



**MAYO CLINIC**  
**Cancer Center**

# **REGISTRATION|RANDOMIZATION USER'S MANUAL v 2.1**

**Cancer Center Systems Management Office**

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# Minimum System Requirements

- Hardware Requirements

- CPU/Processor Speed: 400 MHz
- You will also need a minimum of 150MB of disk space
- RAM – Minimum: 64 MB  
Preferred: 256 MB (or higher)
- Monitor Size: 17 inch (or larger)
- Resolution Setting: 1024 x 768 pixels w/a minimum of 16 thousand Colors; millions of colors would be preferred

- Supported Operating Systems

- Windows 98 (2<sup>nd</sup> Edition)
- Windows ME
- Windows 2000 (SP3+)
- Windows XP Home
- Windows XP Professional (SP2+)
- Windows Server 2003 Edition
- Mac OS 10

- Supported Browser's

- Internet Explorer – Version: 7.0 (or higher)  
Cipher Strength (Encryption Level): 128 bit (or higher)
- Netscape Navigator – Version: 6.0 (or higher)  
Encryption Strength: 128 bit (or higher)
- Mozilla Firefox – Version: 1.02 (or higher)

# Installation Instructions for the Remote Registration Application

This section will walk you through the process of installing the required Java application (auto install and manual install) and the Remote Registration application.

## Hints and Recommendations

- If you already have Java runtime version 1.5.0\_02 or newer installed on your system, you do not need to perform the installation instructions for Java and can go directly to the "Start Using the Remote Registration Application" section of this document. If you have a previous version of Java installed on your system, we recommend you use these instructions to install the latest version of Java runtime. Your system administrator can help you determine what version of Java you have installed on your system.
- It should be noted that the images included all refer to Java 1.6.0\_11. As this may be a previous version of the Java Runtime Environment it could include some enhancements from Sun, the creator of Java. While the current version may have changed, all other aspects of the installation should remain the same.
- Our instructions are created using the Internet Explorer browser. You may use the Firefox browser, however, you may not see the same screens that are described within this document or some of the screens may be slightly different. We have identified the screens that may be different in the sections below.
- If you install a newer version of Internet Explorer or Firefox after you have successfully completed the installation of Java, you must re-install Java. You may use these same instructions to re-install.
- We recommend that you use the same browser for the installation and for the remote applications. For example, if you use Internet Explorer to install Java, we suggest you use Internet Explorer to run the applications.
- Within the instructions you will find red circles on the screenshots indicating the buttons that you will need to click.

You must install Java 1.5.0\_02 or later in order to run the new versions of the Data Entry and Registration systems. We recommend that you install the latest Java release on your computer prior to installing the application. The following instructions will assist you with installing the latest version of Java on your computer. Before starting the installation, we recommend that you print the instructions to guide you through the Java installation.

## Java Installation Instructions

There are two options when proceeding with the installation of Java on your system. The automatic installation will access your system to determine your system platform, download the appropriate Java software, and install it. If you feel more comfortable with stepping through the process manually, advance to the section on manual installation. Depending on your network and computer system environment, your system may require local system administrative privileges to complete the Java installation.

### System Requirements

- Vista
- Windows 2000 (SP3+)
- Windows XP Home
- Windows XP Professional (SP1+)
- Windows Server 2003 Editions

Intel and 100% compatible processors are supported. A Pentium processor with at least 64MB of physical RAM is recommended. A minimum of 98MB of free disk space.

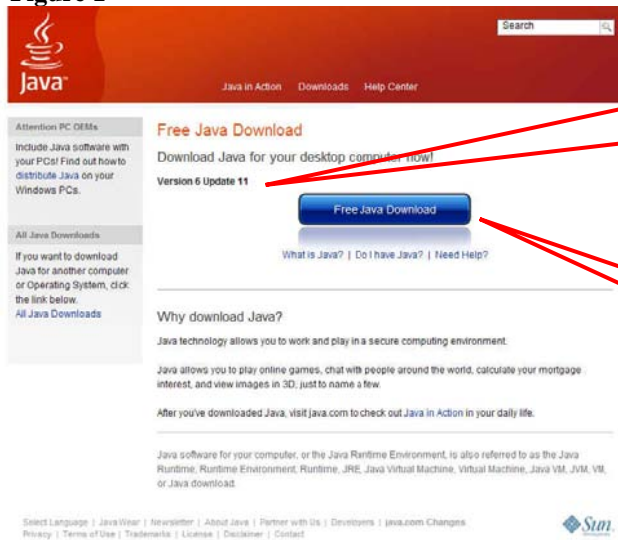
**“Treating Location” field is auto-filled after Participant Sponsor is entered.**

### Automatic Installation of Current Release

The automatic Java installation will automatically install the application with minimal interaction needed from you.

