**TMT Location Details: caTissue >> Master List\_v2.0 >> Biospecimen >> Specimen Collection Group >> 9573\_CONSENT\_Individual\_Withdraw\_At\_Spec\_Coll\_Group**

**Purpose:**

**To ensure that any of the consent tier response can be set to withdrawn at Specimen Collection Group level and the same response is propagated to the child specimens.**

**Pre-requisites:**

Import latest dump located at

Oracle: https://ncisvn.nci.nih.gov/svn/catissue\_persistent/caTissue Database Dump/v2.0/Oracle

MySQL: https://ncisvn.nci.nih.gov/svn/catissue\_persistent/caTissue Database Dump/v2.0/MySQL and deploy application.

**Procedure:**

1. Login into the application as a Superadministrator with the login ID as [admin@admin.com](mailto:admin@admin.com) with password: Test123
2. Navigate to Collection Protocol Based view select “**Z6041**” protocol from the Collection Protocol.
3. Click on Register New.
4. Enter the following under “**Participant Details**” section :

Social Security Number (SSN) – 465-56-9876

Last Name: **Anderson**

First Name: **Jeff**

Birth Date: 06-03-1970

Vital Status: Alive

Gender: Male Gender

1. Enter the following under “**Medical Identifier(s)**”sections

Source: Laboratory for Translational Pathology Research

Medical Record Number: 111\_1234

1. Enter the following under “**Protocol Registration(s)**”sections

Participant Protocol ID: 1234

1. Click on ***Enter Response link*** from the 'Consent' under Protocol Registration(s).(Refer the expected output)
2. Capture the following Participant Responses as follows :

|  |  |  |
| --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** |
| 1 | Consented to being contacted in the future to ask if he/she would like to take part in more research. | Yes |
| 2 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer. | Not Specified |
| 3 | Consented to their tissue samples being kept for use in research to learn about, prevent, or treat other health problem (for example: diabetes, Alzheimer's disease or heart disease) | No |

1. Click on **Done**. (Refer the expected output)
2. Click on **OK.** (Refer the expected output)
3. Click on **Register Participant** Button. (Refer the expected output)
4. Navigate to the **Specimen Details** on the LHS and click on the first event point i.e. **T1.0: Pre-CRT.**
5. On the **Edit Specimen Collection Group** enter the following details

Specimen Group Name: **Z6041\_SCG\_AJ\_1**

Collection Site: **Laboratory for Translational Pathology Research**

Collection Status: **Complete**

1. Click on the **Consent tab** from the Edit Specimen Collection Group.(Refer the expected output)
2. Edit the following consents as follows

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** | **Verify Consent**  **Status** | |
| 2 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer. | Not Specified | **Withdrawn** |
| 3 | Consented to their tissue samples being kept for use in research to learn about, prevent, or treat other health problem (for example: diabetes, Alzheimer's disease or heart disease) | No | **Withdrawn** |

1. Click on **Submit.** (Refer the expected output)
2. Click on **Reset** Button. (Refer the expected output)
3. Click on **OK** Button.
4. On the Specimen Details section check the Coll? Check boxes and specify the labels as **FT\_AJ\_1** for parent and for the childs as **FT\_AJ\_1**\_**1** and **FT\_AJ\_1\_2**.
5. Click on **Add to My List Button**. (Refer the expected output)
6. Select one specimen collected under **T1.0: Pre-CRT** event point. Select events tab from the edit specimen page on RHS. (Refer Expected Output)
7. Navigate to **Search >> My List View**. (Refer the expected output)
8. Click on the **Distribute** radio button.
9. Click on **Submit**. (Refer the expected output)
10. On the “Order” page enter “**DP\_Consent\_SCG\_Withdraw**” in the Order Name. (Refer the expected output)
11. Select the “**DP\_Consent\_Specimen**” from the Distribution Protocol.
12. Select the “**Laboratory for Translational Pathology Research”** from Distribution Site dropdown**.**
13. From the **Distribution Site dropdown select “**Laboratory for Translational Pathology Research**” .**
14. From the Specimen Requests Tab “**Consent for Specimen**” heading click on the “[**View”**](javascript:showNewConsentPage('value(RequestDetailsBean:0_specimenId)','labelStatus0','value(RequestDetailsBean:0_consentVerificationkey)','0'))  hyperlink. (Refer the expected output)
15. Check the **I have verified that the distribution of the specimen is as per consent of the Participant.**
16. Click on **Ok** (Refer the expected output).
17. Again click on the **View link** for the **FT\_AJ\_1**\_**1** and verify the consents. (Refer the expected output).
18. Again click on the **View link** for the **FT\_AJ\_1**\_**2** and verify the consents. (Refer the expected output).
19. From the **Status** Dropdown from **Specimen Request** change the status to “**Distributed and Close**” (Refer the expected output)
20. Click on **Submit**. (Refer the expected output)

