

# Functional Specifications For Pre-Registration Application

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## 1.0 Functional Overview

The Cancer Center Pre-Registration Application is an existing web based application which is utilized to set up authorization dependencies between Pre-Registration and Registration protocols. For example, if a breast cancer study requires a patient to have a cancer tissue type of BRCA+ to participate in the study, the Pre-Registration application can be used to ensure only patients with that specific tissue type are registered to that study. A patient will be pre-registered to the study, prior to undergoing the surgery to remove the cancerous tissue. This will secure that patient's position on the study if they meet the tissue type requirement and will assign them a Subject ID number.

The Registration Office (RO) will use the Pre-Registration Application to set up an approval requirement which indicates a patient must have a tissue type of BRCA+ to participate in the study. In order to move the patient from Pre-Registration to Registration in the Cancer Center Remote Registration Application, this patient must have their status set to 'Approved' for the condition defined. If the condition has any other status (i.e. Pending Approval or Rejected) the Pre-Registration application will prevent the patient from being registered in the Cancer Center Remote Registration Application. This ensures patients are not registered to a study for which they are ineligible.

The Pre-Registration application has two sections: 'Set Up' and 'Approval'. In the 'Set Up' portion of the application, the user defines the approval conditions that must be met before a patient can be registered. The approval condition is in the form of a textual statement clearly defining the condition. Once this portion is defined, patients can only be registered if their status in the 'Approval' portion of the application is set to Approved. The Registration Specialist (RS) must evaluate the patient's information and determine if they meet the conditions defined in the 'Set Up' portion of the application. If a patient does meet the condition(s) defined, the RS will change the 'Approval Status' to 'Approved' and the patient can be registered. If the patient does not meet the condition(s) defined, the RS will change the 'Approval Status' to "Rejected" and the patient cannot be registered to the study. If more information is required before the RS can make a decision, an 'Approval Status' of "Pending Approval" will be entered.

The Pre-Registration Requirement Setup Application is located at:

<http://ccswww:8686/ccswww/servlet/PreRegRegtServlet>

The Pre-Registration Requirement Approval Application is located at:

<http://ccswww:8686/ccswww/servlet/PreRegRegtApprovalServlet>

## 2.0 Staff Access

A user must have access in order to log into the Pre-Registration Requirement 'Setup' and 'Approval' sections of the application. The user must be rostered in the CTMS Site, Staff, and Studies (SSS) application as follows:

- Must be one of the following positions:

- 'regrevapp'
- 'random spec'
- 'reg\_spec'
- Must be rostered to org# 6461 (Alliance)
- SSS takes at least 30 minutes to update before the user can attempt to login

Additionally, the 'Approval' section requires that the user logging in be assigned to studies in the 'Setup' section as a Reviewer, otherwise the user will receive the following error message:

**Mayo Clinic Cancer Center Pre-Registration Requirement Application**

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- **You are not set up to perform any study authorizations.**

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**Please login:**

**Username:**

**Password:**

When a user is not authorized in the 'Setup' section of the application, they will receive the following error message:

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- **Error Logging in.**  
**You are not authorized to modify Preregreqt.**

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**Please enter user and password for authorization:**

**Username:**

**Password:**

When a user is not authorized in the 'Approval' section of the application, they will receive the following error message which includes their Mayo Clinic LAN ID in quotes:

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- Error logging in:  
User ' ' not found.**

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**Please login:**

**Username:**

**Password:**

### 3.0 Setup: Study Reference Screen

When accessing the Pre-Registration Requirement 'Setup' application, the home screen allows the user to enter a Pre-Reg Study Reference ID and Study Reference ID to View. A link to the Pre-Registration Requirement 'Setup' application home screen displays on each page within the application to provide the user a method to return to the Pre-Registration Requirement 'Setup' application login screen.

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**Please enter the studies you would like to View/Edit:**

**Pre-Reg Study Reference:**

**Study Reference:**

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A user must enter a Pre-Reg Study Reference and Study Reference number in order to proceed to the Study Selection Screen or they will receive the following error message:

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- Unable to load studies:**  
**edu.mayo.ccswww.preregreqt.businessobjects.PreRegReqException: Study '' not found.**

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Please enter the studies you would like to View/Edit:

**Pre-Reg Study Reference:**

**Study Reference:**

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#### 4.0 Setup: Study Selection Screen

In the 'Setup' section of the application, the Study Selection feature is used to select the study to set approvals for. The 'preregcomp' option should be selected for the Pre-Reg Study Reference, while the 'protocol' option should be selected for the Study Reference.

