Revision History

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<th>Date</th>
<th>By</th>
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<tr>
<td>1</td>
<td>2014/07/29</td>
<td>Mark Stauffer</td>
<td>Created initial version.</td>
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<tr>
<td>2</td>
<td>2014/11/04</td>
<td>Mark Stauffer</td>
<td>Revised content.</td>
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<tr>
<td>3</td>
<td>2014/11/06</td>
<td>Mark Stauffer</td>
<td>Accepted reviewer updates.</td>
</tr>
<tr>
<td>4</td>
<td>2014/11/19</td>
<td>Mark Stauffer</td>
<td>Updated the list of T&amp;UM validations.</td>
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<tr>
<td>5</td>
<td>2014/01/02</td>
<td>Mark Stauffer</td>
<td>Added a clarification regarding access to Site Transfer records.</td>
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<td>6</td>
<td>2015/03/25</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.1 content.</td>
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<tr>
<td>7</td>
<td>2015/08/31</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.2 content.</td>
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<tr>
<td>8</td>
<td>2016/01/28</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.3 content.</td>
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<tr>
<td>9</td>
<td>2016/07/11</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.4 content.</td>
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<tr>
<td>10</td>
<td>2016/12/12</td>
<td>Thomas Healand, Mark</td>
<td>TH 2016/12/06: Added the OPEN 7.5 content. MS 2016/12/12: Reviewed the document.</td>
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<tr>
<td>11</td>
<td>2017/04/12</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 7.7 content, and OPEN-1639.</td>
</tr>
<tr>
<td>12</td>
<td>2017/07/24</td>
<td>Mark Stauffer</td>
<td>Added the latest document styles.</td>
</tr>
<tr>
<td>13</td>
<td>2017/08/21</td>
<td>Mark Stauffer</td>
<td>Added the OPEN 8.0 content.</td>
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**OPEN T&UM QUICK REFERENCE SITE USER GUIDE**

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1. Introduction

This document provides information for using the Oncology Patient Enrollment Network (OPEN)'s Transfer and Update Module (T&UM), including instructions for creating T&UM requests, reviewing T&UM requests, and additional background information regarding the T&UM.

1.1 Organization of this Document

Section two provides an overview of the T&UM.
Section three describes, and provides instructions regarding Site Transfer requests.
Section four describes, and provides instructions regarding Credentialing Data Update requests.
Section five describes, and provides instructions regarding Demographic Data Update requests.
Section six contains additional information regarding the T&UM.

1.2 Web Addresses for CTSU Applications

Table 1: Web Addresses for CTSU Applications

<table>
<thead>
<tr>
<th>Application</th>
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<td>OPEN Portal</td>
<td><a href="https://open.ctsu.org">https://open.ctsu.org</a></td>
</tr>
<tr>
<td>CTSU Members’ website</td>
<td><a href="http://www.ctsu.org">http://www.ctsu.org</a></td>
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</table>
2. Overview of the T&UM

2.1 Background

Patient enrollment information for a NCI-sponsored cancer clinical trial may need to be updated or corrected. Previously, the update requests were manually processed using the combined efforts of the CTSU, the Network Groups, and the PMB. After the changes were validated and approved, the updates were made in multiple electronic systems (OPEN, RSS, NCI systems) and the lead protocol organization’s Clinical Data Management System (CDMS). This process took a significant amount of time and coordination.

The Transfer and Update Module (T&UM) within OPEN was created as the central location for site staff to request data changes (Site Transfers, Credentialing Data Updates, and Demographic Data Updates) for completed patient enrollments that are maintained in OPEN. Each request will undergo automatic validations, and the system also allows Lead Protocol Organization (LPO) staff to manually approve requests (per their preference). The T&UM will automatically update (when possible) systems outside of OPEN that also contain the patient’s data (such as Rave, and the LPO RandoNodes).

