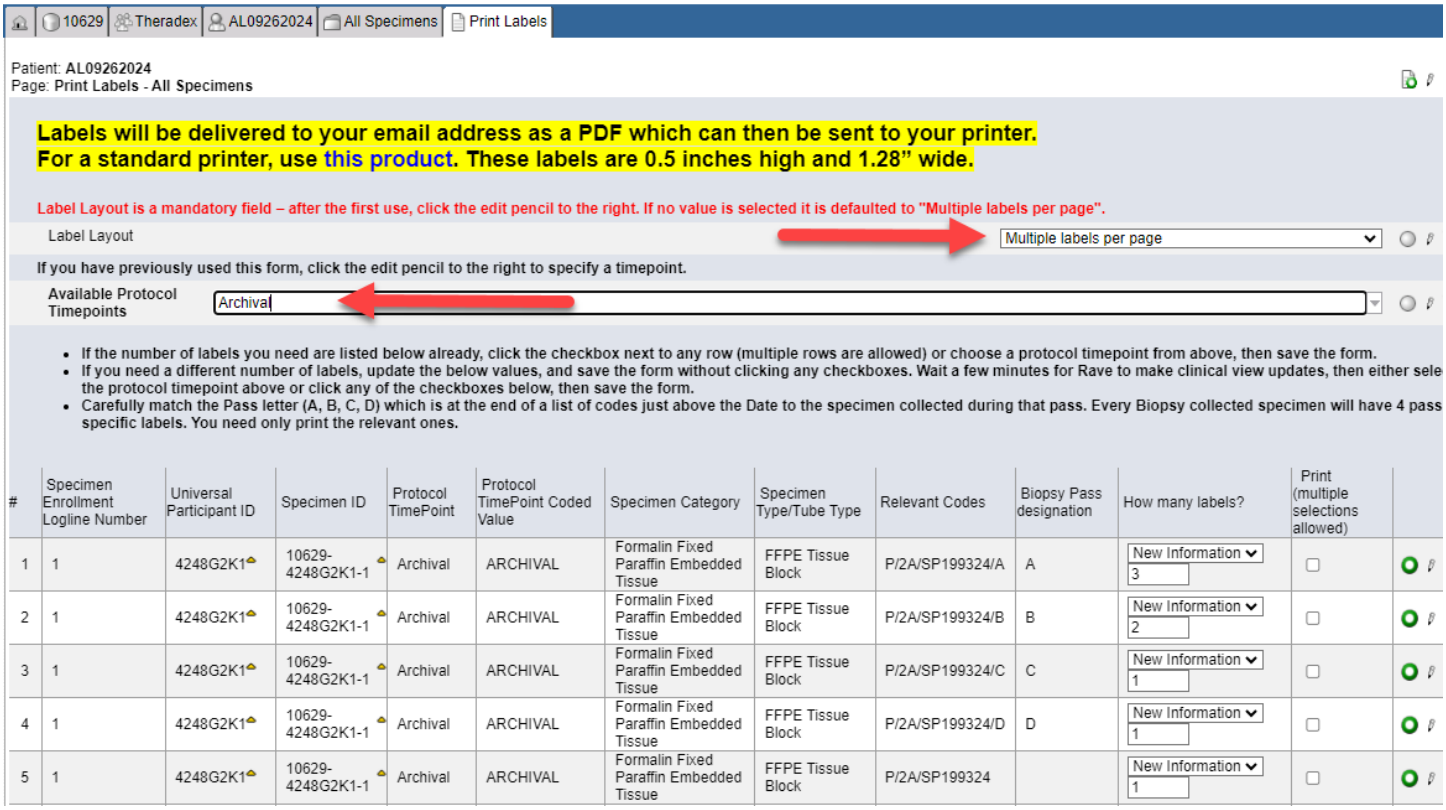
*If both protocol timepoint and the print check box are used, no email will be issued. Only **one type** should be chosen.*

Printing labels by Available Protocol Timepoints



1. Select the **Label Layout:**
    a. **Multiple labels per page** (default) — for standard laser printers
    b. **One label per page** — for special purpose thermal label printers
2. Select one of the **Available Protocol Timepoints** from the dropdown.
3. **Skip over** the Print checkbox.
4. Click the **Save** button.

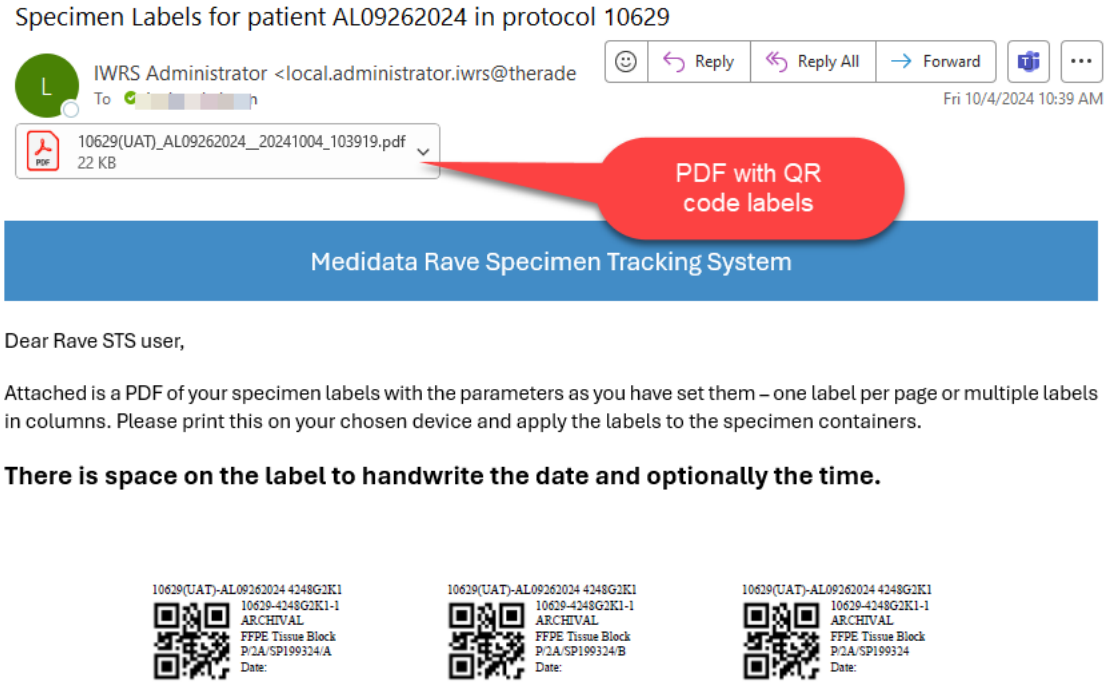
---

*If both protocol timepoint and the print check box are used, no email will be issued. Only **one type** should be chosen.*

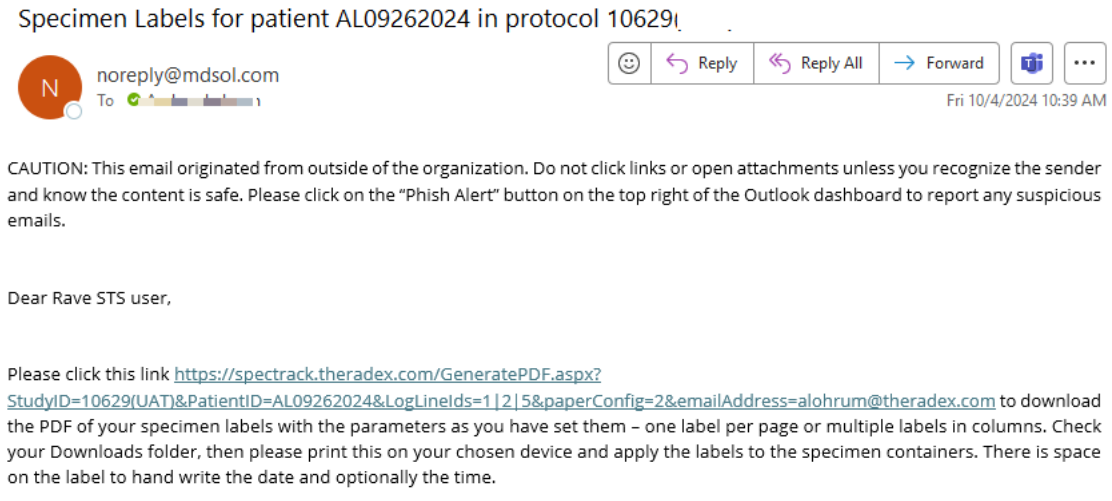
Label emails

After saving the Print Labels form, the system will generate the same two emails shown above for manual selection, however these will include the timepoints that match the user selected values.

