**Purpose: To ensure collection protocol can be created successfully as a superadministrator.**

**Prerequisites:**

Import dump located at /files/caTissue/dump and deploy application.

**Procedure:**

1. Login as ***super administrator***([admin@admin.com](mailto:admin@admin.com), Test123)
2. Navigate to Administrative Data-🡪Collection Protocol-🡪Add page.
3. Select user ***last***, ***Sci1*** as Principal Investigator.
4. Select user ***last***, ***Sci2***as Protocol Coordinator.
5. Enter title as ***Myeloid Leukemia Study***, short title as ***MLS***.
6. For clinical diagnosis field select following values from the list using Add button:

* Sub acute myeloid leukemia.
* Monocytic Leukemia.
* Chronic Monocytic Leukemia.

1. Specify the label format as:

* Parent Specimen Label format: %SYS\_UID%\_%SP\_TYPE%\_%YR\_OF\_COLL%
* Aliquot Specimen Label format: Blank
* Derivative Specimen Label format: %SYS\_UID%\_%SP\_TYPE%\_%YR\_OF\_COLL%

1. Click on Privileges tab. Select Site ***Laboratory for Translational Pathology***, Click on Save Privileges. Refer the Expected Output.
2. Click on Add consents tab. Enter consents statements as:

* Consent given for participation in the Cancer Genome Atlas project
* Consent given for further contact regarding specimen
* Consent given for tissue specimen use for research unrelated to the patient's cancer
* Consent given for tissue specimen use for research on the patient's cancer

1. Click on Add events. Enter event details as shown in following table:

|  |  |
| --- | --- |
|  | **First Event** |
| Study Calendar Event Point | 0.0 |
| Collection Point Label | Initial Diagnosis |
| Clinical Diagnosis | New Diagnosis |
| Clinical Status | Sub acute myeloid leukemia |

1. Verify the list of clinical diagnosis values displayed in Clinical Diagnosis sub-set list on event details page. Refer the Expected Output.
2. Click on Add Specimen requirements. Refer the Expected Output.
3. For the first event , enter following details on Specimen Requirements page as in table:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **First Event** |  |  |  |  |
|  | **First Set of Requirements** |  | **Second Set of Requirements** |  |  |
|  | **Parent Specimen** | **Derivative** | **Parent Specimen** | **First Derivative** | **Second Derivative** |
| Class | Tissue | Tissue | Fluid | Cell | Fluid |
| Type | Fresh Tissue | Frozen Tissue | Whole Blood | Cryo preserved Cell | Plasma |
| Tissue side | Not Specified |  | Not Specified |  |  |
| Tissue site | Skin, NOS |  | Blood |  |  |
| Pathological Status | Non Malignant |  | Malignant |  |  |
| Storage Location | Virtual |  | Virtual |  |  |
| Initial Quantity | 0 | 0 | 0 | 1.5E8 | 3 |
| Concentration | 0 | 0 | 0 |  |  |
| Collector | admin |  | admin |  |  |
| Receiver | admin |  | admin |  |  |
| Collection Procedure | Needle Core Biopsy |  | Vein puncture |  |  |
| Collection Container | Not Specified |  | EDTA Container |  |  |
| Received Quality | Not Specified |  | Not Specified |  |  |
| Label Format | % PPI% \_%SYS\_UID% | %SYS\_UID% | % PPI% \_%SYS\_UID% | %SYS\_UID% | %SYS\_UID% |
| Aliquot Count |  |  |  | 10 | 3 |
| Aliquot Quantity |  |  |  | 1.0E7 | 1 |
| Aliquot Storage Location | None | None | None | Auto | Auto |
| Aliquot Label Format |  |  |  | Blank | Blank |

1. Click on Save Specimen requirements. Refer the expected Output.
2. Click on Add events. Enter event details as shown in following table.

|  |  |
| --- | --- |
|  | **Second Event** |
| Study Calendar Event Point | 1.0 |
| Collection Point Label | Relapse |
| Clinical Diagnosis | Relapse, Not Specified |
| Clinical Status | Sub acute myeloid leukemia |

