**TMT Location Details: caTissue >> Master List\_v2.0 >> Biospecimen >> Participant >> 9567\_CONSENT\_Not\_Mandatory\_Part\_Reg\_Later\_Editable**

**Purpose:**

**Test to ensure that a participant can be registered without capturing any consent responses and these consent responses can be later captured on participant edit page. Also the consent hierarchy remains the same test from participant to specimen collection group to specimen pages.**

**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 Supervisor with the login ID as [supervisor\_ltp@gmail.com](mailto:supervisor_ltp@gmail.com) with password: Global!@#4.
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 :
   * 1. Social Security Number (SSN) – 987-39-9484
     2. Last Name: Jones
     3. First Name: Timothy
     4. Birth Date: 04-24-1983

Vital Status: Alive

Gender: Female Gender

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

Source: Laboratory for Translational Pathology Research

Medical Record Number: 876545

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. On the **Consent Form** do not enter any **consent responses** and click on **Done**. (Refer to the excepted output)
3. Click on **OK** on the message from the webpage pop up. (Refer to the excepted output)
4. Click on Register Participant. (Refer to the excepted output)
5. On the Edit Participant page >> Protocol Registration(s) >> Consent >> click on ***Edit Response link***. (Refer the expected output)
6. From following "**Participant Responses**" capture the appropriate consent as follows and also observe the **Participant Responses** dropdown values

|  |  |  |
| --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** |
| 1 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer | Yes |
| 2 | 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 |
| 3 | Consented to being contacted in the future to ask if he/she would like to take part in more research | No |

1. Click on **Done**.
2. Click on **OK**
3. Now click on **Register Participant**.
4. Navigate to LHS of the page and from “**Specimen Details**” section click on the **T1.0: Pre-CRT** event point. Enter the mandatory details as Specimen Collection Group Name , Collection Site and Collection Status (Refer the expected output)
5. Click on **Consent** tab and observer the **Verify Consent Status** for specimen collection group (Refer the expected output)

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** | **Verify Consent Status** |
| 1 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer | Yes | Yes |
| 2 | 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 | Yes |
| 3 | Consented to being contacted in the future to ask if he/she would like to take part in more research | No | No |

1. Navigate to LHS of the page and from “**Specimen Details**” section click on the **T1.0: Pre-CRT** event point and select any of the **specimen i.e. TJ\_1**(Refer the expected output)
2. Click on **Consent** tab and observer the **Verify Consent Status** for specimen collection group (Refer the expected output)

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Consent Tier** | **Participant Responses** | **Verify Consent Status** |
| 1 | Consented to their tissue samples being kept and used in research to learn about, prevent, or treat cancer | Yes | Yes |
| 2 | 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 | Yes |
| 3 | Consented to being contacted in the future to ask if he/she would like to take part in more research | No | No |

**Expected Output:**

6) Under Protocol Registration(s) verify the following

1. **Collection Protocol** should be by default specified as the one selected from Collection Protocol RHS i.e. **Prostate** Protocol
2. The **Registration Date** should be displayed as current date.
3. **Activity Status** should be disabled with “Active” selected.
4. **Enter Response link** should be present under **Consent.**

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

8) **Message from webpage pop up** should be displayed with the “Consent Status updated, register participant to save the changes.” should be displayed. Consent Form pop up should be closed.

9) **Message from webpage pop up** should be closed.

10) “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

11) Default **Participant Responses** should be **Not Specified** and the **Consent Tiers – Participant Responses** in edit mode should display the following dropdown values

* Yes
* No
* Not Specified
* Withdrawn

15) “Participant successfully created for Jones, Timothy.” message should be displayed.

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

17) Identical responses should be captured and displayed at Participant Responses and **Verify Consent** **Status** levels.

18) RHS of the page should display **Specimen Details** page.

19) Identical responses should be captured and displayed at Participant Responses and **Verify Consent** **Status** levels.

**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 | Timothy |
|  | Last Name | Jones |
| 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\_TJ\_1** |
| ConsentTier | Id | Not Null |
| ConsentTier Status | Id | Not Null |

**iii) Specimen level consent query**

**Specimen 🡪ConsentTier**

**|**

**|-----🡪 ConsentTier Status**

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