Once the user saves the form, two emails will be sent. One email will be sent with the QR Coded labels as a pdf attachment. Open in Acrobat Adobe reader and follow the printing instructions.



A second email will be sent to the user with an active link to download the QR code pdf. Users can copy / paste the link into a browser or click on the active link and pdf will be downloaded in the download folder.

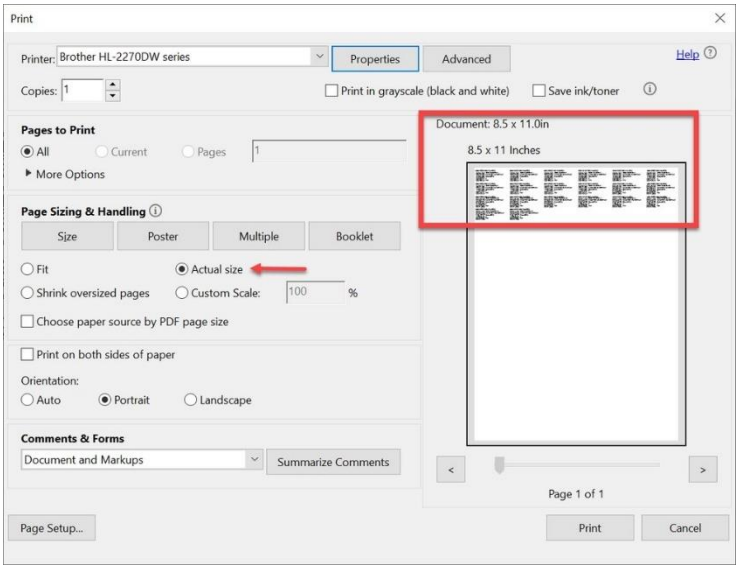


Apply labels to the specimen(s), and hand write the collection date and time on the label.

Printing in Adobe

The PDF document needs to be printed through Adobe Acrobat reader (free version) and not the embedded PDF viewer in Chrome or Edge.

Multiple Labels per page:

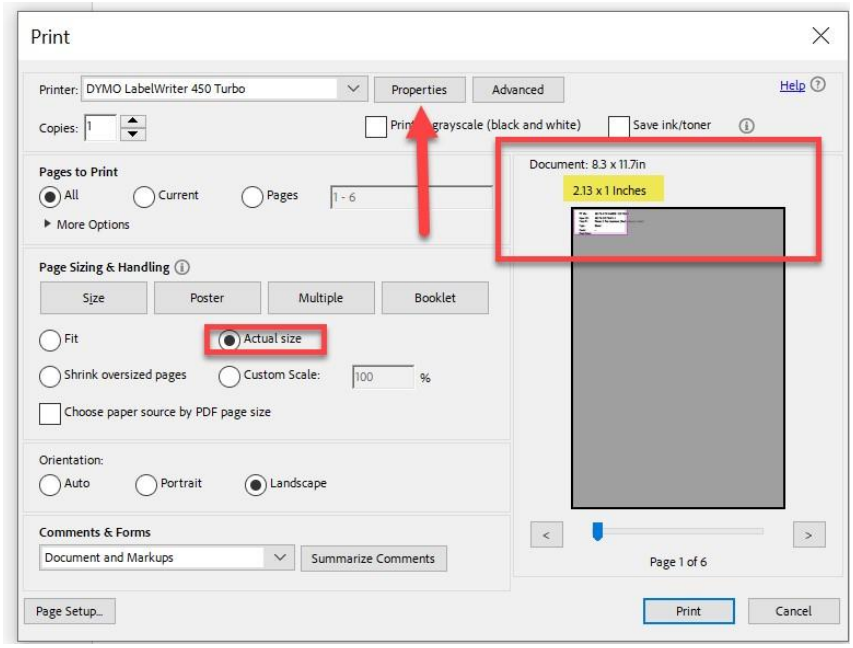


In the Print menu:

Under **Page Size and Handling**, select **Actual Size**.

In the preview, the document is 8.5 x 11, there are grey lines on the outside of the document, these are the programmed margins to match the LabTag supported laser printer labels.

One per page:



In the Print menu:

Under **Page Size and Handling**, select **Actual Size**.

Under **Properties**, the **Paper Size** needs to match the label size loaded into the printer.

In the **Document** preview, the white printing area should overlay the label that is in the top right hand corner of the document. You can confirm that the correct label size is selected (highlighted in image). You may need to set the **Portrait/Landscape** orientation, again refer to the preview.

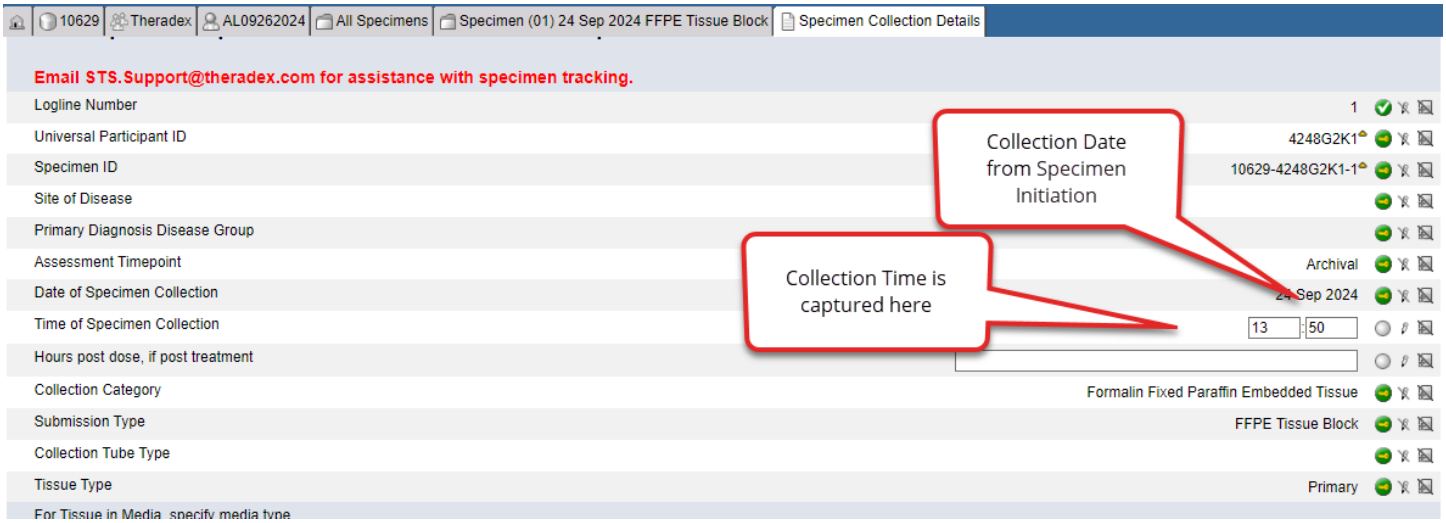
Once you have tested and found the correct settings. Be sure to change the page size in the Windows Printer settings for the label printer so you will not have to do this each time they print through adobe. The Actual Size and Orientation should remain selected in Adobe but may change if toggling between printers.

Specimen Collection Details

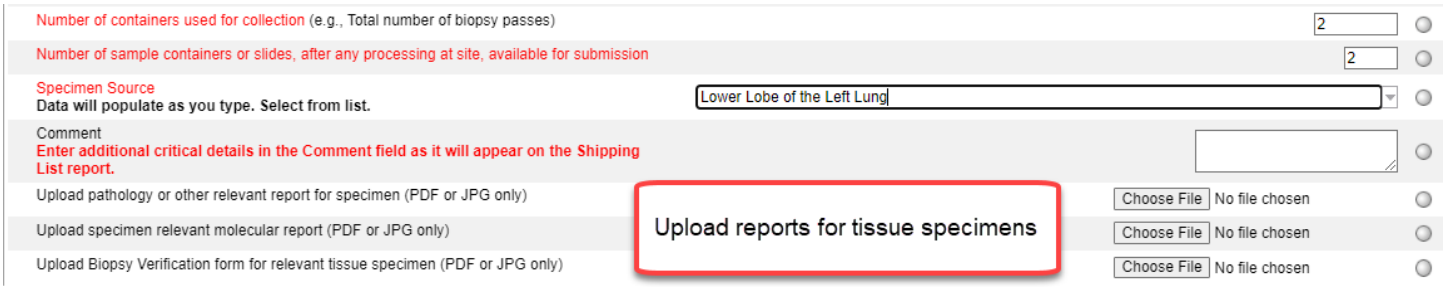
This form should be completed the same day as specimen collection even if the specimen is to be shipped at a later date.