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Please select the studies you would like to View/Edit:

**Pre-Reg Study Reference:**

**Study Reference:**

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When selecting the respective 'Pre-Reg Study Reference' and 'Study Reference' components, a 'transcomp' component may display depending on how the study is set up. The 'transcomp' component will generally not be used because pre-registration approvals are not needed prior to registering a patient to a translational component. Picking the 'preregcomp' and 'protocol' components ensures the system will require the approvals in between the pre-registration and registration of a patient.

A user must select a component for each of the 'Pre-Reg Study Reference' and 'Study Reference' fields. If only one field is fulfilled, the user will receive the following error message:

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- **One or both studies isn't a number.**

Please select the studies you would like to View/Edit:

**Pre-Reg Study Reference:**

**Study Reference:**

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## 5.0 Setup: Registration Requirements Page

The 'Registration Requirements' page is used to enter requirement/approval information. A user can enter a free-text description, navigate to the 'Pre-Reg Requirements' page, select an 'Approval Reviewer' for a requirement/approval, and navigate to the 'Approvers' page to specify what 'Type of Approval' a reviewer has. This page will also display existing types of review specific users have in this format: *last name, first name, (Mayo Clinic LAN ID): either/both Generic Case Review or Pathology Review.*

### Requirement for registering 'MC1365 - Mayo (protocol)' after 'MC1365 - Mayo (preregcomp)'

**Description:**

C , C , (m ): Generic Case Review, Pathology Review  
F , R (m ): Generic Case Review, Pathology Review  
R , J , (m ): Generic Case Review, Pathology Review

Add/Remove/Modify approval types for a person on this study requirement:

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## 6.0 Setup: Approvals Page

The 'Approval Set Up' page is used to create, view, modify, and remove Approvals for Registering. A user can enter a Step #, Approval Type, Eval Sequence, and comment of an Approval. The 'Use' checkbox is utilized to save/delete approvals. When a user is creating an approval, they must select the Use checkbox, enter a positive Step #, select an Approval Type, and enter Eval Sequence.

Screenshot of error when one of the required fields is not entered:

- **Errors encountered while saving:  
You must BOTH select an Approval Type AND enter an Evaluation Sequence.**

The 'Approval Type' dropdown provides three options: Pathology Review, Generic Case Review, and Re-Registration Review. 'Pathology Review' is utilized when the user wishes to set an approval for a specific lab result. The 'Generic Case Review' encompasses any non-lab approval which the user would like to review. The 'Re-Registration Review' is utilized when the user wishes to setup an approval condition for a 'CrossOver'. The 'Comment' field offers the user the ability to enter a free-text comment pertaining to the specific approval setup.

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**Approvals for registering 'MC1365 - Mayo (protocol)' after 'MC1365 - Mayo (preregcomp)'**

<input checked="" type="checkbox"/> Use			
Step#:	<input type="text" value="1"/>	Approval Type:	<input type="text" value="Generic Case Review"/>
Eval Sequence:	<input type="text" value="1"/>		
Comment:	<input type="text" value="What is happening?"/>		
<input type="checkbox"/> Use			
Step#:	<input type="text"/>	Approval Type:	<input type="text"/>
Eval Sequence:	<input type="text"/>		
Comment:	<input type="text"/>		
<input type="checkbox"/> Use			
Step#:	<input type="text"/>	Approval Type:	<input type="text"/>
Eval Sequence:	<input type="text"/>		
Comment:	<input type="text"/>		
<input type="checkbox"/> Use			
Step#:	<input type="text"/>	Approval Type:	<input type="text"/>
Eval Sequence:	<input type="text"/>		
Comment:	<input type="text"/>		

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It is important that a user selects the correct 'Step#' when creating approvals. In the case of "Path Approval for Eligibility" (Step 0 or Step 1), the user will select the 'Step#' **prior** to the step that requires eligibility conformation. For example, if a user was creating an approval for "Step 1 Registration", they would enter a 'Step#' of "0" (the previous step) when they create the Approval.

**Approvals for registering 'MAY2013-02-02 - CPN (protocol)' after 'MAY2013-02-02 - CPN (preregcomp)'**

**Use**

**Step#:**       **Approval Type:**       **Eval Sequence:**

**Comment:**

In the case of a "Re-Registration Approval" (CrossOver/Step 2) the 'Step#' selected needs to match the 'Step#' that requires approval. For example, if a user was creating an approval for a "Crossover" (Step 2), they would enter a 'Step#' of "2" when they create the Approval.

**Use**

**Step#:**       **Approval Type:**       **Eval Sequence:**

**Comment:**

If a user does not enter a Step #, the field is automatically filled with a '-1' and it will not work. The application will not prevent patients from moving from pre-registration to registration no matter their status (i.e. Rejected or Pending).