**Expected Output:**

7) **Consent Form** pop up should be displayed with following details

1. Signed consent form URL : [www.consentdata-ltp.com](http://www.consentdata-ltp.com)
2. Witness Name: Select admin1@wustl.edu, [admin1@wustl.edu](mailto:admin1@wustl.edu) user.
3. Consent Date/time. : Select current date and time.

Default **Participant Responses** should be **Not Specified** and the **Consent Tiers – Participant Responses** should display the following dropdown values

* Yes
* No
* Not Specified

9) A pop up should be displayed with the following question “Consent status updated, register participant to save the changes.” with **OK** button.

10) The pop up should be disappeared.

11) “Participant successfully created.” message should be displayed and **Edit participant** page should be displayed on the RHS of the page and on the LHS Specimen Details should auto populate the 2 event points as

* **T1.0 :Pre-CRT**
* **T1.0:Surgery**

13) **Consent Form** page should be displayed with the

1. Signed consent form URL : [www.consentdata-ltp.com](http://www.consentdata-ltp.com)
2. Witness Name: Select admin1@wustl.edu, [admin1@wustl.edu](mailto:admin1@wustl.edu) user.
3. Consent Date/time. : Select current date and time.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** | **Verify Consent**  **Status** | |
| 1 | Consented to being contacted in the future to ask if he/she would like to take part in more research. | Yes | Yes |
| 2 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer. | Not Specified | Not Specified |
| 3 | Consented to their tissue samples being kept for use in research to learn about, prevent, or treat other health problem (for example: diabetes, Alzheimer's disease or heart disease) | No | No |

**Withdraw All Button**

**Add Multiple Specimen Section**

**Submit and Delete Buttons (enabled)**

**Add Specimens and Add Multiple Specimen (disabled)**

16) **Withdraw Consent Tier** pop up should be displayed with following details

* **Specimen Details**
* **What do you want to do with the withdrawn specimens?**
* To Discard the specimen and all sub-specimens, click 'Discard'
* To return the specimen to the Collection Site, click 'Return'
* To take no action on the specimens, click 'Reset'

17) “Are you sure you do not want to perform any action on the specimen? “ Pop up should be displayed with **OK** and **Cancel** buttons.

**Note: Reset** option sets the response as it is across the hierarchy. Hence resetting a response will navigate that/those specific response/responses across the specimen collection group/specimen

18) The pop up should be closed and the RHS should display the **Edit Specimen Collection Group** page with page refresh.

**Note:** If **Cancel button** was clicked then the pop up would have got closed but Withdraw Consent Tier window would have still be shown.

20) “3 Records are added in the List.” message should be displayed with **Edit Specimen Collection Group.**

21) The consent response captured at Specimen Collection group propagated down the hierarchy to Specimens. The consent response at specimen level will be same as captured at Specimen Collection Group level.

22) **My List View** page should be displayed with the following sections

* The specimen details grid
* Delete and Export Buttons
* Select the operation to be performed on the selected specimens and click 'Submit' with the following radio buttons
* **Order Biospecimen (Default Selected)**
* Multiple Specimen Page
* Specimen Event
* Request Shipment
* Create New Shipment
* Distribute
* Print Labels

24) **Order** should be displayed with the message "A pending order has been created with order name Order\_63 for the items selected. If required, you can finish the distribution later from the pending order list" with two different section

* **Order Details**
* **\*Order Name**
* **\*Distribution Protocol**
* **Requestor's Name**
* **Requested Date**
* **Distribution Site**
* **Specimen Request and Array Request** tabs

With the following table

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Ordered Specimen Details** | | **Requested Specimen Details** | | **Consent for Specimen** | **Status** | **Comment** |
| **Specimen** | **Type, Available Quantity** | **Request For** | **Type, Available Quantity** |

Comment Text Area

2 Buttons:

* **Submit**
* **Submit and Notify Button**

25) The Order Name should be auto populated with a system generated name as Order\_66 which is successfully edited with the user defined name as **Order for SCG\_Withdraw.**

29) **Consent Form** pop up should be displayed. This Consent Form should have the following

* Signed Consent Form URL
* Witness Name
* Consent Date Current Date

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** | **Verify Consent Status** |
| 1 | Consented to being contacted in the future to ask if he/she would like to take part in more research. | Yes | Yes |
| 2 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer. | Not Specified | **Withdrawn** |
| 3 | Consented to their tissue samples being kept for use in research to learn about, prevent, or treat other health problem (for example: diabetes, Alzheimer's disease or heart disease) | No | **Withdrawn** |

Check box: **I have verified that the distribution of the specimen is as per consent of the Participant.**

**Ok** Button

**Note**: Please note that the **Participant Responses should** be the same as captured while registration and but **Verify Consent Status** should be the one that are propagated from Specimen Collection Group to Specimen.