After completing a logline in the **Specimen Initiation** form, a folder will have populated, **Specimen (#)** for each specimen line. **Specimen Collection Details** is the first form in the Specimen (#) folder. Required fields are in red font. Not all fields are relevant for all specimens.

At top of the form, several fields have a key icon These fields are display only as the data is taken from other forms or not applicable to the Specimen Type. If changes are needed to the **Collection Date** or **Tissue Type**; the changes need to be made on the corresponding **Specimen Initiation** log line. Refer to the **Logline Number** in the first field of the form.



Number of containers used… : Enter the number of tubes for blood or other liquid samples. For tissue in formalin, each cassette counts as 1 container. Do not submit free-floating tissue as it can be damaged during shipping.
Number of sample containers … submission: Enter the number of samples that are available after any processing that will be submitted to the repository or testing lab.



Example 1: 2 tubes of blood are collected and there is no processing. Number of containers used is 2, number to submit is 2.

Example 2: 2 tubes of blood are collected then processed for plasma; 4 aliquots are made. Number of containers used is 2, number to submit is 4.

Example 3: 1 FFPE block is collected and processed into 20 unstained uncharged slides. Number of containers used is 1, number to submit is 20.

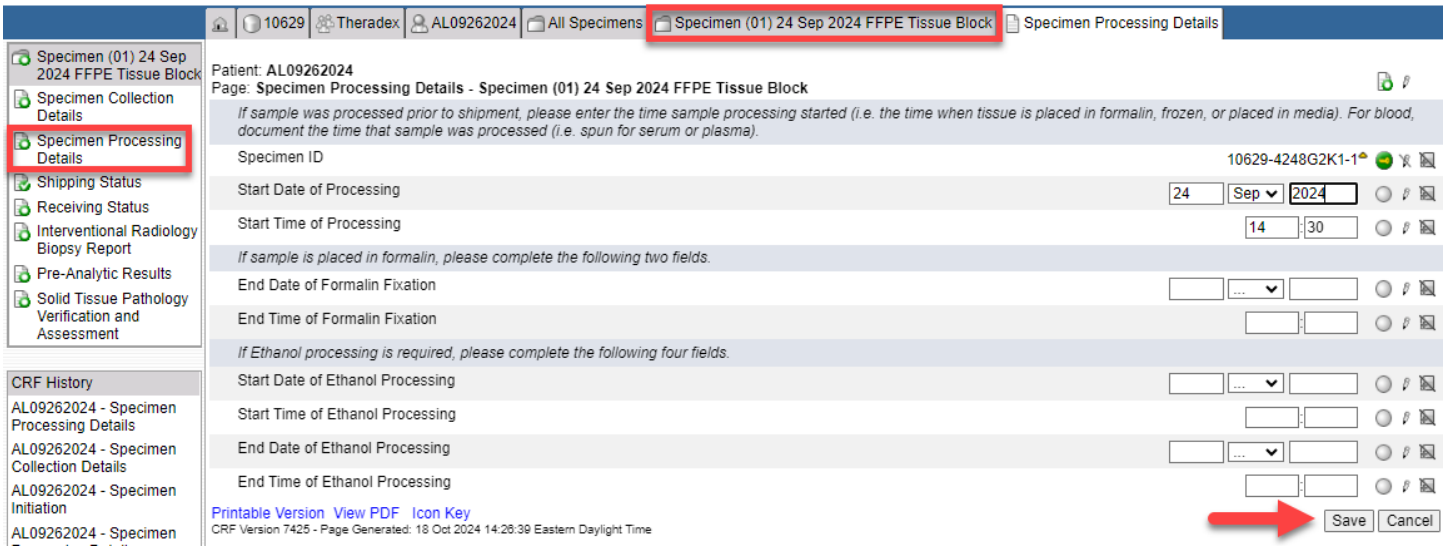
Specimen Source: If the specimen is blood, select **Blood** from drop down. For tissue specimens, specify the anatomical site.

Report Upload: The remaining three fields are for the upload of related reports for tissue specimens. Please upload the pathology, molecular or Biopsy Verification form using the appropriate field. Click **Choose File** and the Windows file explorer box will open for you to select the **De-identified** report (including removal of **PII/PHI** from filename).

After all necessary fields are entered, click **Save**.

Specimen Processing Details

This form records the processing start and end time associated with the specimen. This information is not applicable to all specimen types.



For processing blood specimens, the date and time recorded should be the start of centrifugation. If the blood specimen is not centrifuged, the date and time the cap is removed should be recorded.

For formalin fixed tissues, enter the start date and time of formalin fixation. The end date and time are recorded in the next two fields. If the tissue is to be further processed in Ethanol, use the next four lines to record the start and end date/time.

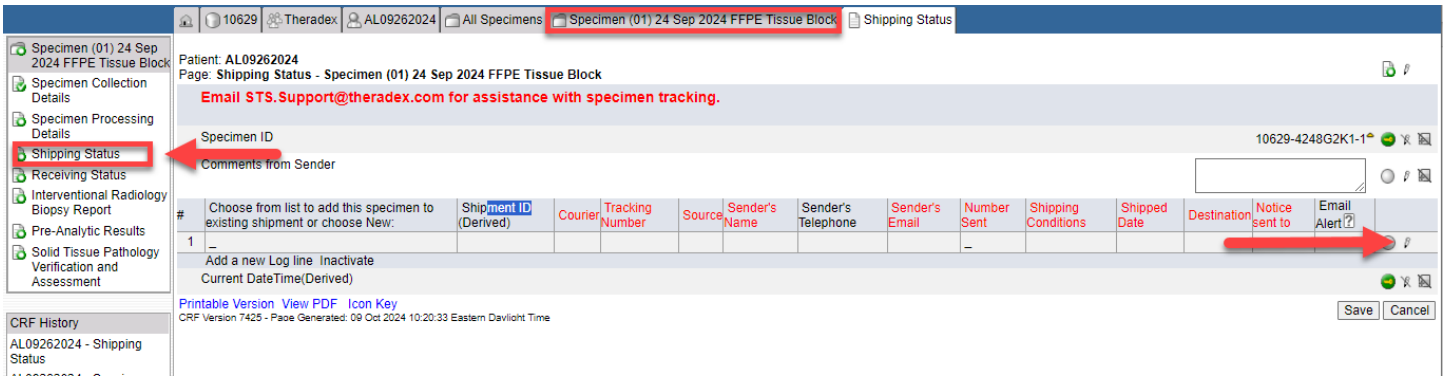
Shipping

Shipping Status form

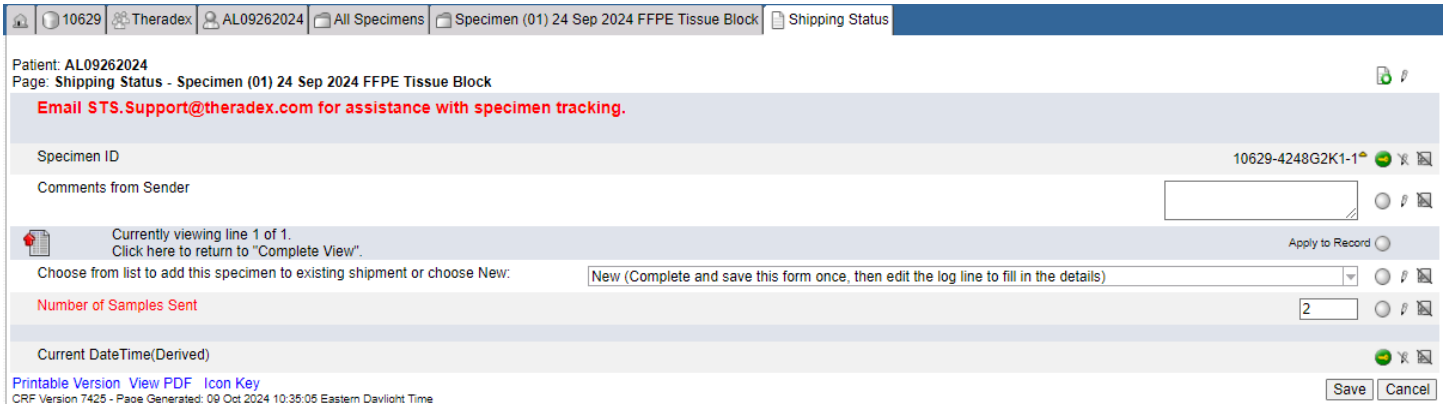
Complete the **Shipping Status** form for **each specimen** when it is ready to ship. The data on this form should only pertain to the specimen recorded on the Specimen Transmittal form. Each **Shipping Status** log line corresponds to a line item on the **Shipping List** report.

