Revision Information for the OPEN Slot Reservation Quick Reference Site User Guide

Revision History

<table>
<thead>
<tr>
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</thead>
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<td>Mark Stauffer</td>
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This document was prepared by:
WESTAT, Cancer Trials Support Unit
1600 Research Boulevard
Rockville, Maryland 20850
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1. Introduction

This document is designed to provide Site staff with an overview of the full version of the Slot Reservation feature in the Oncology Patient Enrollment Network (OPEN) Portal.

This document will provide instructions for patient enrollment onto a slot reservation protocol, as well as additional information regarding the slot reservation feature that a site user may find useful.

1.1 Web Addresses for CTSU Applications

Table 1: Web Addresses for CTSU Applications

<table>
<thead>
<tr>
<th>Application</th>
<th>URL</th>
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<tbody>
<tr>
<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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</tbody>
</table>
2. How to Enroll a Patient on a Slot Reservation Protocol

For protocols that are configured for slot reservation, a slot must be reserved for a patient before OPEN will allow them to proceed with enrolling onto the protocol’s initial step.

The slot reservation system allows users to secure a position for patients on specific protocols (that utilize this feature) in order to assure that a consented patient can participate on the study. This feature is commonly used for Phase I studies, which requires site registrars to reserve a slot prior to discussing or enrolling a patient onto a study.

To enroll a patient on a slot reservation protocol, a site user must obtain an OPEN patient number unless one already exists. Use the OPEN patient number to reserve a slot for the protocol and then use the slot reservation number to enroll the patient onto the protocol. Each patient has only one OPEN patient number and that patient number is used to reserve slots for that patient across all protocols that require a slot reservation. The OPEN patient number is not a Network Group patient ID.

The following are important details regarding slot reservations:

- Only pre-determined amounts of slots are available for each protocol. Slot limits are dictated by the protocol administrators.
- A slot reservation is performed if a slot is available. If the slot is available and upon registration, the user receives a message stating, “slot is reserved”.
- A slot reservation is NOT performed if a slot is unavailable. If no slots are available and the waiting queue is turned on for the protocol, the slot reservation enters a waiting queue until a slot opens up.
- A “reserved” slot expires at a pre-determined amount of time, as dictated by the protocol administrators. A reserved slot expires if the time limit is reached and no subsequent step is performed. Once the slot expires, the slot becomes available for the next reservation.

The sub-sections that follow will provide general instructions for completing the steps necessary for reserving a slot and enrolling a patient on a slot reservation protocol.

2.1 Getting a Patient Number

If a patient already has an OPEN Patient Number (PT-###########), then a user may proceed to the next section to reserve a slot for their patient (see section 2.2).

If a patient does not have an OPEN patient number, the user must create one for their patient. The next sub-section provides instructions for creating a patient number.
2.1.1 Instructions for Getting an OPEN Patient Number

1) Log into OPEN Portal.
2) Click the Slot Reservation tab.
3) Click the Create New Patient button in the Patients subtab.
4) Complete the necessary fields in the Create New Patient screen.
5) Click the Continue button.
6) Click Ok on the confirmation pop-up window.
7) A confirmation page displays the patient number, in the format PT-#############. For added clarity, the user is informed that only a Patient Number has been created. To reserve a slot for their patient, they need to click the Reserve Slot button.

![Figure 2: Confirmation Page for the Patients Screen](image)

2.2 Creating a Slot Reservation

The following sub-section provides instructions for creating a slot reservation.

2.2.1 Instructions for Creating a Slot Reservation

After an OPEN patient number is obtained, a slot is reserved for the patient. To create a slot reservation:

1) Log into OPEN Portal.
2) Click the Slot Reservation tab.
3) Locate the patient by entering the OPEN patient number in the Patient # free-text box, and click the Search button.
4) Click the Reserve button adjacent to the row for the patient.

![Figure 3: Patient Browser Screen](image)
5) The user is taken to the Create Slot Reservation screen.
6) Select the protocol from the Protocol Number field.
7) If available, enter a Network Group Patient ID.
8) Select a person in the Site Contact Person field.
9) The user’s name is prefilled in the Site Contact Person field, if the user is a site registrar.
10) Make a selection in the Stratum/Dose field.

11) Click Submit.
12) Click OK on the confirmation pop-up window.
13) The users request is processed automatically, or after manual approval, based on the Lead Protocol Organization’s (LPO) configuration of the protocol.

a) If the slot reservation does not require approval by the LPO, the user arrives at a confirmation page that displays the slot reservation number (in the format: SR - ############), as well as the slot expiration date and time.
b) If the slot reservation requires manual approval by the LPO, the user arrives at a confirmation page that displays the slot reservation number, as well as a note stating that the user is informed once a review decision is made via email.