2.2 Accessing the T&UM

The T&UM is located within its own tab of OPEN, and it is accessible to site users with either the Site Registrar, or Site Admin, OPEN roles.

The structure of the T&UM tab is similar to the Enroll tab (they both have In Progress, Create New, and History sub tabs); however it contains different types of data.

When a user clicks the T&UM tab they will be defaulted to the T&UM’s In-Progress sub tab (see Figure 1), which lists the In-Progress T&UM requests that the user has access to (based on their active roster affiliations), and it allows users to review existing requests.

![Figure 1: The T&UM Tab of OPEN](image-url)
The T&UM’s Create New sub tab (see Figure 2) enables site users to initiate T&UM requests, and to view the list of lead organizations that participate on the T&UM.

![Figure 2: The T&UM Create New Sub Tab](image)

The T&UM’s History sub tab (see Figure 3) lists T&UM requests that have entered a terminal status (CANCELLED, REJECTED, APPROVED) for the institutions that the user has active roster affiliations with. The T&UM History sub tab also shows records that were previously associated with the user’s sites (but have since moved due to a T&UM Site Transfer).

![Figure 3: The T&UM History Sub Tab](image)
The T&UM’s Help Tool sub tab (see Figure 4) contains a tool to assist with locating Receiving Sites for patients that will be moving (and require a replacement site).

Figure 4: The T&UM Help Tool Sub Tab
3. Site Transfer Requests

Site Transfer requests are for transferring a patient to a different site, which may involve a change to credentialing information as well.

Below is a list of data points that can be updated with a Site Transfer request (please note that the LPO may have set some of these fields to be non-updateable):

- Institution Code
- Persons associated with the Patient (Treating Investigator, Site Registrar, etc., per each study’s setup)
- Network Group Credit (the credit must remain the same if the Receiving Site is a member of the Network Group that was credited for the enrollment, otherwise the site may credit any other participating Network Group that they are a member of)
- Credit Investigator
- Courier Account Name (if the field is configured as available for the study)
- Courier Account Number (if the field is configured as available for the study)

Once a Site Transfer has been approved, the only OPEN users that will have access to the patient’s information will be those that have a roster affiliation with the patient’s new institution.

Figure 5 provides a high-level overview of a Site Transfer request’s workflow.

---

**Figure 5: High-Level Workflow for a Site Transfer Request**

The remainder of this section will provide instructions for the three main processes that are involved with creating and completing a Site Transfer request:

1) Initiation of the Site Transfer request by the Transferring Site.
2) Review of the Site Transfer request by the Receiving Site.
3) (If required) Review of the Site Transfer request by the LPO.
3.1 Initiating a Site Transfer Request

The first step in the process for a Site Transfer request is the initiation of the request by the Transferring Site (the site that the patient will move from) user. Site users with the OPEN Site Registrar or OPEN Site Admin role may create T&UM requests.

A user from the Transferring Site can use the Help Tool (which is located in the T&UM’s Help Tool sub tab, or within the T&UM’s Create New screen for a Site Transfer request) to locate potential Receiving Sites, and the contact information for those institutions. After the Transferring Site user communicates with the Receiving Institution and comes to an unofficial agreement regarding the transfer of the patient, the Transferring site user will initiate the Site Transfer request in OPEN.

Below are the steps that Transferring Site users will follow to initiate Site Transfer requests:

1) Login to OPEN.
2) Click the T&UM tab, and arrive at the In Progress sub tab by default.
3) Click the T&UM’s Create New sub tab.
4) Click the Site Transfer option.

5) Locate the patient enrollment, and click the Select button for the patient. For multi-step protocols, only the most recent patient enrollment step is displayed (the prior enrollment steps are not updated using the T&UM).

6) Enter the code for the “Receiving Institution CTEP ID” field and press the Tab key, or use the Help Tool to select the code.