The Specimen Tracking System will now create a unique **Shipment ID** to organize and batch the specimens into a shipment. The Tracking Number provided by the shipper is still recorded but can be entered at a later time and is no longer required to create an outgoing shipment.

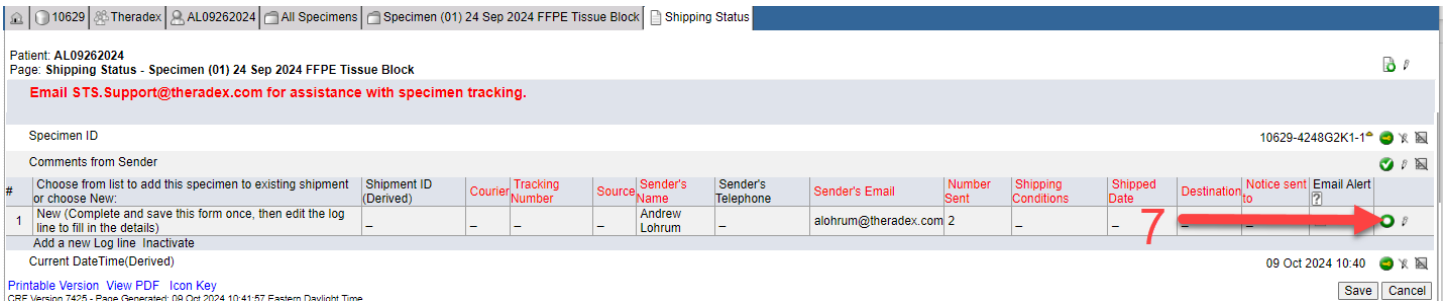
Creating a new Shipment

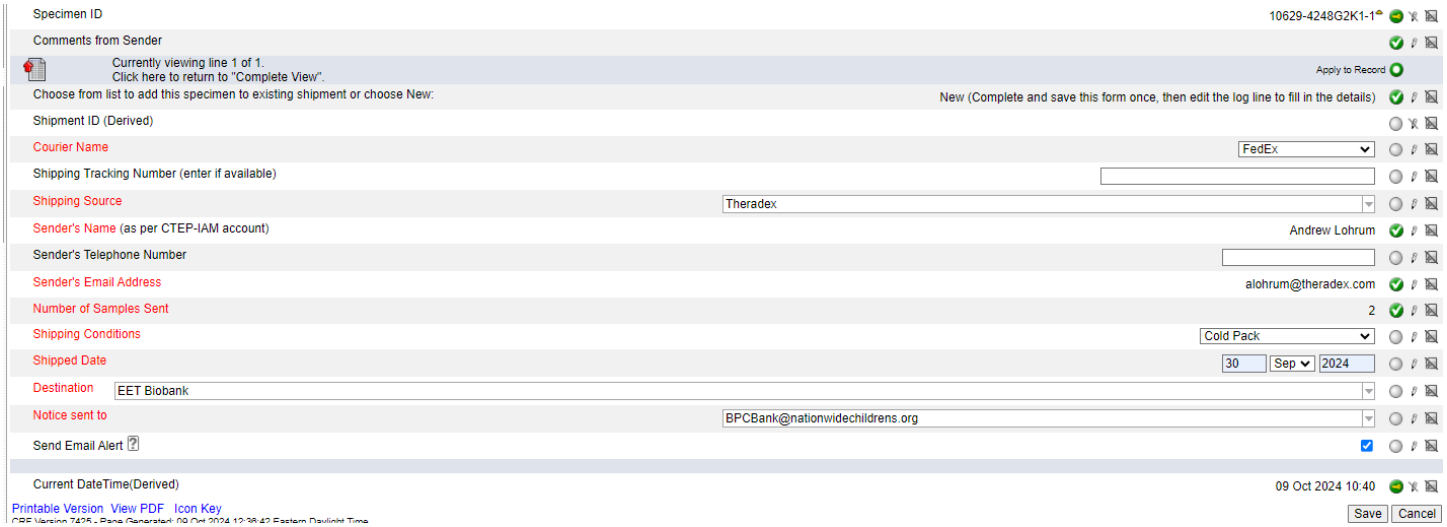


1. In the **All Specimens** folder click on the **Specimen (#)** folder for the first specimen.
2. Click on the **Shipping Status** form in the folder panel.
3. Click the **Edit** pencil on empty logline.

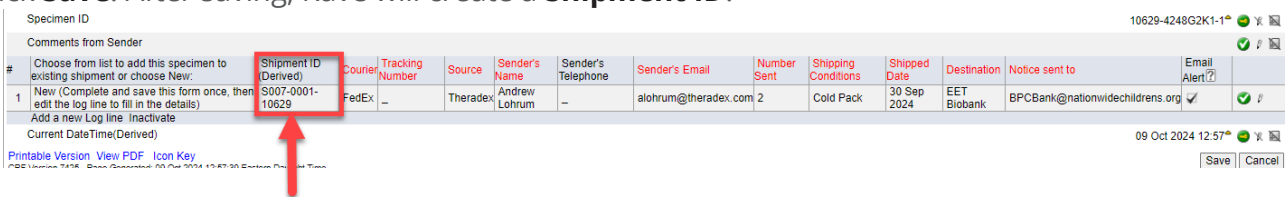


4. To start a new shipment, select **New** in the Choose from list … menu. This entry will always be at the bottom of the list.
5. Enter the quantity in the **Number of Samples Sent** field. This number should match the quantity in the Specimen Collection Details form if everything is being sent.
6. Click **Save**.



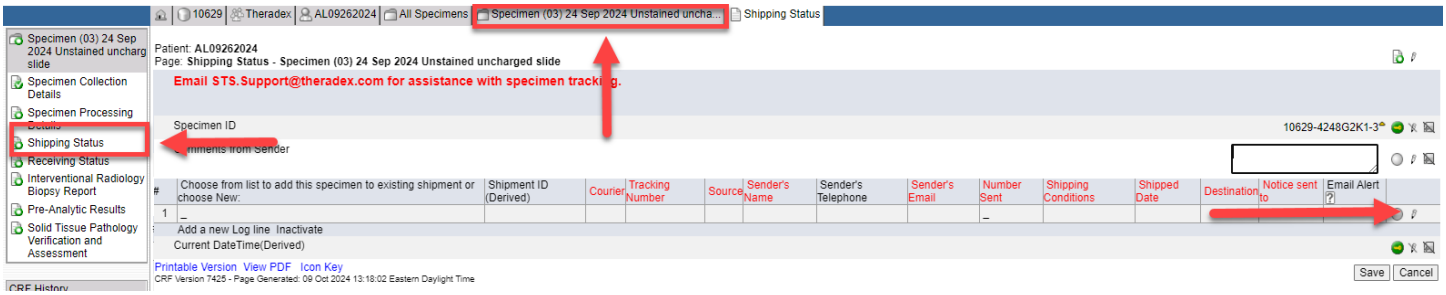


7. After saving, click the **Edit** pencil again.
8. Complete the fields in red:
   Courier: Select the courier used by your institution. The tracking number is not required at this time but should be entered for completeness of data and to allow tracking of the specimen on the courier website.
   Shipping Source: Your site. This field will have your site at the top.
   Shipping Conditions: Select the temperature of the shipping container.
   Destination: Choose the destination from the drop down menu. **If the drop down does not populate, go back to the Histology & Disease form and be sure it is complete**. **Do not manually enter data into this field**. **The destination must be selected from the drop down menu.**
   Notice sent to: This field changes based on the entry made in the *Destination* field above it.
   Email Alert: Click the checkbox to send a shipment announcement to the destination. **This field only needs to be used once per shipment.**
9. Click **Save**. After saving, Rave will create a **Shipment ID**.