![Confirmation Page](image)

**Figure 6: Confirmation Page (For Manual Approval)**

![Notification Email](image)

**Figure 7: Notification Email Sent To Site User**

14) The patient enrollment for the slot reservation must be completed before the slot reservation expires. Otherwise, a validation prevents the user from completing the enrollment (unless the slot reservation is configured for automatic renewal).

### 2.2.2 Duplicate Slot Reservation Check

The user encounters a duplicate slot reservation error message if a user attempts to create a slot reservation for an OPEN Patient ID that already had a slot reservation in a WITHDRAWN, EXPIRED, or CANCELLED status for the same patient in the same study and stratum. A hyperlink to reactivate the patient’s existing slot reservation is included in the error message (see Figure 130).
2.3 Completing a Patient Enrollment

After a slot reservation is obtained, the user proceeds with enrolling the patient onto the protocol. The following sub-section provides instructions for enrolling a patient onto a slot reservation protocol.

2.3.1 Instructions for Enrolling a Patient onto a Slot Reservation Protocol

1) Log into the OPEN Portal.
2) Click the Slot Reservation tab.
3) Click the In Progress subtab.
4) Enter the patient’s slot reservation ID in the free-text box above the SR ID field and click the Search button.
5) Click the Select button in the row for the patient’s slot reservation.
6) Click the Create Enrollment button.
7) The user is taken to the Create New screen on the Enroll tab (most of the fields are prefilled).

8) Select the appropriate Person Type(s) along with the corresponding choice(s) in the Person Name field.

9) Select a group to receive credit in the Network Group Credit field.

10) Select a physician in the Credit Investigator field (if required). Click Continue.

11) Click OK on the confirmation pop-up window.

12) Click Continue on the tracking number confirmation page.

13) Complete the necessary fields on the Demography screen. Click Continue.

14) Complete the necessary fields on the Checklist screen. Click Continue.

15) Review the data on the Review & Submit screen for accuracy. Click Submit.

16) Click OK on the confirmation pop-up window.

17) The user arrives at a confirmation screen.
2.3.2 Slot Reservation Waiting Queue

If a user attempts to make a slot reservation when no slots are available, the patient is assigned a slot reservation number and placed into the waiting queue for the protocol (if the waiting queue is turned on for the protocol).

Figure 13: Waiting Queue Confirmation

When a slot becomes available, the slot reservation request is automatically approved or manually approved by the group, depending on how the study is configured. Once the slot leaves the Waiting queue, the user is notified by email. The user can also check the status by going to the Slot Reservation tab and clicking the In Progress subtab. If multiple patients are in the Waiting Queue for an evaluation, the patients are promoted based on the order they entered the queue (earliest entry is released first, and so on).
3. Additional Information

3.1 Requesting Updates for OPEN Slot Reservation Patient Information

If information needs to be updated for an OPEN Slot Reservation Patient, please contact the CTSU Help Desk (1-888-823-5923, option 1 or ctsucontact@westat.com) to request the update.

The following fields are updated:

- Institution CTEP ID
- Patient Initials
- Date of Birth
- Gender
- Zip Code

3.2 How to Delete an OPEN Slot Reservation Patient Number

OPEN slot reservation patient numbers are deleted if no slot reservations are associated with the OPEN slot reservation patient number.

**Accessing this Feature:**

1) Log into OPEN.
2) Click the Slot Reservation tab.
3) Click the Patients subtab.
4) Locate the Patient # free-text box.
5) Click the Delete button for the patient’s record (see Figure 14).

![Figure 14: Delete Button for OPEN Slot Reservation Patient Numbers](image)

6) A confirmation pop-up window asks whether to continue with the deletion action. Click Ok.
7) A confirmation message appears in OPEN acknowledging that the patient record is deleted.

3.3 How to Edit a Slot Reservation

Site users have the ability to update the Network Group Patient ID for a slot reservation until an OPEN enrollment is associated with the slot reservation.
Accessing this Feature:

1) Log into OPEN.
2) Click the Slot Reservation tab.
3) Click the In Progress subtab.
4) Locate the slot reservation, and click the Select button for the record’s row.
5) Click the Edit Slot button.
6) Update the value for the Network Group Patient ID field.
7) Click the Submit button to save the changes.

If the Site Contact Person needs to be modified for an ‘in progress’ slot reservation, contact the CTSU Help Desk in order to modify the information. Once slot reservation information is updated, the site user receives an email notifying them that their slot reservation information is edited.