7) Make selections for following fields:
   a) Requested Treating Investigator
   b) Receiving Institution Contact
c) Case Status

d) Transferring Site Contact Person

8) Provide a response in the Comments field.

9) When done, click the Submit button to validate and create the Site Transfer request.

![Image of Site Transfer Request Form]

**Figure 7: Complete the Site Transfer Request Form**

10) The screen will refresh with a T&UM request number, informing the user that the Receiving Institution will review the request, and a complete Summary of the request will be provided.

![Image of Site Transfer Request Initiated]

**Figure 8: T&UM Site Transfer Request Initiated**

**NOTE:** Email recipients will be sent a reminder notification every 14 days that a request remains In Progress. Automatic cancellation will occur for T&UM requests that have been in the In Progress sub tab for 45 days (or more) without activity.
3.1.1 Cancelling a Site Transfer Request

Transferring Site users have the ability to cancel a Site Transfer request so long as it remains in a REQUESTED status. Follow the steps below to cancel a Site Transfer request:

1) Login to OPEN.
2) Click the T&UM tab, arrive at the T&UM’s In Progress sub tab by default.
3) Locate the T&UM request and click the request’s “Select” button.
4) Enter a comment in the Reason for Cancelling Request field.
5) Click the “Cancel Request” button.

![Image of cancelling a Site Transfer request]

Figure 9: Cancelling a Site Transfer that is in a REQUESTED Status

6) Click “OK” on the confirmation pop-up window to complete the cancellation request.

3.2 Review of the Site Transfer Request by the Receiving Site

The second step in the process for a Site Transfer request is the review of the request by the Receiving Institution (the site that the patient will move to).

Users at the Receiving Site will automatically be notified by email that a T&UM request is pending their review.

Below are the steps that Receiving Site users will follow to review pending Site Transfer requests:

1) Login to OPEN.
2) Click the T&UM tab, arrive at the T&UM’s In Progress sub tab by default.
3) Locate the request, and click the “Select” button for its row.
4) Click the “Review Request” button.

5) The screen will refresh with the Site Transfer request.

6) Read the “Review Patient Information” section.

7) Read the “Review the Request from the Transferring Site” section.
Figure 12: Complete the Review Request Form for a Site Transfer
8) If Accepting the Site Transfer request:
   a) Complete the “Select the Persons associated with the Patient” section. The Treating Investigator selected by the Transferring Site will automatically prefill, however it is at the discretion of the Receiving Site as to which staff are associated with the patients care.
   b) Complete the “Select the Credited Group and Credit Investigator” section. If the receiving site is a member of the Group credited with the initial enrollment, the credit group for the patient transfer must remain the same. Credit group can only change if the receiving site is not a member of the original credited group.

9) If Rejecting the Site Transfer request:
   a) If Rejecting the request, skip the “Select the Persons associated with the Patient” and “Select the Credited Group and Credit Investigator” sections.

10) Select a “Receiving Site Contact”.

11) Provide a comment regarding the review decision in the “Reviewer Comments” field. If the LPO for the protocol is COG or COGC, a mandatory “Transplant Credit” question will appear below the Reviewer Comments field (see Figure 13) to allow the user to specify whether transplant credit is involved.

The “Transplant Credit” field will appear for T&UM Site Transfers, when a Receiving Site user is reviewing a request for COG or COGC protocols.

Figure 13: A Transplant Credit Question Will Appear for COG and COGC Protocols

12) Click either the Reject Request or Accept Request buttons to make a review decision.

13) Review the message in the popup window and click the OK button.

14) The screen will refresh and the outcome of the request submission will display at the top of the screen. Accepted requests may require LPO review (and this information would be displayed at the top of the screen as an informational note).

Figure 14: Message Confirms that the Site Transfer was Accepted, and Awaiting LPO Review
3.3 (If Applicable) Review of the Site Transfer Request by the Lead Protocol Organization

The third step in the process for a Site Transfer request is review of the accepted Site Transfer request by the LPO. Some protocols may not require LPO review, in which case this step is not needed, and accepted requests are automatically set to an approved status and the data updates are applied.

