**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**To ensure that any of the consent tier response can be set to withdrawn at Specimen Collection Group level and the same response is propagated to the child specimens.**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. Navigate to **Search >> My List View**. (Refer the expected output)
7. Click on the **Distribute** radio button.
8. Click on **Submit**. (Refer the expected output)
9. On the “Order” page enter “**DP\_Consent\_SCG\_Withdraw**” in the Order Name. (Refer the expected output)
10. Select the “**DP\_Consent\_Specimen**” from the Distribution Protocol.
11. Select the “**Laboratory for Translational Pathology Research”** from Distribution Site dropdown**.**
12. From the **Distribution Site dropdown select “**Laboratory for Translational Pathology Research**” .**
13. 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)
14. Check the **I have verified that the distribution of the specimen is as per consent of the Participant.**
15. Click on **Ok** (Refer the expected output).
16. Again click on the **View link** for the **FT\_AJ\_1**\_**1** and verify the consents. (Refer the expected output).
17. Again click on the **View link** for the **FT\_AJ\_1**\_**2** and verify the consents. (Refer the expected output).
18. From the **Status** Dropdown from **Specimen Request** change the status to “**Distributed and Close**” (Refer the expected output)
19. 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.

19)” 3 Records are added in the List.” message should be displayed with **Edit Specimen Collection Group.**

21) **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

23) **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**

24) 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.**

28) **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.

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

31) 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**.

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

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

**Verification Logic:**

**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 |