31) The **Consent Form** pop up should disappear and View link now should be a **Verified** Link.

32) The **Consent Form** should pop up and once the consents are verified the pop up should be closed and **View** link should be changed to **Verified**.

33) The **Consent Form** should pop up and once the consents are verified the pop up should be closed and **View** link should be changed to **Verified**.

34) For the specimen the status should change to “**Distributed and Close”.**

35) **Distribution Event** page should be displayed with “Order successfully updated.” message and the Distribution Report.

**Verification Logic:**

1. **Audit**

Following changes should be reflected in below tables:

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 UPDATE.

2)In CATISSUE\_DATA\_AUDIT\_EVENT\_LOG table Object\_Name should contain CATISSUE\_PARTICIPANT, CATISSUE\_RACE, CATISSUE\_COLL\_PROT\_REG and CATISSUE\_PART\_MEDICAL\_ID. Object\_ID is the unique ID of the object inserted. Parent\_ID will be null for the main object. Containment or reference type objects getting added will have a parent\_id equal to the ID of the main Object being inserted. This table refers to CATISSUE\_AUDIT\_EVENT\_LOG table which relates to the CATISSUE\_AUDIT\_EVENT table.

3)In CATISSUE\_AUDIT\_EVENT\_DETAILS table Element\_name contains the list of attributes that are in CATISSUE\_PARTICIPANT, CATISSUE\_COLL\_PROT\_REG CATISSUE\_RACE and CATISSUE\_PART\_MEDICAL\_ID tables. Previous\_value will be values before update and Current\_value will be the value updated through UI. CATISSUE\_SITE and CATISSUE\_COLL\_PROT\_REG will have their ID's audited only as they have reference association with the main object. ID of CATISSUE\_PART\_MEDICAL\_ID and CATISSUE\_RACE will also be audited along with their attributes as it is a containment type attribute.

One more row gets added for the containment and reference association i.e., edu.wustl.catissuecore.domain.<attribute\_name>\_PREV\_CURR\_IDS\_LIST. In this case following gets added:

edu.wustl.catissuecore.domain.Site\_PREV\_CURR\_IDS\_LIST

edu.wustl.catissuecore.domain.ParticipantMedicalIdentifier\_PREV\_CURR\_IDS\_LIST

edu.wustl.catissuecore.domain.CollectionProtocolRegistration\_PREV\_CURR\_IDS\_LIST

edu.wustl.catissuecore.domain.Race\_PREV\_CURR\_IDS\_LIST

1. **Advance Query –**

**Execute each of the individual queries and verify that the same consents are reflected in the advance query also .**

**i) Participant level consent query**

**Participant 🡪ConsentTier Response**

**|**

**|--------🡪 ConsentTier Status**

**Query Conditions :**

|  |  |  |
| --- | --- | --- |
| **Object** | **Operator** | **Value** |
| Participant | First Name | Jeff |
|  | Last Name | Anderson |
| ConsentTier | Id | Not Null |
| ConsentTier Response | ID | Not Null |

**ii) Specimen Collection Group level consent query**

**Specimen Collection Group 🡪ConsentTier**

**|**

**|------------------🡪 ConsentTier Status**

**Query Conditions:**

|  |  |  |
| --- | --- | --- |
| **Object** | **Operator** | **Value** |
| Specimen Collection Group | Name | **Z6041\_SCG\_AJ\_1** |
| ConsentTier | Id | Not Null |
| ConsentTier Status | Id | Not Null |

**iii) Specimen level consent query**

**Specimen 🡪ConsentTier**

**|**

**|-----🡪 ConsentTier Status**

|  |  |  |
| --- | --- | --- |
| **Object** | **Operator** | **Value** |
| Specimen | Name | FT\_AJ\_1\_2 |
| ConsentTier | Id | Not Null |
| ConsentTier Status | Id | Not Null |