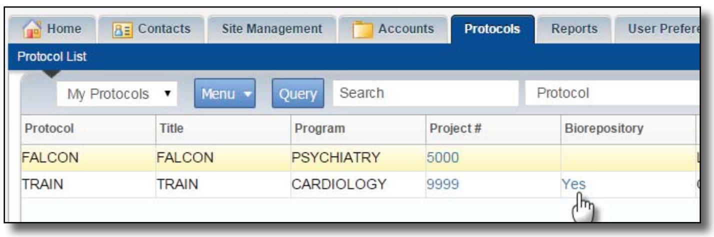
Locating Biorepository Protocols

- *Protocol Team* members typically locate biorepository protocols by searching the **Protocols** screen tab (follow the “Using the Protocols Screen Tab” procedure).
- *Biorepository Team* members typically locate biorepository protocols by searching the **Biorepositories** screen tab (follow the “Using the Biorepositories Screen Tab” procedure).

> If your protocol has a biorepository, but it has not yet been set up in the CTMS, submit a *CTMS Access Form* to the *DCRI Service Desk* (see “Getting Help”).

▶ Using the Protocols Screen Tab



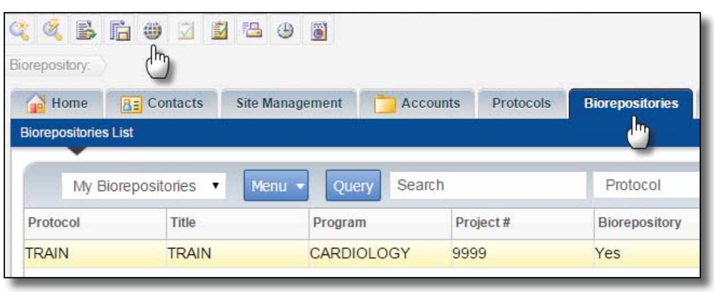
1. Go to the **Protocols** screen tab.
2. Using the **Search Box** or **Query** tool, search for the value *Yes* (case-sensitive) in the **Biorepository** field.

   A list of biorepository protocols appears.

   Note: *Protocol Team* members only see the protocols that are assigned to them. *Biorepository Team* members see all biorepository protocols.
3. Click the blue *Yes* hyperlink in the **Biorepository** field.

   The **Biorepositories** screen tab opens.

▶ Using the Biorepositories Screen Tab



1. Click the **Biorepositories** screen tab.

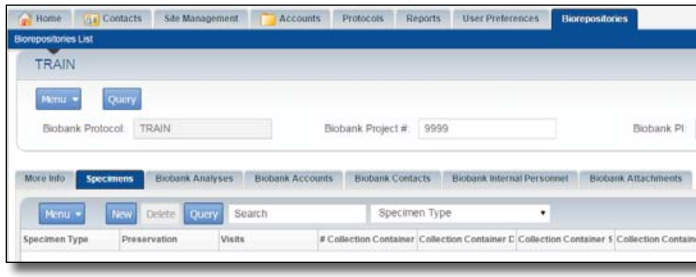
   Note: If you do not see the **Biorepositories** screen tab:

   a. Click the **Site Map** button at the top of the window.

   b. Click the **Biorepositories** link to view a list of associated screens and views.

   c. Click the **Biorepositories** link again to open the screen tab.
2. Use the **Search Box** or **Query** tool to locate the biorepository study.

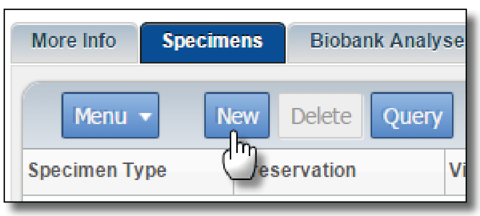
Working with Collection Data



Specimens View Tab

- Displays a list of specimens that have been collected during studies to be used in future research.
- Includes how specimens were collected, their quantity, and how they were stored—to help determine if they can be used for specific analysis studies.
- Can be populated from data found in laboratory manuals.

