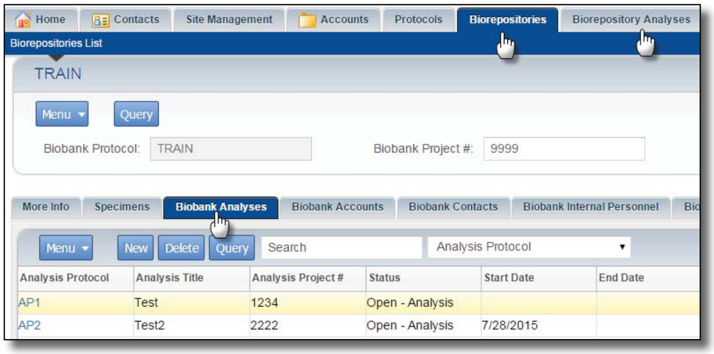
Locating Biorepository Analysis Protocols



Do one of the following:

1. From the **Biorepositories** screen tab, click the **Biobank Analyses** view tab. (Refer to the *CTMS Biorepositories - Collection QRC* for details about the **Biorepositories** screen tab.)
2. Click the study's **Analysis Protocol** blue hyperlink.

OR

1. Click the **Biorepository Analyses** screen tab.

   Note: If you do not see the **Biorepository Analyses** screen tab:

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

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

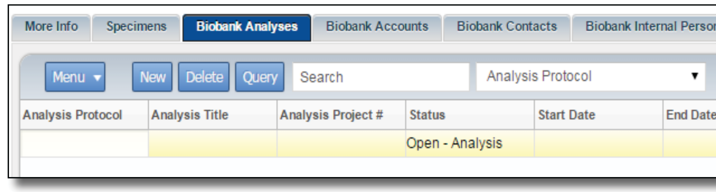
   c. Click the **Biorepository Analyses** link again to open the screen tab.
2. Use the **Search Box** or **Query** tool to locate the biorepository analysis study.

Tip: To view the **Biorepositories** and **Biorepository Analyses** screen tabs by default, go to **User Preferences** and *unhide* them in the **Tab Layout** list.

Creating a New Analysis Protocol

- If the analysis protocol uses only *one* biorepository, create the new analysis protocol from the **Biorepositories** screen tab's **Biobank Analyses** view tab (follow the first procedure below).
- If the analysis protocol uses *multiple* biorepositories, create the new analysis protocol from the **Biorepository Analyses** screen tab (follow the second procedure below).

▶ Using the Biobank Analyses View Tab to Associate a Protocol to One Biorepository



1. From the **Biorepositories** screen tab, select the protocol, and then click the **Biobank Analyses** view tab in the lower portion of the window.

   Note: This tab displays a list of analysis protocols that are using specimens from the biorepository, and IRB details indicating when each analysis protocol received IRB approval (since the original collection study may be already closed).
2. Click **New** to open the list of existing biorepository analysis protocols.
3. To associate the biorepository specimens to an *existing* analysis protocol, select the protocol and click **Add**.
4. To create a *new* analysis protocol, click **New**.

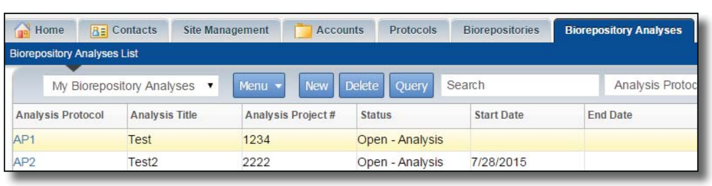
   You are returned to the **Biobank Analyses** view tab with a new blank yellow line for entering the new record.
5. Use the table below as a guideline for completing the new record.

   Note: Data can be entered in the list view or in the table view below the list.

Field	Guidelines
Analysis Protocol	Enter the protocol name.
Analysis Title	Enter the protocol title.
Analysis Project #	Enter the project number **Note**: This could be an EPM number or another project number that was assigned.
Status	Select a status from the drop-down list.
Start Date	Enter the protocol start date.
End Date	Enter the protocol end date.
IRB Type	Select the IRB type from the drop-down list.
Testing IRB #	Enter the testing IRB number.
Testing IRB Renewal	Enter the testing IRB renewal date.

Field	Guidelines
Testing Operations Description	Enter testing details, up to a maximum of 2,000 characters.
Analysis PI	Automatically populated with the **Analysis Internal Personnel** record(s) with a **Role** of *Analysis PI*. **Note**: Click the blue **Analysis Protocol** hyperlink to get to the **Analysis Internal Personnel** view tab.
Analysis Sponsor	Automatically populated with the **Analysis Account** record(s) with an **Account Role** of *Analysis Sponsor*. **Note**: Click the blue **Analysis Protocol** hyperlink to get to the **Analysis Sponsor** view tab.
Analysis Sponsor Type	1 Click the selection icon to open the Sponsor Type window. 2 Click **New**. 3 Select a type from the drop-down list. 4 Click **OK**.
Extra	Enter additional details, as needed, up to a maximum of 150 characters.

▶ Using the Biorepository Analyses Screen Tab to Associate a Protocol to Multiple Biorepositories



1. Go to the **Biorepository Analyses** screen tab.
2. Click **New**.
3. Use the table below as a guideline for completing the new record.