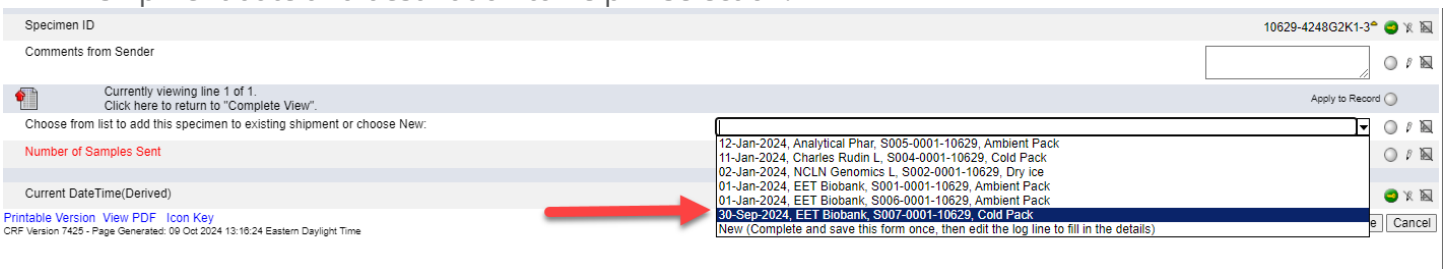


Additional Specimens

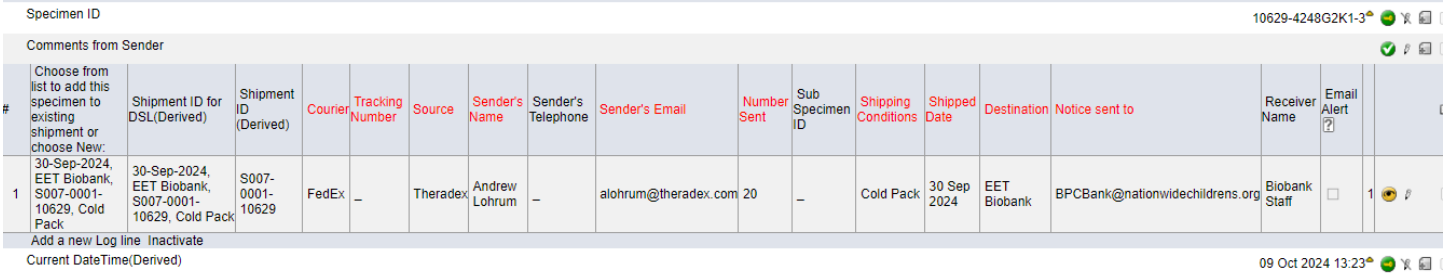
The Shipping ID was created by following the steps above. Now it will be available to select for any additional specimens added to the shipment.



1. In the **All Specimens** folder click on the **Specimen (#)** folder for the first specimen.
2. Click on the **Shipping Status** form in the folder panel.
3. Click the **Edit** pencil on empty logline.
4. Select the **Shipment ID** from the drop-down menu. The menu entry will also include the shipment date and destination to help in selection.



5. Enter the quantity in the **Number of Samples Sent** field. This number should match the quantity in the Specimen Collection Details form if everything is being sent.
6. Click **Save**.



The information for the shipment will automatically populate. This specimen is complete, proceed to add any further specimens to the shipment using the same steps above.

Receiving Status form

This form is used by the recipient lab only. **The sending lab should not enter or modify any data in this form.**

The number of samples listed in Shipping Status will correspond to the number of loglines in Receiving Status.

If queries are noticed on the Receiving Status form, check the **Shipping Status** form for errors (such as quantity sent) and address them on the **Shipping Status** form.

Tracking Contacts form

This form is machine controlled. **Rave Users should not enter or modify any data in this form.**

If no Destinations are present in the Shipping Status form and the Tracking Contacts form is blank. Go to the **Enrollment** folder and complete the **Histology and Disease** form.

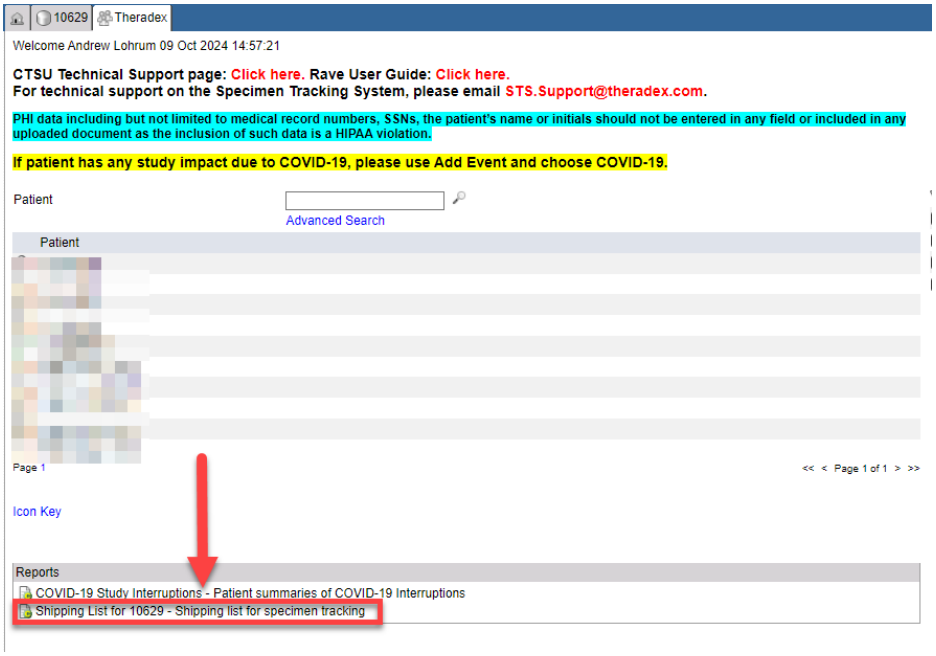
If you believe changes are needed in this form, please contact sts.support@theradex.com.

Shipping List

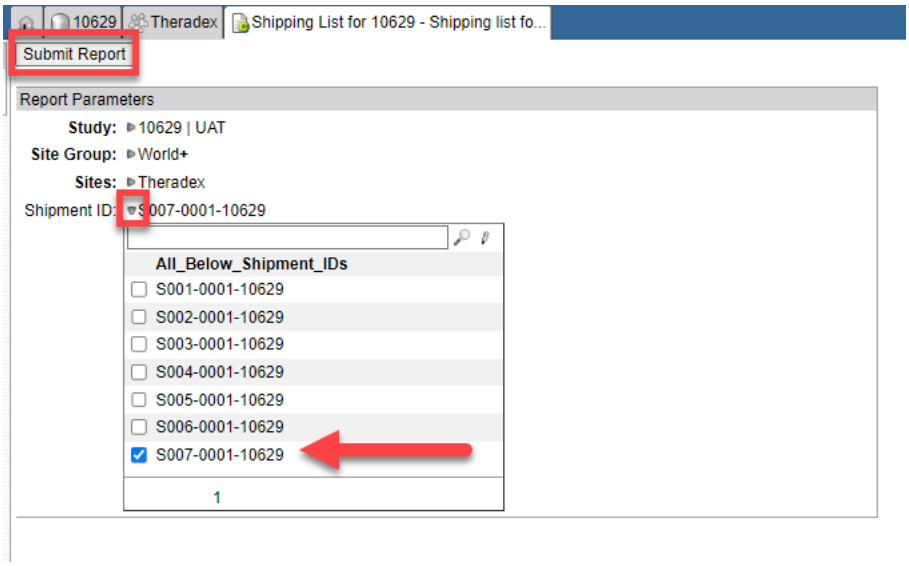
The Shipping List is indexed on the tracking number. Rave will pull entries from the Shipping Status forms with the same tracking number form and create a line in the Shipping List.

Check contents of the shipping container against the Shipping List prior to shipping.

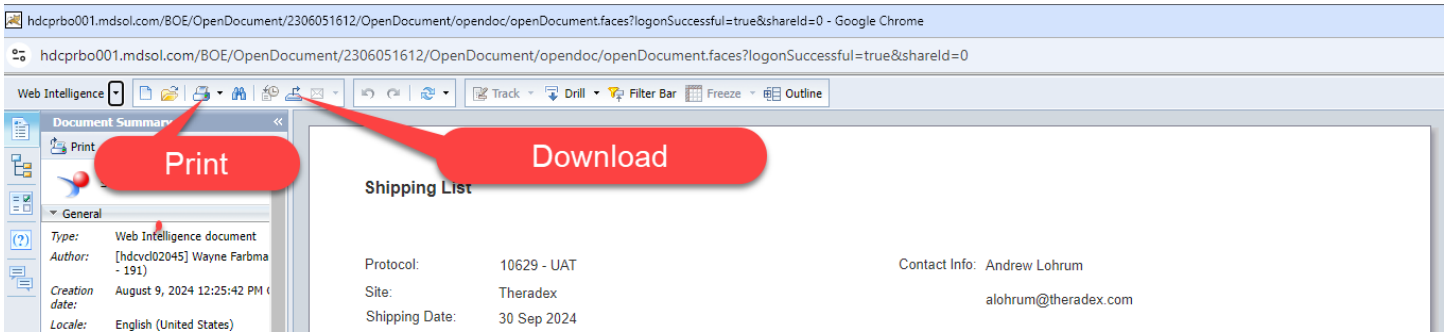
1. Click on the tab with your site name. Below the list of participants, in the **Report** box, click **Shipping List**.