▶ Entering Collection Data



1. Click **New**.
2. Use the table below as a guideline for entering data.

* Fields marked with an asterisk (*) allow you to enter a new value if it is unavailable from the drop-down list.
Note: Entering new values will *not* make the value available for other records. To request a new value to be added to a list, submit a *CTMSR* to the *DCRI Service Desk* (See “Getting Help”).

Field	Guidelines
Specimen Type	Select the type from the drop-down list.
Preservation	Select the preservation used to collect the specimen. If unknown, you can leave this field blank.

Field	Guidelines
Visits	Track one or more visits. The field shows *Single Visit* or *MultiVisit*, depending on the number of records that are tracked by clicking the selection icon. **Important!** Each row represents the kits that were collected at *each* visit. Although this field allows you to track multiple visits in one record, if there are different numbers of containers collected at each visit, you should record each visit as a separate row. 1 Click the selection icon. 2 Click **New**. 3 Enter a **Visit** description (for example, *Visit 1*). 4 Enter a **Timepoint** (for example, *pre-dose*). 5 Optionally, enter **Comments** (for example, *follow-up visit*). 6 Click **OK**.
# Collection Containers	Enter the number of containers collected during this (or each, if multivisit) visit.
Collection Container Description *	Select the description from the drop-down list.
Collection Container Size	Enter the size of the collection container (for example, *5*).
Collection Container Units *	Select an option from the drop-down list to go along with the **Collection Container Size** (for example, *ml*).
# Storage Tubes	Enter the number of storage tubes. **Note**: Since final storage is usually processed at the lab, the lab manual can be referenced to get this information.
Storage Tube Description *	Select the description from the drop-down list.
Storage Tube Size	Enter the size of the tube (for example, *7.5*).

Field	Guidelines
Storage Tube Units *	Select an option from the drop-down list to go along with the **Storage Tube Size** (for example, *ml*).
Fill Volume	If specimen is a liquid, enter the volume.
Fill Units *	Select an option from the drop-down list to go along with the **Fill Volume** (for example, *ml*).
Storage Location	Specify the name of the laboratory where the specimen is stored. 1 Click the selection icon. 2 Click **New**. 3 Check the **Current** box. 4 Click the selection icon in the **Storage Location** field to select from a list of **Biobank Accounts** where one of the **Services** is *Biobank*. **Note**: You can go to the **Biobank Accounts** tab to create the account (see "Biobank Accounts View Tab") and then return to this field. 5 Enter the **Storage Start Date** and **Storage End Date**. 6 Enter the **Count** of storage containers, the **Date of Count**, **# of Subjects**, and **Storage Comments**, as needed. **Note**: To update the **Count** details, create a *new* record each time to maintain a storage history. 7 Repeat steps 2-6 to add another location where specimens are being stored. 8 Click **OK**.
Count	(Automatically populated from the record marked **Current** in the **Storage Location** field.)

Field	Guidelines
Protocol Version	Enter consent documentation and any restrictions associated to the sample. **Note**: Only enter details here if the version change affects the samples that were collected or will affect the way they are collected moving forward 1 Click the selection icon. 2 Click **New**. 3 Check the **Current** box. 4 Enter the protocol **Version Number** for which the sample was consented. 5 Select an option from the **Consent Category** drop-down list, or enter a new value. For example, select *Future Use Restricted*. 6 If applicable, enter the **Consent Restriction** details. For example, enter *Only to be used for Type II Diabetes therapeutic area*. 7 Enter a **Start Date** and **End Date**. 8 Click **OK**.
Consent Category	(Automatically populated from the record marked **Current** in the **Protocol Version** field.)
Consent Restrictions	(Automatically populated from the record marked **Current** in the **Protocol Version** field.)
Preparation	Enter specific details about the specimen from the lab manual, up to a maximum of 250 characters.
Extra	Enter additional details, as needed, up to a maximum of 150 characters.