Figure 15: Notification Email Sent To Site User

3.4 How to Renew a Slot Reservation

When a slot reservation is about to expire, site users have the ability to renew the slot reservation to extend the expiration period.

Accessing this Feature:

1) Log into OPEN.
2) Click the Slot Reservation tab.
3) Click the In Progress subtab.
4) Locate the slot reservation and click the Select button in the row associated with the slot reservation.
5) Click the Renew button.
Figure 16: Click the Renew Button

6) A pop-up window appears on screen.
7) Enter a reason in the Comments field and click the Renew button.

Figure 17: Pop-up Window for Renewing a Slot Reservation

8) The user receives a confirmation message with information on whether the request has automatically been reviewed (see Figure 18) or if the request is sent to the LPO for manual review (see Figure 19).

Figure 18: Confirmation Message for the Slot Renewal Request (Automatic Approval)
When a slot reservation nears expiration, the site registrar associated with the slot reservation receives an automatic notification email (see Figure 20). The LPO configures when site users receive the automatic notification emails.

**Figure 20: Automatic Renewal Notification Email**

Dear Registrar,

The slot reservation for the Slot Reservation ID SR-0000000573 (protocol E2511 and site PA042) will expire on 02/20/2013 11:13:51 EST. The renewal request period for this slot has begun. The slot renewal process needs to be completed (including manual approval of the request by the lead group) within the renewal period or else the slot reservation cannot be renewed.

You may login to OPEN ([https://stg.ctsu.org/open](https://stg.ctsu.org/open)) to view additional details. Navigate to the Slot Reservation tab, click the In Progress sub tab, and search for the above Slot Reservation ID to continue.

Please contact the CTSU Help Desk if you have questions. The CTSU Help Desk can be contacted by phone (1-888-823-5923 option 1), as well as by email ([ctsucontact@westat.com](mailto:ctsucontact@westat.com)).

Regards,
The CTSU OPEN Team

**3.5 How to Perform a Practice Mode Slot Reservation Enrollment**

OPEN users have the ability to create slot reservation enrollments in Practice mode, which simulates the enrollment process without creating a real enrollment.

A Practice mode slot reservation enrollment differs from the process for creating a real slot reservation enrollment in the following ways:

- Users bypass the process for creating the OPEN Patient Number and Slot Reservation Number.
- Users select a system-generated Slot Reservation Number at the Create New screen of the Enroll tab.
- Questions in the OPEN EC that prefill slot reservation values, such as stratum and dose names, are prefill the first value by default.

**Accessing this Feature:**

1) Log into OPEN.
2) Click the Start Practice button on the Welcome subtab of the Home tab.
3) A “Practice/Test Registration” watermark appears in the background.
4) Click the Enroll tab.
5) Click the Create New subtab.
6) Select the slot reservation protocol number from the Protocol Number drop-down menu.
7) Select the Registration Step.
8) Select any Slot Reservation Number from the Slot Reservation Number drop-down menu (the Slot Reservation Numbers are system-generated by OPEN during Practice Mode).

![Figure 21: Initiating a Slot Reservation Enrollment in Practice Mode](image)

9) Perform the remainder of the enrollment like a regular enrollment. Please note that questions in the OPEN EC, which use slot reservation prefill widgets, also prefill the first valid value by default.

### 3.6 Slot Reservation Report

The slot reservation report provides slot availability information for slot reservation protocols that the user has access to.
In addition to the slot reservation report, a user can access detailed information on slot availability for each evaluation.

![Figure 22: Slot Reservation Report](image1)

In addition to the slot reservation report, a user can access detailed information on slot availability for each evaluation.

![Figure 23: A Site User's View Details Screen for a Slot Reservation Evaluation](image2)

**Accessing this Feature:**

1) Log into OPEN.
2) Select the Slot Reservation tab.
3) Select the Report subtab.
4) General information displays for all slot reservation protocol evaluations that the user has access to based on the user’s roster affiliations (as shown in Figure 22).
5) If information that is more detailed is desired, click the View Slot Reservation Report Information icon in the row for the desired protocol’s evaluation.
6) A detailed slot availability report displays for the user (as shown in Figure 23).

### 3.7 Slot Reservation Statuses

A slot reservation can have eleven different states during its lifecycle. The table below lists each of the eleven states as well as their descriptions.