2. Click on the **Shipment ID** arrow.
3. Select the Shipment ID from the list. As each ID is created, the serial number increases so the most recent shipment will be the highest number.
4. Click **Submit Report**.

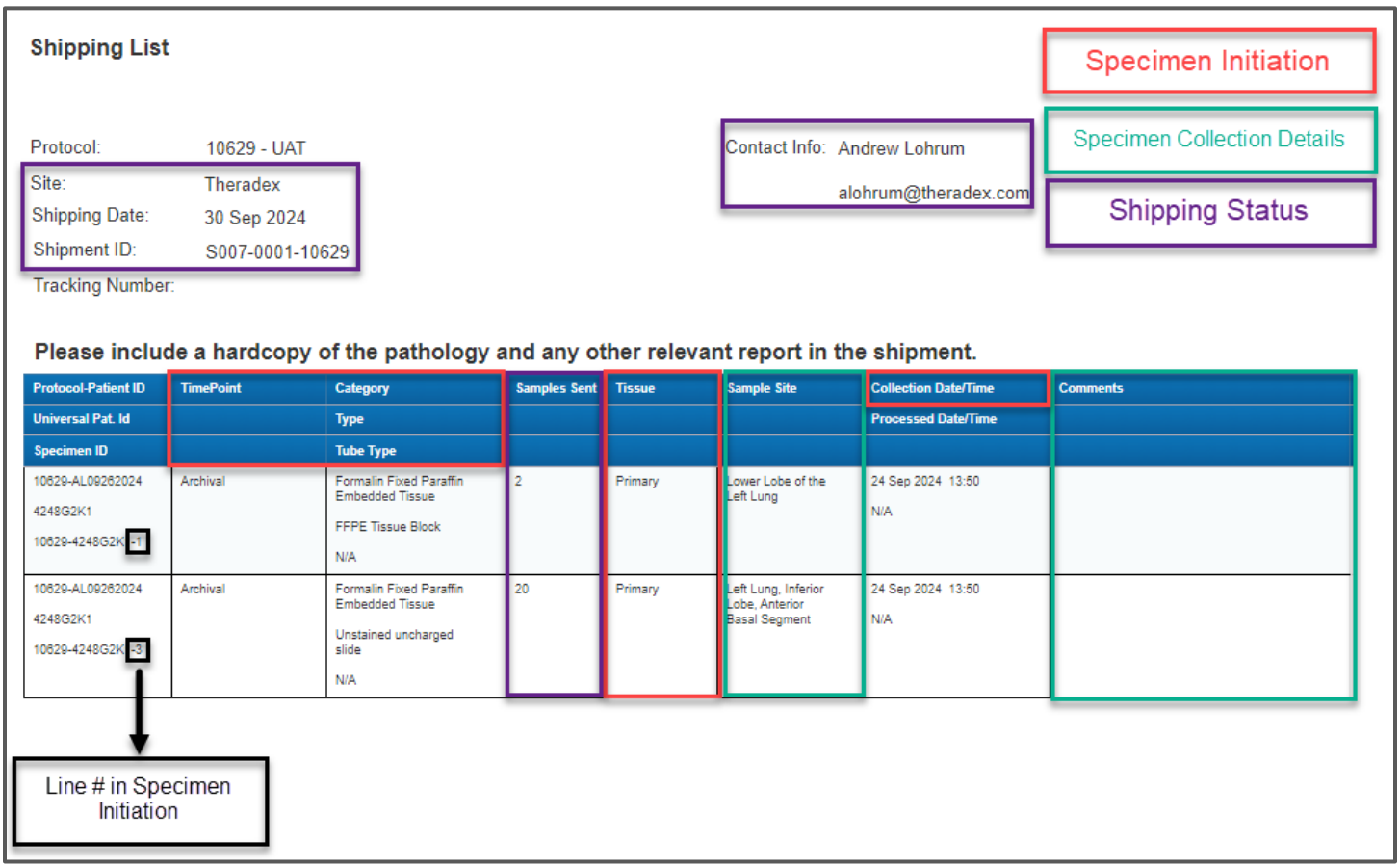


5. Use the print icon or the download icon in the pop-up window.
6. Put shipping list report and hardcopies of relevant pathology reports in the box with the specimens.



NOTES:

- If the shipment includes specimens from multiple participants, the Shipping List will have a separate page for each participant.
- The number sent on the shipping list must correspond to the number of that specific sample that are packed in the box. This value is recorded on the Shipping Status form.

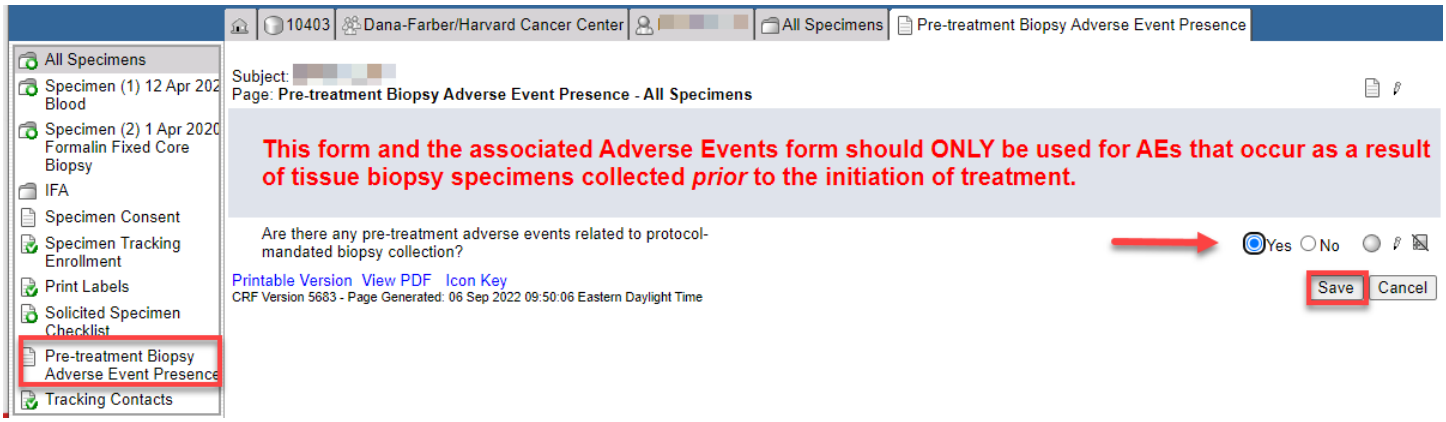


Adverse Events in Specimen Collection

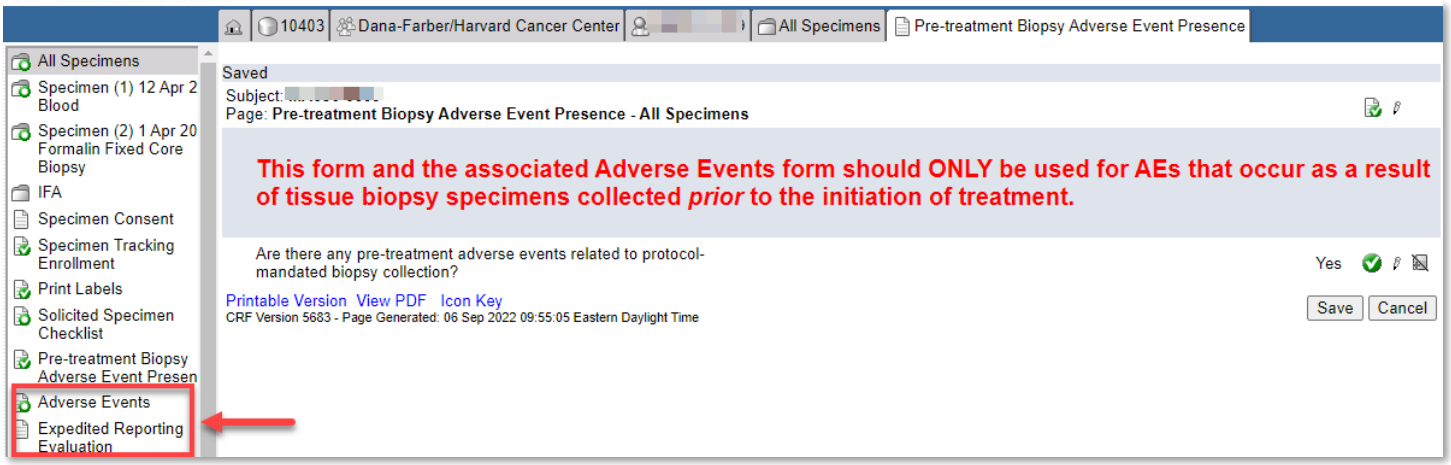
Adverse events that occur as a result of specimen collection **prior to treatment** are recorded on forms within the STS. These forms may not be present for your study.

