**TMT Location Details: caTissue >> Master List\_v2.0 >> Biospecimen >> 9564\_** **CONSENT\_Individual\_Withdraw\_At\_Participant**

**Purpose:**

**To ensure that any of the consent is withdrawn at participant level then the same response is captured while distribution of all the specimens that are collected under that participant**

**Pre-requisites:**

Import dump located at /files/caTissue/test\_data\_dump on 10.39.196.222 and deploy application.

**Procedure:**

1. Login into the application as Administrator 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. Select “Parker, Steven” from the **Participant Protocol (ID)**.
4. On the Edit Participant page >> Protocol Registration(s) >> Consent >> click on ***Edit Response link***. (Refer the expected output)
5. From following "**Participant Responses**" capture the appropriate consent as follows

|  |  |  |
| --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** |
| 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). | **Withdrawn** |

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

Specimen Group Name: **Z6401\_SCG\_PS\_2**

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

Collection Status: **Complete**

1. Once the details have been specified click on **Submit.**
2. On the Specimen Details section check the Coll? Check boxes and specify the labels as FT\_31 for parent and for the child specimens as FT\_31\_1 and FT\_31\_2.
3. Click on **Add to My List** Button. (Refer the expected output)
4. Navigate to **Search >> My List View**. (Refer the expected output)
5. Click on the **Distribute** radio button.
6. Click on **Submit**. (Refer the expected output)
7. On the “Order” page enter “**Order\_Participant\_Withdrawn**” in the Order Name. (Refer the expected output)
8. Select the “**DP\_Consent\_Specimen**” from the Distribution Protocol.
9. Select the “**Laboratory for Translational Pathology Research”** from Distribution Site dropdown**.**
10. Click on **View All Consent** link.(Refer the expected output)
11. Check the **I have verified that the distribution of the specimen is as per consent of the Participant.**
12. Click on **Ok** (Refer the expected output).
13. From the **Status** Dropdown from **Specimen Request** change the status to “**Distributed and Close**” (Refer the expected output)
14. Click on **Submit**. (Refer the expected output)

**Expected Output:**

4) **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.

The participant response should be displayed 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 | No |
| 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) | Yes |

7) “Participant successfully updated.” Message should be displayed with Participant Details page.

8) The RHS of the page should display the **Edit Specimen Collection Group** page.

12) “3 Records are added in the List.” Message should be displayed on the Edit Specimen Collection Group page.

13) **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

15) **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**

16) The Order Name should be auto populated with a system generated name as Order\_64 which is successfully edited with the user defined name as **Order\_Participant\_Withdrawn.**

19) **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 | No | No |
| 2 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer | Yes | Yes |
| 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) | **Withdrawn** | **Withdrawn** |

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

**Ok** Button

**Note**: 3 Consent table should be displayed as the number of specimen for which the consents should be verified.

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

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

23) **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 | Parker |
|  | Last Name | Steven |
| 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 | **Z6401\_SCG\_PS\_2** |
| ConsentTier | Id | Not Null |
| ConsentTier Status | Id | Not Null |

**iii) Specimen level consent query**

**Specimen 🡪ConsentTier**

**|**

**|-----🡪 ConsentTier Status**

|  |  |  |
| --- | --- | --- |
| **Object** | **Operator** | **Value** |
| Specimen | Name | FT\_31\_1 |
| ConsentTier | Id | Not Null |
| ConsentTier Status | Id | Not Null |