## 7.0 Setup: Person Approval Types Page

Under the 'Add/Remove/Modify approval types for a person on this study requirement' heading on the 'Registration Requirements Page' resides a dropdown containing users which the RO has set up to be reviewers of various approval types. The dropdown menu is populated with the names of rostered users. A user can either select their own name or that of another user from the dropdown and click the 'Modify This Person's Approval Types' button. In order for a user to assign a patient an approval status, they must be a reviewer for that study.

Approvals for 'F', R (m) on study 'MC1365 - Mayo (preregcomp)'

Approval Type	Start Date	End Date	
<input type="text" value="Pathology Review"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="add"/>
<input type="text" value="Generic Case Review"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="add"/>

*Note: Entering date formats (e.g. 12-jan-2005, 1/12/2005, 1/12/05 or today)*

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The Start Date and End Date fields are optional and used only for tracking purposes.

## 8.0 Approval: Login Screen

A user must log into the 'Approval' section of the application in order to review approvals. If the user is not defined as a Pathology and/or Generic Case reviewer in the 'Setup' section of the application for any study, they will receive the following error:

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- You are not set up to perform any study authorizations.**

**Please login:**

**Username:**

**Password:**

## 9.0 Approval: Approval Selection Screen

A user has the ability to select a study they are defined as a reviewer for from the dropdown.

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Please select the study you would like to enter an approval for:

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## 10.0 Approval: Enter Approval Page

The 'Enter Approvals Page' is used to set specific patient approvals and/or view a specific patient's approval status.

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Please enter the subject you would like to enter an approval for:

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If the user attempts to click either the 'Modify Approvals for Subject' or 'Display Subject's Approval Status' buttons without entering a valid subject number, they will receive the following message.

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**• You MUST enter a subject to continue.**

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Please enter the subject you would like to enter an approval for:

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If the user types in an improper subject number, they will receive the following error message:

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- Error loading next approval:  
Case not found for subject 'TEST'.**

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**Please enter the subject you would like to enter an approval for:**

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In order to access the 'Modify Approvals for Subject' or 'Display Subject's Approval Status' pages, a user must enter a Subject Number of a patient pre-registered to that study in the Remote Registration Application. To find the Subject Number, access the Master Sheet Listing in the Remote Registration Application.

## 11.0 Approval: Modify Approvals Page

The 'Approval Status' dropdown is used to select a specific patient's approval status. The status options include the following: Approved, Pending Approval, and Rejected. Approval Status is used to determine if a patient can move from Pre-Registration to Registration. If a patient's status is 'Approved', a user can move the patient from Pre-Registered to Registered in the Remote Registration Application. If a patient has a status of 'Pending Approval' or 'Rejected', that patient cannot be registered. A user may also add a free text comment in the 'Approver's Comment' field.

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**Please modify your approvals:**

**Approval Type:** Generic Case Review    **Step#:** 1    **Eval Seq#:** 1  
**Approval Description:** What is happening?

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**Approval Status:**   
**Approver's Comment:**

Once a status has been added/modified for a patient, an audit trail will be generated, including the user's name, LAN ID, and date of change:

<b>Approval Type:</b> Generic Case Review	<b>Step#:</b> 1	<b>Eval Seq#:</b> 1
<b>Approval Description:</b> What is happening?		
<hr/>		
<b>Last updated by:</b> R , J , (m ) on May 11, 2015		
<b>Approval Status:</b> Approved ▼	<b>Approver's Comment:</b> This subject is approved	

## 12.0 Approval: Display Approval Status Screen

The 'Display Approval Status Screen' is a read only page to view approval information.

<b>Mayo Clinic Cancer Center Pre-Registration Requirement Application</b>		
<hr/>		
<b>Approvals for 5555555 on MC1365:</b>		
<b>Approval Type:</b> Generic Case Review	<b>Step#:</b> 1	<b>Eval Seq#:</b> 1
<b>Approval Description:</b> What is happening?		
<hr/>		
<b>Not yet evaluated.</b>		
<b>Approval Type:</b> Generic Case Review	<b>Step#:</b> -1	<b>Eval Seq#:</b> 2
<b>Approval Description:</b>		
<hr/>		
<b>Not yet evaluated.</b>		
<b>This subject is still pending final approval(s).</b>		

Once an 'Approval Status' has been captured, it will display along with the name of the individual who entered the status as well as the date it was captured.

<b>Approvals for 5555555 on MC1365:</b>		
<b>Approval Type:</b> Generic Case Review	<b>Step#:</b> 1	<b>Eval Seq#:</b> 1
<b>Approval Description:</b> What is happening?		
<hr/>		
<b>Evaluated by:</b> F , R , (m ) on May 8, 2015		
<b>Approval Status:</b> Approved	<b>Approver's Comment:</b>	