If the event occurs during treatment, record the adverse event form in the current Course folder. See the Rave User Guide for more information.

Pre-treatment Biopsy Adverse Event Presence



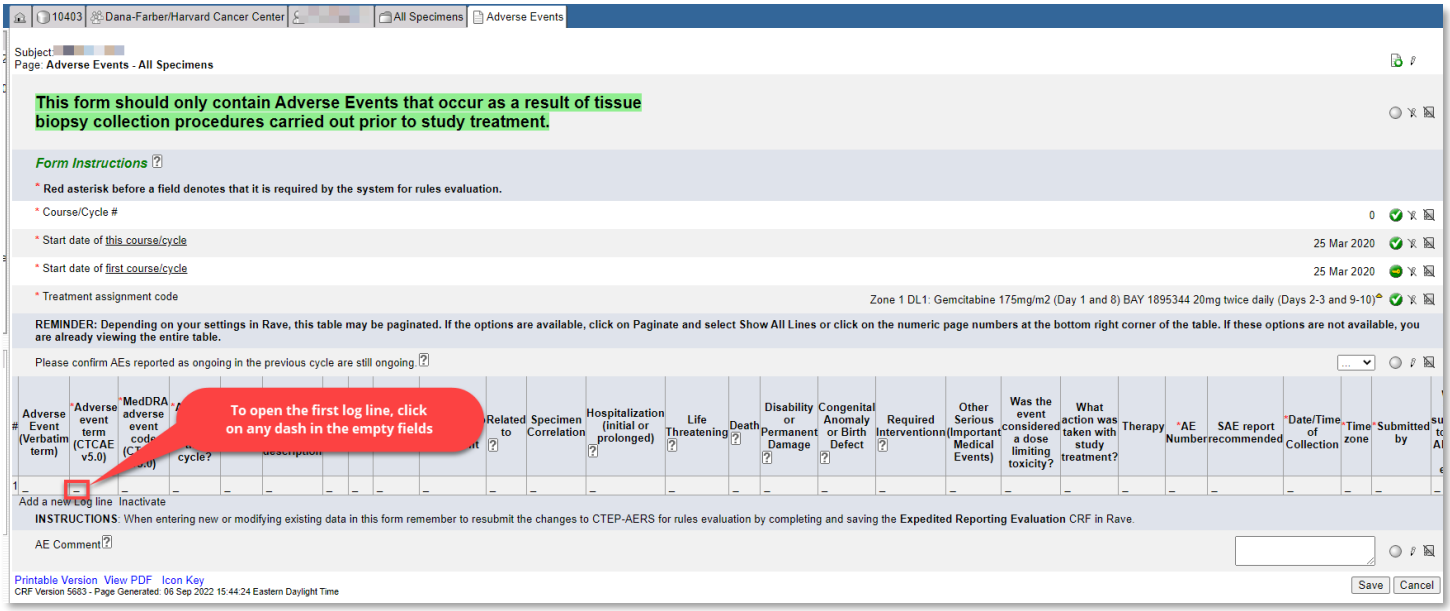
If an adverse event occurs during the collection of a tissue specimen prior to treatment, click the **Yes** radio button and then click **Save**.



After saving the form, the **Adverse Events** and **Expedited Reporting Evaluation** form will be available to collect more information.

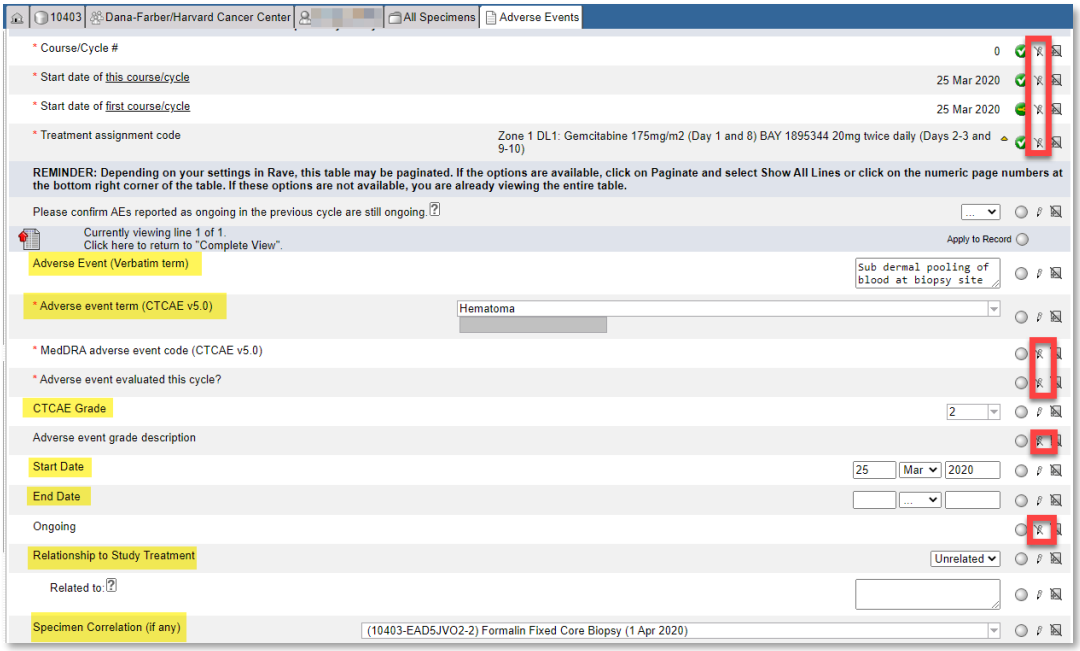
Adverse Events (All Specimens)

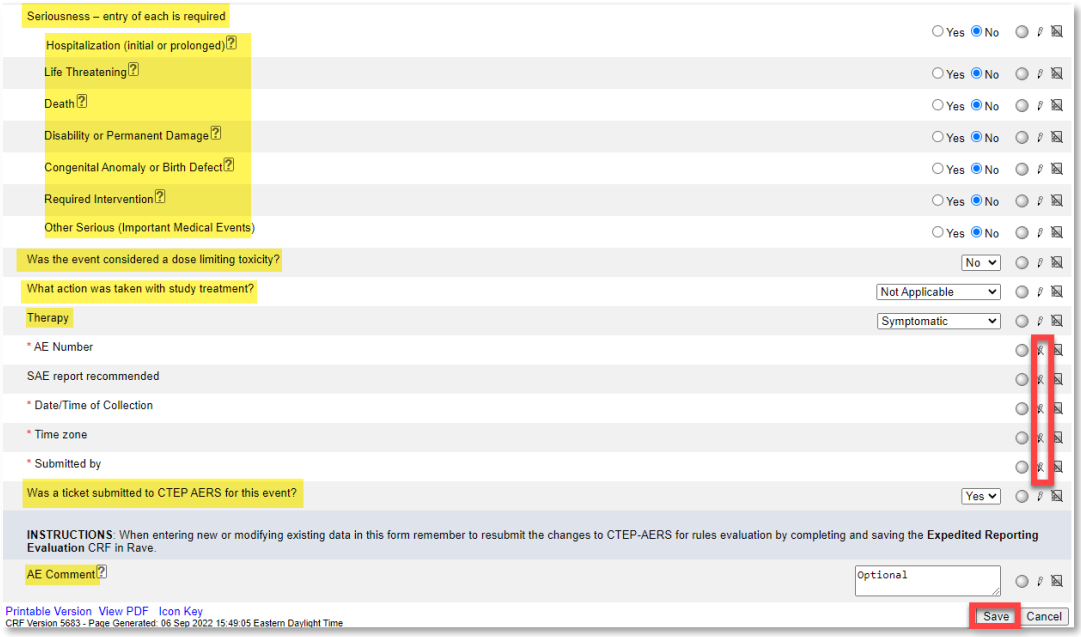
The specimen associated with the adverse event must be entered into **Specimen Tracking Enrollment** and **Specimen Transmittal** before completing this form.