Site and LPO users will be notified by email when a decision has been made regarding the T&UM request.
4. Credentialing Data Update Requests

Credentialing Data Update requests are used for changing credentialing information for a patient that is staying at the same site. Site users with the OPEN Site Registrar or the OPEN Site Admin role may create T&UM requests. Unlike a Site Transfer request, the institution code for the patient cannot be changed with this type of request, and this request type does not involve a review process by additional parties.

Below is a list of data points that can be updated with a Credentialing Data Update request (please note that the LPO may have set some of these fields to be non-updateable):

- Persons associated with the Patient (Treating Investigator, Site Registrar, etc., per each study’s setup)
- Network Group Credit (if within 7 calendar days of the patient’s enrollment onto the selected enrollment step)
- Credit Investigator
- Courier Account Name (if the field is configured as available for the study)
- Courier Account Number (if the field is configured as available for the study)

Figure 15 provides a high-level overview of the Credentialing Data Update request process.

The remainder of this section will provide instructions for creating and completing a Credentialing Data Update request.

4.1 Creating a Credentialing Data Update Request

1) Login to OPEN.
2) Click the T&UM tab, arrive at the In Progress sub tab by default.
3) Click the T&UM’s Create New sub tab.
4) Select the Credentialing Data Update action.
5) The screen will refresh to display a list of patients that are at the institution(s) that the user has active roster affiliations with.

6) Locate the desired patient’s enrollment, and click the Select button for the enrollment’s row.

7) The screen will refresh.

8) Make the necessary change(s) to the data using the available fields, and complete the required fields (those which contain a red asterisk).

   a) Please note: if the Network Group Credit is for pre-NCTN organization (a.k.a. the “Cooperative Groups” such as GOG, ECOG, NSABP, etc.), the Network Group Credit and the Credit Investigator fields will not be updateable. This is because the 7 calendar day rule requires the group to remain the same, and the cooperative group rosters no longer exist.
9) Click the “Submit” button.

10) The screen will refresh and the user will be informed that the LPO has been notified, and the data changes are being implemented. This completes the process for creating a Credentialing Data Update request.

Figure 18: Make the Needed Updates on the Credentialing Data Update Request Form

Figure 19: Screen Confirming the Credentialing Data Update was Approved
5. Demographic Data Update Requests

Demographic Data Update requests are used for changing demography screen information for a patient. Site users with the OPEN Site Registrar or the OPEN Site Admin role may create T&UM requests.

Below is a list of data points that can be updated with a Demographic Data Update request (please note that the Lead Protocol Organization can set some of these fields to be non-updateable):

- Last (initial)
- First (initial)
- Middle (initial)
- Patient SSN
- Patient Hospital Number
- Patient’s Date of Birth
- Ethnicity
- Gender of a Person
- Country of Residence
- ZIP Code
- Race
- Method of Payment

Figure 20 provides a high-level overview of the Credentialing Data Update request process.

![Figure 20: High-Level Overview of the Demographic Data Update Process](image)

Figure 20: High-Level Overview of the Demographic Data Update Process

The remainder of this section will provide instructions for the two main processes that are involved with creating and completing a Demographic Data Update request:

1) Initiation of the Demographic Data Update request by the Requesting Institution.
2) (If required) Review of the Demographic Data Update request by the LPO.
5.1 Initiating a Demographic Data Update Request

1) Login to OPEN.

2) Click the T&UM tab, arrive at the In Progress sub tab by default.

3) Click the T&UM’s Create New sub tab.

4) Select the Demographic Data Update action.

5) The screen will refresh to display a list of patients that are at the institution(s) that the user has active roster affiliations with.

6) Locate the desired patient’s enrollment, and click the Select button for the enrollment’s row.