1. Click on Save Specimen Requirements, for the second event, enter following details on Specimen Requirements page as in table. Refer the table below for the Specimen requirement details.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Second Event** |  |  |  |  |  |
|  | **First Set of Requirements** |  |  | **Second Set of Requirements** |  |  |
|  | **Parent Specimen** | **First Derivative** | **Second Derivative** | **Parent Specimen** | **First Derivative** | **Second Derivative** |
| Class | Fluid | Cell | Fluid | Fluid | Cell | Fluid |
| Type | Whole Blood | Cry preserved cell | Plasma | Whole Bone Marrow | Cryo preserved Cells | Bone Marrow plasma |
| Tissue side | Not Specified |  |  | Not Specified |  |  |
| Tissue site | Blood |  |  | Bone Marrow |  |  |
| Pathological Status | Malignant |  |  | Malignant |  |  |
| Storage Location | Virtual | Virtual | Virtual | Virtual | Virtual | Virtual |
| Initial Quantity | 0 | 1.5E8 | 3 | 0 | 1.5E9 | 3 |
| Concentration | 0 | 0 | 0 | 0 | 0 | 0 |
| Collector | admin |  |  | Admin |  |  |
| Receiver | admin |  |  | Admin |  |  |
| Collection Procedure | Vein puncture |  |  | Needle aspirate |  |  |
| Collection Container | EDTA Container |  |  | EDTA Container |  |  |
| Received Quality | Not Specified |  |  | Not Specified |  |  |
| Label Format | % PPI% \_%SYS\_UID% | %SYS\_UID% | %SYS\_UID% | % PPI% \_%SYS\_UID% | %SYS\_UID% | %SYS\_UID% |
| Aliquot Count |  | 10 | 3 |  | 15 | 3 |
| Aliquot Quantity |  | 1.0E7 | 1 |  | 1.0E7 | 1 |
| Aliquot storage location |  | Auto | Auto |  | Auto | Auto |
| Aliquot label format |  | Blank | Blank |  | Blank | Blank |

1. Click on Save Specimen Requirements. Refer the expected Output.
2. Click on Save Collection Protocol.

**Expected Output:**

8 On click of Save Privilege a row should be added in privileges summary section as:

Laboratory for Translational Pathology -----All users---All default privileges

11 The Clinical Diagnosis list on events page should display the subset list of clinical diagnosis values.

12 On click of Add Specimen requirements, the added events should be displayed in the CP details tree on L.H.S.

14 On Submit of Specimen requirements, the added specimen requirements should be displayed in the CP details tree on L.H.S.

16 A message should be displayed as “Collection Protocol successfully created”

**Verification Logic:**

1. Navigate to Collection Protocol--🡪Edit page. Search for the created collection protocol with short title MLS.
2. Once the collection protocol opens in edit mode.

* Verify the CP details for the protocol.
* Verify label format at CP details page such as Parent, Aliquot and Derivative specimen label format.
* Verify the Privileges section display the privileges details.
* Verify details such as study calendar event point, clinical diagnosis, and clinical status are saved correctly. (The details should be as per the event details table)
* Verify all the specimen requirement details such as Specimen Class, Specimen type, Pathological Status are saved correctly. (The details should be as per the specimen requirements table)

1. In CATISSUE\_AUDIT\_EVENT table new record should be entered with IP address equal to the IP address of the machine from which the action was performed and Event\_Timepstamp equal to the date on which the action was performed. Event Type should contain INSERT.
2. In CATISSUE\_DATA\_AUDIT\_EVENT\_LOG table Object Name should contain CATISSUE\_COLLECTION\_PROTOCOL, catissue\_<specimen type>\_req\_specimen, CATISSUE\_COLL\_PROT\_EVENT and CATISSUE\_CONSENT\_TIER.
3. Object\_ID is the unique ID of the object inserted. Parent\_ID will be null for the main object (Collection protocol). Containment or reference type objects getting added will have a parent\_id equal to the ID of the main Object (CP) being inserted. This table refers to CATISSUE\_AUDIT\_EVENT\_LOG table which relates to the CATISSUE\_AUDIT\_EVENT table.
4. In CATISSUE\_AUDIT\_EVENT\_DETAILS table Element name contains the list of attributes that are in CATISSUE\_COLLECTION\_PROTOCOL, catissue\_<specimen\_type>\_req\_specimen, CATISSUE\_COLL\_PROT\_EVENT and CATISSUE\_CONSENT\_TIER tables. Specimen LABEL FORMAT, aliquot LABEL FORMAT and derivative LABEL FORMAT should be inserted.
5. CATISSUE\_USER will have their ID audited only as they have reference association with the main object. ID of CATISSUE\_Coll\_PROT\_EVENT and catissue\_<specimen\_type>\_req\_specimen will also be audited along with their attributes as it is a containment type attribute.
6. Elements inserted have the following format:

* edu.wustl.catissuecore.domain<attribute\_name>\_PREV\_CURR\_IDS\_LIST.
* In this case following elements gets added:
* edu.wustl.catissuecore.domain.<specimneType>SpecimenRequirement\_PREV\_CURR\_IDS\_LIST
* edu.wustl.catissuecore.domain.CollectionProtocolEvent\_PREV\_CURR\_IDS\_LIST
* edu.wustl.catissuecore.domain.User\_PREV\_CURR\_IDS\_LIST
* edu.wustl.catissuecore.domain.ConsentTier\_PREV\_CURR\_IDS\_LIST

1. Refer the data model and audit metadata.xml to find out the classes with containment and reference association with the main class.All the classes and attributes should be audited in respective audit tables.