The standard fields at the top of the form are auto-populated with values from the Enrollment folder. To enter the first observed adverse event, click on the dash (-) in any empty field or use the Edit pencil to expand the log line.

The auto-populated fields in the form are not open to editing. The fields are either derived from previously entered data or will auto-populate with data based on your entries after saving the form. These fields will have a crossed out Edit pencil as they cannot be edited. See red boxes below.





Succinctly describe the symptom/adverse event in the **Adverse Event (Verbatim term)** field. Do not simply retype the CTCAE term. *DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS (DASHES, COMMAS, PLUS SIGN, APOSTROPHE, ETC.).* Select the appropriate **CTCAE term** from the drop down menu. You can type in the menu to filter the selections. The **MedDRA code** will automatically populate after saving the form.

Choose the **CTCAE Grade** and enter the **Start** and **End dates** of the event. Enter the **Relationship to Study Treatment**.

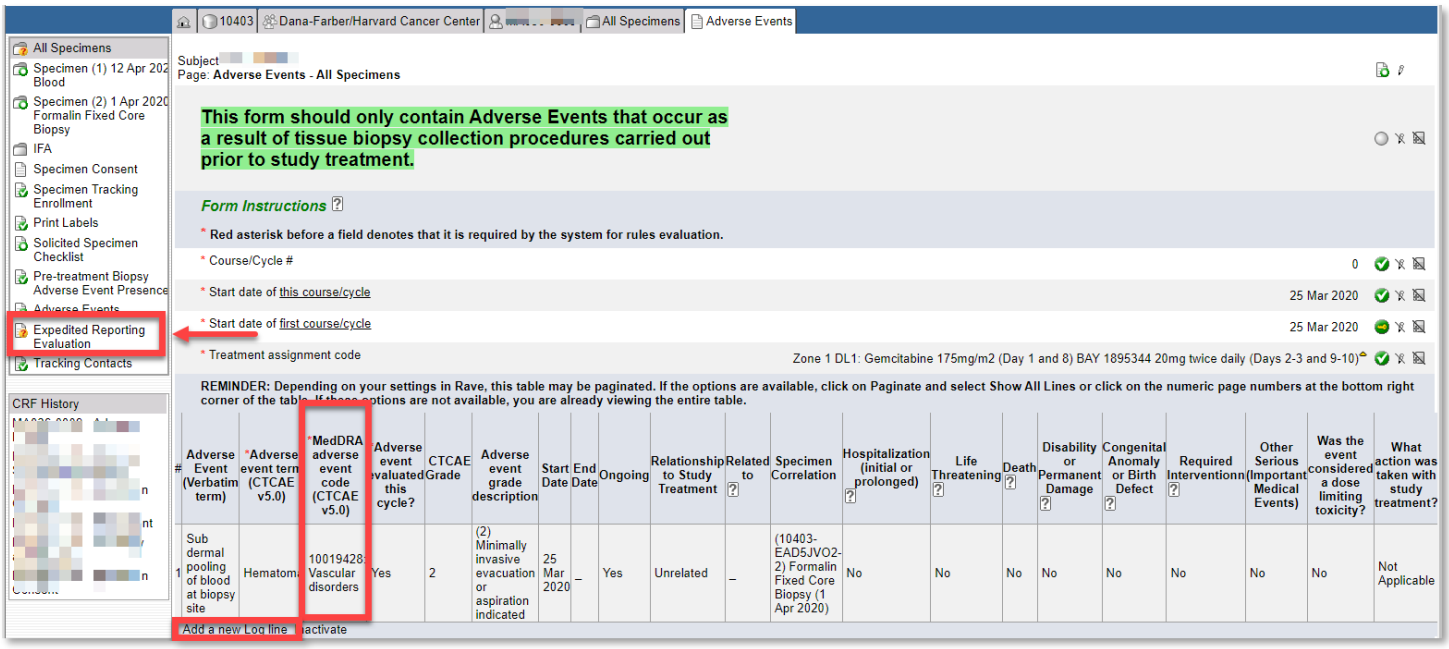
From the **Specimen Correlation (if any)** drop down, select the specimen which correlates to the adverse event. A specimen must be selected for this field, **do not leave blank**. If the drop-down is empty, the specimen must be entered into the Specimen Tracking Enrollment form and the Specimen Transmittal form must be completed prior to completion of the Adverse Events form.

Select Yes or **No** for each question pertaining to the **Seriousness** of the adverse event. Do not leave any blank.

Indicate if a ticket was submitted to **CTEP-AERS**. You can enter an optional **AE Comment**. *DO NOT INCLUDE SPECIAL CHARACTERS SUCH AS SYMBOLS (DASHES, COMMAS, PLUS SIGN, APOSTROPHE, ETC.).*

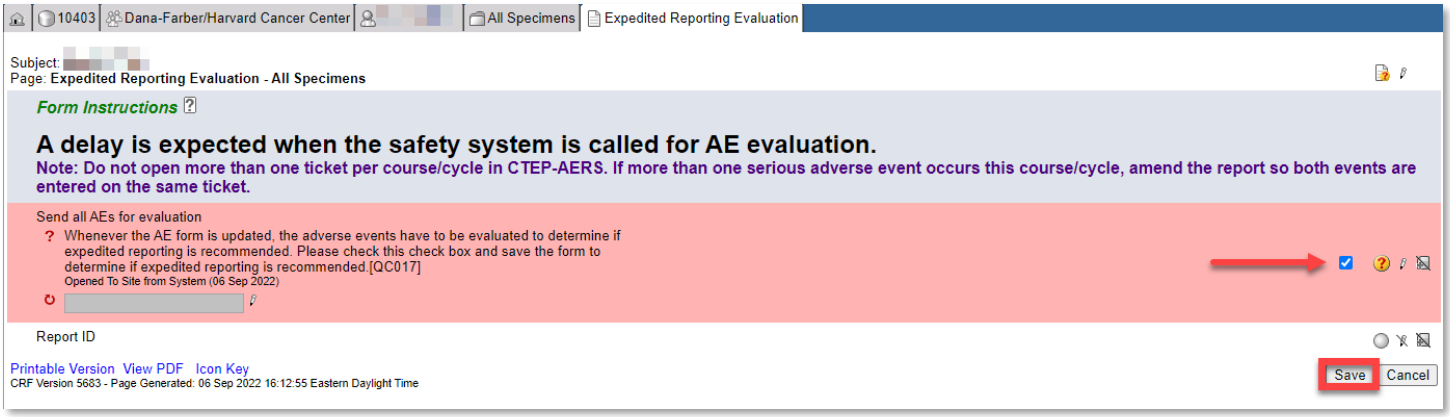
After saving, the form will create a log line. To edit the entries, use the **Edit** pencil to the right of the log line. To add entries, click **Add a New Log line**.

Note the MedDRA field in the next image, this has auto populated based on the selected CTCAE term. Also, a query has been opened on the Expedited Reporting form. This will be covered in the next section.



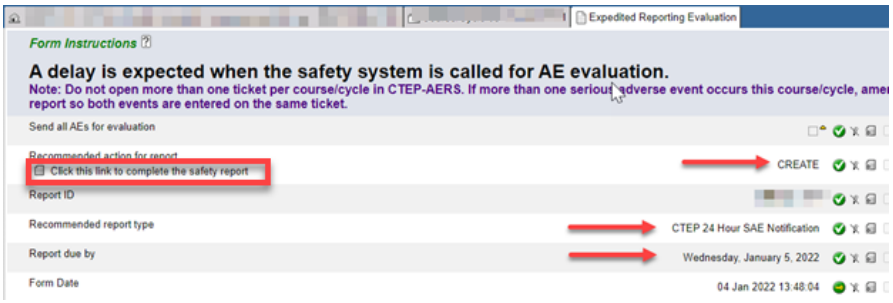
Expedited Reporting Evaluation (All Specimens)

Whenever the AE form is updated, the adverse events must be evaluated to determine if expedited reporting is recommended each time. Use the Send all AE's checkbox and save the form to determine if expedited reporting is recommended



After completing the adverse events form, a query is opened on the Expedited Reporting Evaluation form. **Click** the checkbox and then click the **Save** button. The query will automatically resolve when the box is checked and the form is saved.

If the CTEP-AERS determines that a report is needed (i.e. CREATE or EDIT) it will advise on the report type and due date. Click on the link to complete the safety report (see red box in next image).



Please see the Adverse Events form, under the Course section, in the Rave User Guide for more information.