---

**Figure 21: Select the Demographic Data Update Choice**

**Figure 22: Select the Patient Enrollment**
7) The screen will refresh.

8) Make the necessary change(s) to the Demography screen data and click the “Continue” button.

Figure 23: First Page of the Demographic Data Update Request Form

9) The screen will refresh.

10) Review the summary of the requested changes.

11) Select a “Requesting Institution Contact Person”.

12) Provide a comment regarding the change in the “Comments” field.
13) Click the Submit button.

14) Click OK on the confirmation popup window.

15) The screen will refresh, providing a T&UM request ID.

**NOTE:** Email recipients will be sent a reminder notification every 14 days that a request remains In Progress. Automatic cancellation will occur for T&UM requests that have been in the In Progress sub tab for 45 days (or more) without activity.
16) LPO review of the request may be necessary:

   a) If LPO review is needed, the user will be informed when the screen refreshes.

   b) If LPO review is not needed, the user will be informed that the request will be auto-approved, changes implemented, and the LPO will be notified. Under this circumstance, this will complete the process for creating a Demographic Data Update request.
6. Additional Information Regarding the T&UM

6.1 List of Organization that Participate in the T&UM

The T&UM Create New sub tab provides an automated list (see Figure 26) of lead organizations that participate in the T&UM.

![Figure 26: Automated List of Organizations that Participate in the T&UM](image)

To view the T&UM configuration details (including any protocol-level exceptions) for any of the listed organizations, click their hyperlink (see Figure 27) to view a T&UM Configuration Report. The report will list which T&UM request types the organization participates in, and the report will list any protocol-level exceptions.

![Figure 27: T&UM Configuration Details for an Organization](image)
6.2 T&UM History Sub Tab

The T&UM History sub tab contains information on T&UM requests that have entered an APPROVED, REJECTED, or CANCELLED status.

For site users, the T&UM History sub tab is divided into the Browse sub tab, and the Archive sub tab.

- The Browse sub tab contains T&UM requests that are associated with the user’s site affiliations.

- The Archive sub tab contains T&UM requests that were previously associated with the user’s site affiliations, but have since been transferred to an unrelated site (due to a T&UM Site Transfer).

Accessing this Feature:

1) Login to OPEN.

2) Click the History sub tab of the T&UM tab. The Browse sub tab will display by default (see Figure 28).

   a) To view a summary for a T&UM request, click the corresponding record’s Select button.

   ![Figure 28: The Browse Screen Shows Patients that are still at the User's Site(s)](image)

   b) To view a list of T&UM requests for patients that are no longer affiliated with the user’s site, click the Archive sub tab (see Figure 29). To view a summary for a T&UM request in the Archive screen, click the record’s corresponding Select button.

   ![Figure 29: The Archive Screen Shows Patients that are No Longer Affiliated with the User's Site(s)](image)
6.3 T&UM Patient History Report

A T&UM Patient History Report is available in the Summary screens in the History tab of OPEN, for patient enrollments that have approved T&UM requests. Once a user clicks the “T&UM Report” button, a report will appear in a popup window that lists all of the T&UM changes that are associated with the patient. This provides users with the ability to have a complete picture of the T&UM changes that were applied to their patient, across all enrollment steps.

**Accessing this Feature:**

1) Login to OPEN.
2) Select a patient from the Browse sub tab, of the History tab.
3) In the Summary screen, click the T&UM Report button (if present).

4) The T&UM Patient History Report will load in a popup window (see Figure 31).
6.4 T&UM Help Tool

The T&UM Help Tool assists site users with locating potential Receiving Sites for patients that need to move to a different site. Site users may contact the LPO if additional assistance is needed with locating a Receiving Site for their patient.

Google Maps functionality was integrated into the T&UM Help Tool so OPEN users can see where potential Receiving Sites are located.