Tip: To make a copy of a record (copying most of the details from the record), highlight the record and then press **Ctrl + B**.

Form Fields

Field	Guidelines
Biobank Protocol	(Automatically populated with the original protocol name.)
Biobank Project #	Automatically populated with the original project number, but allows you to enter the new project number associated to the biorepository protocol after the original protocol is locked. **Note**: The original **Project #** can be seen on the **More Info** view tab.
Biobank PI	(Automatically populated with the **Biobank Internal Personnel** record(s) with a **Role** of *Biobank PI*.)

More Info View Tab

Includes general protocol fields (read-only) and biorepository-specific fields (open for editing).

Field	Guidelines
Therapeutic Population	1 Click the selection icon. 2 Click **New**. 3 Click the **Primary** checkbox. 4 Select a value from the **Population** drop-down list, or enter a new value. 5 Click **OK**.
Grant Number	If applicable, enter the grant number associated with the biorepository.
NCT Number	If applicable, enter the National Clinical Trial (NCT) number listed on the *clinicaltrials.gov* website.
Biobank Sponsor	(Automatically populated with the **Biobank Account** record(s) with a **Role** of *Biobank Sponsor*.)

Field	Guidelines
Biobank Sponsor Type	Click the selection icon to select the sponsor type.
Biobank Project #	Click the selection icon to select the project number.
Biobank PI	Automatically populated with the **Biobank Internal Personnel** record(s) with a **Role** of *Biobank PI*.

Scroll down to view/edit other biorepository-specific applets below the **More Info** view tab.

Specimen Collection Operations Applet

Field	Guidelines
Operations Description	Enter details regarding DCRI's obligations for maintaining the samples.

IRB Information Applet

Field	Guidelines
Duke IRB #	Enter the protocol's IRB number.
Duke IRB Renewal Date	Enter the protocol's IRB renewal date.
Biobank IRB #	After the protocol is closed, enter the new IRB number assigned to the biorepository.
Biobank IRB Renewal Date	Enter the biorepository's IRB renewal date.

Governance Applet

Field	Guidelines
Governing Body	Click the selection icon to select the governing body.
Specimen Governance Description	If the **Governing Body** is a *Committee*, enter details in this field describing who is involved.
Use Restriction Description	Based upon governance, enter any restrictions (maximum: 2,000 characters).

Duke Index Annotation Applet

Enter details to be included/considered when publishing to the Duke Index of Biospecimens (*http://biobank.duke.edu/index-biospecimens*). This task is typically completed by the Biorepository Team.

Biobank Accounts View Tab

Add the accounts associated to the biorepository.

- Record(s) with the **Role** of *Biobank Sponsor* will automatically populate the **Biobank Sponsor** field on the **More Info** tab.
- Record(s) where one of the **Services** is *Biobank* will automatically be available to select from the **Specimens** view tab's **Storage Location** field.

Biobank Contacts View Tab (non-DCRI employees)

Add the non-DCRI contacts associated with the biorepository.

Biobank Internal Personnel View Tab (DCRI employees)

Add the DCRI personnel associated with the biorepository.

The record(s) with the **Role** of *Biobank PI* will automatically populate the **Biobank PI** field on the **More Info** tab.

Biobank Attachments View Tab

Attach important documents, such as the lab manual and protocol.

Biobank Analyses View Tab

Refer to the *CTMS Biorepositories - Analysis QRC* for details about the **Biobank Analyses** view tab.

Getting Help

If you have questions or comments about the content of this QRC, please email IT Training [**dcriittrain@dm.duke.edu**]. If you experience any technical problems working with the CTMS Biorepository tabs that you are unable to resolve, email the DCRI Service Desk [**dcriservicedesk@dm.duke.edu**] or, for time-sensitive issues, call them Monday through Friday (6 a.m. to midnight, Eastern time, except holidays) at 919.668.8916.