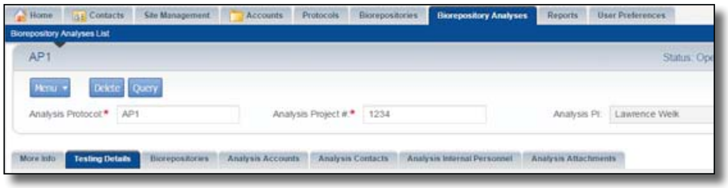
   Note: Data can be entered in the list view, or in the table view below the list.

Field	Guidelines
Analysis Protocol	Enter the protocol name.
Analysis Title	Enter the protocol title.
Analysis Project #	Enter the project number.
Status	Select a status from the drop-down list.
Start Date	Enter the protocol start date.
End Date	Enter the protocol end date.
IRB Type	Select the IRB type from the drop-down list.
Testing IRB #	Enter the testing IRB number.
Testing IRB Renewal	Enter the testing IRB renewal date.
Testing Operations Description	Enter testing details, up to a maximum or 2,000 characters.
Analysis PI	Automatically populated with the **Analysis Internal Personnel** record(s) with a **Role** of *Analysis PI*. **Note**: Click the blue **Analysis Protocol** hyperlink to get to the **Analysis Internal Personnel** view tab.
Analysis Sponsor	Automatically populated with the **Analysis Account** record(s) with an **Account Role** of *Analysis Sponsor*. **Note**: Click the blue **Analysis Protocol** hyperlink to get to the **Analysis Sponsor** view tab.
Analysis Sponsor Type	1 Click the selection icon to open the Sponsor Type window. 2 Click **New**. 3 Select a type from the drop-down list. 4 Click **OK**.
Extra	Enter additional details, as needed, up to a maximum of 150 characters.

Understanding and Working with Analysis Data

Note: The **More Info** view tab displays the same fields outlined in the tables above.

Form Fields



These fields are visible after you click any view tab on the **Biorepository Analyses** screen tab.

Field	Guidelines
Analysis Protocol	Enter the protocol name.
Analysis Project #	Enter the EPM number associated to the protocol.
Analysis PI	Automatically populated with the **Analysis Internal Personnel** record(s) with a **Role** of *Analysis PI*.

Testing Details View Tab

Use this tab to enter details about the analysis testing that occurs during the analysis protocol.

1. Click **New**.
2. Refer to the table below when completing the record.

Field	Guidelines
Test Type	Select the type from the drop-down list. If the type is not listed, you can type a new type in this field. **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”).
Test Name	Enter the test name, up to a maximum of 150 characters.
AIM	Enter details to describe the aims for the test, up to a maximum of 250 characters. For example, type *Aim 1A: Proteomics of plasma*.
Biobank Project #	If there is *only one* biorepository project associated to this analysis, this field will be automatically populated with the **Biobank Project #** for that biorepository. If there is *more than one* biorepository associated, click the selection icon to select the correct one. If there is no project number assigned, you can leave this field blank.
Specimen/Visit Data	Select the specimen(s)/visit(s) that are being used for this test. Displays *Single Visit* or *MultiVisit*, depending on the number of records that are tracked by clicking the selection icon. 1 Click the selection icon to open the **Specimen Type/Preservation/Visit** window. 2 Click **Show Available**. **Note**: If the window is blank, this is an indicator that the biorepository study (displayed in the **Biobank Project #** field) has not been populated with specimen data. This must be populated before you can continue. 3 Select the protocol, and then click **Add**. 4 Click **OK**.
# Samples	Enter the number of samples that were run.
# Returned	If applicable, enter the number of samples that were returned to the biorepository.
Start Date	Enter the start date of the test.
End Date	Enter the end date of the test.
Laboratory	Click the selection icon to associate the laboratory where the samples were tested.

Field	Guidelines
Analysis Dataset Location	Enter details regarding where the analysis data is now located (maximum: 250 characters). For example, type *DCRI Biostatistics*.
Test Dataset Location	Enter details regarding where the test data is now located (maximum: 250 characters). For example, type *DCRI CDM*.
Description	Enter additional information that you would like to add about the test, up to a maximum of 2,000 characters.
Extra	Enter additional details, as needed, up to a maximum of 150 characters.

Biorepositories View Tab

This view tab displays as *read-only* the list of protocols that are associated with the analysis record. (Repository specimens can be used in more than one analysis study.)

- Click the **Add** button to associate an additional *existing* biorepository to this analysis study.
- Click the hyperlink in the **Biobank Protocol** field to view the biorepository definition for the protocol.

  You can only view protocol definitions for protocols assigned to you. Otherwise, you will see an error message stating that you do not have permission to view the protocol.

Note: If there is no data loaded into the original biorepository, you must first ask the Biorepository or Protocol Team to enter the specimen data before you can use it in the analysis study.

Analysis Accounts View Tab

This tab displays the accounts associated to the analysis protocol.

The record with the **Account Role** of *Analysis Sponsor* automatically populates the **Analysis Sponsor** field on the analysis protocol's **More Info** tab.

Analysis Contacts View Tab

This tab displays the contacts associated to the analysis protocol.

Analysis Internal Personnel View Tab

This tab displays the internal personnel associated to the analysis protocol.

The record with the **Role** of *Analysis PI* will automatically populate the **Biobank PI** field on the analysis protocol's **More Info** tab.

Analysis Attachments View Tab

Use this view tab to attach important documents associated with the analysis protocol.

> 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").

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.