Accessing this Feature:

1) Login to OPEN.
2) Click the T&UM tab.
3) Click the Help Tool sub tab.
4) Provide the necessary values for the “Protocol”, “Zip Code”, and “Radius” fields (see Figure 32).
Figure 32: Enter Search Criteria in the T&UM Help Tool

5) Click the Search button.

6) The screen will refresh, and display results using the Google Map interface (see Figure 33). The Google Map will display on the left side of the screen, and a list of the different Receiving Institutions (complete with their addresses) will display on the right side of the screen. A searchable list of all the results will display at the bottom of the screen.

Figure 33: T&UM Help Tool Results
7) To see contact information for a particular site, click the corresponding Details button. A popup window will appear with the contact information for the Administrator and Data Administrator (if available) for the site.

![Figure 34: Details Popup for the T&UM Help Tool](image)

6.5 Locating T&UM Requests in the History Tab of OPEN

The “T&UM Type” column in the History tab of OPEN can be used for identifying enrollments that are associated with approved T&UM requests.

**Accessing this Feature:**

1) Login to OPEN.

2) Click the History tab. The Browse sub tab will display by default.

3) Enrollments that have an approved T&UM request will have a designation (or multiple designations) in the T&UM Type column. Enrollments that have not involved any approved T&UM requests will have no entries in the T&UM Type column.

![Figure 35: The "T&UM Type" Column Identifies Enrollments with Approved T&UM Requests](image)

4) To filter through the enrollments by a particular T&UM Type (none, Credentialing Data Update, Demographic Data Update, Site Transfer), click the text-entry box above the T&UM Type column and select the appropriate choice.
5) After making a selection in the text-entry box above the T&UM Type column, the results will refresh as requested (see Figure 37).

Figure 36: Results can be Filtered by the T&UM Type

Figure 37: The Filtered Results for the T&UM Type
6.6  T&UM Statuses

During the lifecycle of a T&UM request, the request will go through a series of statuses. The status begins with REQUESTED, it can enter a series of intermediary statuses, and then it ends in a terminal status. Table 2 describes the different T&UM statuses.

Table 2: T&UM Statuses

<table>
<thead>
<tr>
<th>#</th>
<th>Status Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>REQUESTED</td>
<td>The initial T&amp;UM status for all requests. During this stage the request ID is generated, and the request enters the In-Progress sub tab.</td>
</tr>
<tr>
<td>2</td>
<td>CANCELLED</td>
<td>A user from the Transferring or Requesting Site cancelled the request while it was in a REQUESTED status. This is a terminal status (these requests cannot be re-activated). The request will enter the T&amp;UM History sub tab.</td>
</tr>
<tr>
<td>3</td>
<td>ACCEPTED</td>
<td>A Site Transfer request was accepted by the Receiving Site. Depending upon the configurations, this request will either go to the LPO for manual review, or automatically enter an APPROVED status. This status only applies to Site Transfer requests.</td>
</tr>
<tr>
<td>4</td>
<td>REJECTED</td>
<td>A request that is not accepted or approved by the reviewing party (either the Receiving Site or the LPO). This is a terminal status. The request will enter the T&amp;UM History sub tab. No updates will be applied. This status only applies to Site Transfer and Demographic Data Update requests.</td>
</tr>
<tr>
<td>5</td>
<td>QUERIED</td>
<td>A Site Transfer request that was sent back to the Receiving Site for review. These requests will remain in the In-Progress sub tab. This status only applies to Site Transfer requests.</td>
</tr>
<tr>
<td>6</td>
<td>APPROVED</td>
<td>A request that was approved by the LPO reviewer, or was automatically approved due to configurations. This is a terminal status. The request will enter the T&amp;UM History sub tab.</td>
</tr>
</tbody>
</table>

6.7  T&UM Roles

Access to the T&UM tab is controlled by the OPEN role of the user, as well as their institution roster affiliation(s).