**Table 2: Slot Reservation Statuses**

<table>
<thead>
<tr>
<th>Slot Reservation State</th>
<th>Description</th>
</tr>
</thead>
</table>
| RENEW_APPROVAL                | A slot is in this state when a renewal request is pending and requires Group approval. Slots in ‘Reserved’ status or ‘Pre Enroll’ status can move to RENEW_APPROVAL status.  
(i.e. When a user initiates an enrollment using a reserved slot, but is unable to complete the enrollment prior to the expirations date, the user can request to renew the slot. If a manual approval is required (based on group confirmation) the slot will be in “RENEW_APPROVAL” state until it is approved by the group.) |
| NEW_APPROVAL                  | A slot is in this state when a user requests to reserve a slot for a patient and the protocol is configured to send slot reservation requests to the LPO for a review decision.  
A slot that is in the waiting queue can also reach this state when a new slot opens up provided WAITING was the first state that the reservation entered into.                                                                                       |
| REACTIVATE_APPROVAL           | A slot in a WAITING state can enter REACTIVATE_APPROVAL when a new slot opens up and manual approval is required provided it was previously once in the RESERVED state.                                                                                       |
| RESERVED                      | The status which a new slot reservation can enter, if the protocol is configured to allow automatic approval; or, the status which a slot that was in a status of WITHDRAWN, EXPIRED, or CANCELLED can automatically become, at the request of a user, if the protocol is configured for automatic approval.  
A slot in a RENEW_APPROVAL, NEW_APPROVAL, or REACTIVATE_APPROVAL state becomes RESERVED when approved by the group.                                                                                       |
### Slot Reservation State

<table>
<thead>
<tr>
<th>Slot Reservation State</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>WITHDRAWN</td>
<td>A slot is in a WITHDRAWN state when a user requests to withdraw a reservation that was in a WAITING, RENEW_APPROVAL, or RESERVED state.</td>
</tr>
<tr>
<td>EXPIRED</td>
<td>A slot that was previously in a state of RENEW_APPROVAL, NEW_APPROVAL, REACTIVATE_APPROVAL, RESERVED, or PRE_ENROLL reaches its expiration date and time.</td>
</tr>
<tr>
<td>CANCELLED</td>
<td>A slot that was in a RENEW_APPROVAL, RESERVED, or PRE_ENROLL state is cancelled by a CTSU or Group OPEN Administrator; or, the status of which a slot that is in a WAITING state can automatically become CANCELLED if the patient is enrolled onto another conflicting protocol. When a patient in a WAITING queue becomes cancelled, the patient’s site registrar will automatically be notified by email. If an enrolling site becomes suspended, “in progress” slot reservations for the enrolling site will enter the CANCELLED state.</td>
</tr>
<tr>
<td>PRE_ENROLL</td>
<td>The status which a slot that was in a RESERVED status can enter once a user initiates an enrollment; or, the status which a slot that was in a RENEW_APPROVAL state can enter, after receiving group approval.</td>
</tr>
<tr>
<td>WAITING</td>
<td>The status which a slot that was in a WITHDRAWN, EXPIRED, or CANCELLED state can enter, when a reactivation request is automatically approved and no slots are available. Also, a slot for a new reservation can enter this status, if the slot request is automatically approved and no slots are available.</td>
</tr>
<tr>
<td>ENROLLED</td>
<td>The status which a slot that was in a PRE_ENROLL state can enter, once the patient is successfully registered onto the protocol.</td>
</tr>
<tr>
<td>REJECTED</td>
<td>The status which a slot that was in a NEW_APPROVAL or REACTIVATED_APPROVAL state becomes, when the users slot request is denied by the Group, or when an enrollment is CANCELLED and the slot reservation is delinked.</td>
</tr>
</tbody>
</table>

### 3.8 Daily Release of Slot Reservations to the Pool of Available Slots

The LPOs have the ability to configure a daily release time for moving slot reservations that enter a CANCELLED, EXPIRED, WITHDRAWN, or REJECTED status, to the pool of “Available Slots”. This feature allows OPEN users to know when slot reservations will enter the pool of “Available Slots”. This feature configures per protocol and it cannot be used in conjunction with the Waiting Queue feature.

If the feature is enabled and a slot reservation is pending in a CANCELLED, EXPIRED, WITHDRAWN, or REJECTED status, OPEN users are informed of pending slot releases when they attempt to reserve a slot (see Figure 25). The information is shown in the other locations where the slot availability information is displayed, to help reduce the “checking” activities that some site users perform.
If no slots are available for an evaluation, and a slot is pending release to the pool of available slots, the release details will be displayed in the Create New screen of the Slot Reservation tab.

Figure 25: A Message Lists When Slots are Pending Release to the Pool of "Available Slots"