Users with the following OPEN roles will have the ability to create and review T&UM transactions:

- Site Registrar
- Site Admin

6.8  Systems that are Automatically Updated

After T&UM requests are approved, the updates are automatically applied to the following systems:

- OPEN/RSS.
- LPO RandoNodes (some LPOs will manually apply the T&UM requests to their databases).
- Rave (exceptions: the LPOs will manually apply Site Transfer updates to Rave, and LPO’s that initialize patients to Rave will perform the T&UM updates to Rave for those patients).
6.9 T&UM Data Validations

This section lists the validations that are performed on the data included in T&UM requests.

**General Validations**

- If a patient enrollment has an In Progress next-step OPEN patient enrollment, a T&UM request cannot be created for that patient enrollment.
- If a patient enrollment has an In Progress T&UM request, another T&UM request cannot be created for that patient enrollment.
- If an In Progress T&UM request exists for a patient enrollment, a next-step OPEN patient enrollment cannot be initiated for that patient’s enrollment.
- The person drop-down menus will load persons who have an active roster affiliation with the site in question (for all persons except Credit Investigator).

**Site Transfer Validations**

When a user clicks the Submit button to initiate a Site Transfer request, the following validation will run:

- For studies with a PIO status other than Active, the Receiving Site must have a current IRB Approval.
- The Treating Investigator at the Receiving Site must have an Active status with CTEP.
- Receiving Sites with a "Withdrawn" Site Registration status will not be allowed, even if the study is Active or the Receiving Site has a valid IRB Approval.
- The Treating Investigator must have an Active roster affiliation with a participating organization.

During a Site Transfer request, when a site user clicks the Accept button for a request, or a LPO user clicks the Approve button for a request, the following validations will run:

- For studies with an Active status, the Receiving Site must have an Approved Site Registration status for the study.
- For studies with a PIO status other than Active, the Receiving Site must have a current IRB Approval.
- The Treating Investigator at the Receiving Site must have an Active status with CTEP.
- The Receiving Site must be an Active Treatment member of the organization receiving followup credit.
- The Treating Investigator at the Receiving Site must have an Active status on the credited organizations roster for the Receiving Site.
- Receiving Sites with a "Withdrawn" Site Registration status will not be allowed, even if the study is Active or the Receiving Site has a valid IRB Approval.
- If the Receiving Site is a member of the Network Group that was credited by the Transferring Site, the credited organization must stay the same.
For pre-NCTN enrollments, the credited group must be the post-NCTN Network Group that replaced the pre-NCTN Cooperative Group; however, if the Receiving Site is not a member of the post-NCTN Network Group, another group may be selected.

The Treating Investigator must have an Active roster affiliation with a participating organization.

**Credentialing Data Update Validations**

During a Credentialing Data Update, when a Site user clicks the Submit button, the following validations will run:

- For studies with an Active status, the site must have an Approved Site Registration status.
- For studies with a status other than Active, the site must have a current IRB approval.
- The Treating Investigator must have an Active status with CTEP.
- The site must be an Active treatment member of the organization receiving followup credit.
- The Treating Investigator is Active on the credited organization roster for the site.
- Sites with a "Withdrawn" status cannot complete and T&UM request, even if the study is Active or the IRB Approval is valid.
- If the patient enrollment was completed more than 7 calendar days ago, the credited Network Group must stay the same.
- The Credit Investigator drop-down menu will only display persons that are Active on the credited organization’s roster.
- If the credited group is an NCTN organization, a validation will run when a user clicks the Continue button, to ensure that the Credit Investigator is Active on the credited group’s roster. If the credited group is a pre-NCTN Cooperative Group, the Credit Investigator validation will not run because the Credit Investigator is no longer on the pre-NCTN Cooperative Group’s roster (and the Network Group Credit field will not be updateable).

**Demographic Data Update Validations**

During a Demographic Data Update, when a Site user clicks the Submit button, Demography screen validations configured by the LPO will validate the data. If any of the validations fail, the user will receive an error message.