- Click [here](#) to access the Sun Java Software download web page.
- If you do not have the most recent version of Java installed on your system, the version will be displayed to the left of the “Free Java Download” button.

Figure 1



**If you do not have the most recent version of Java installed on your system, you will see the version available displayed here**

**Click on the ‘Free Java Download’ button to start the Java installation**

- Click on the “Free Java Download” button.
- The “Downloading Java Installer” will initialize and a separate pop-up window will appear.

**Figure 2**



- The installation process starts and the “Java Setup – Welcome” window will appear. The installer presents an option to view the License Agreement. After reading the agreement, click the “Accept” button to accept its terms and to continue with the installation. If you'd like to change the installation directory, or customize other features, place a check in the “Change destination folder”.

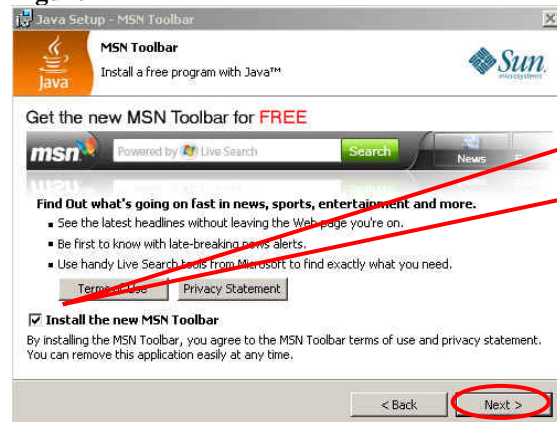
**Figure 3**



Click on the 'Accept' button to accept the Java License Agreement and continue the Java

- The “Java Setup - MSN Toolbar “ window is displayed. By default the “Install the new MSN Toolbar” box is checked. If you do not want this installed, you will need to remove the check mark by clicking the box to remove the check mark. Then click on the “Next” button to continue the Java installation.

**Figure 4**



If you choose not to have the MN Toolbar installed, click in the box to remove the check mark

Then click the ‘Next’ box to continue the Java installation

- The “Java Setup - Progress” window will appear and Java will be installed.

**Figure 5**



- After the Java installation is completed you will see the “Java Setup – Complete” window that indicates that you have successfully installed Java. Click the “Finish” button to complete and close the Java installation window.

**Figure 6**



Click on the ‘Finish’ button to complete the Java installation and close the window

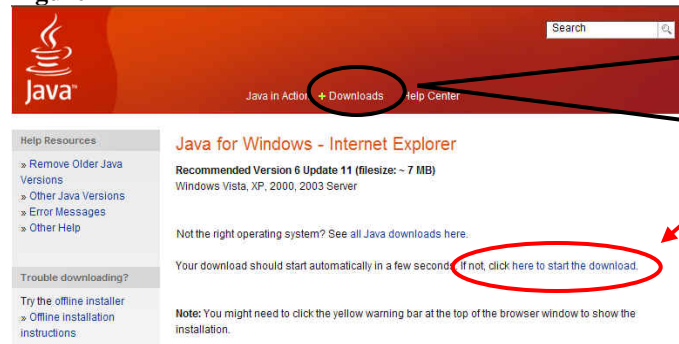
- Once the installation is successfully completed, you may need to restart (close and re-open) your browser to enable the Java installation.

## Manual Installation of the Current Release

The manual installation is designed for experienced system administrative users and will require you to walk-thru the Java installation step-by-step.

- Click [here](#) to access the Sun Java SE download page.
- Click on “Downloads” – your system is accessed and if you do not have the latest version of Java installed on your system, it will automatically start the installation.
- If your Java download does not start automatically in a few seconds, click where it says, “click here to start the download” and follow the screen instructions as indicated in the “Automatic Installation of Current Release” section of this manual.

**Figure 7**



Click on ‘Downloads’ – you download should start automatically in a few seconds. If not, click where it says, “Click here to

- To manually select the appropriate system platform and environment for



your system, click where it says, “See all Java downloads here”. Please note that if your system environment requires an earlier version of Java, this will not be an issue as long as the release is not older than the 1.5.0\_02 release.

- Click on the appropriate system platform for your system.

**Figure 8**

Downloads are subject to our license agreement

Once you have installed Java on your computer, you might be required to restart your browser. You can verify that it has been installed correctly by clicking 'Verify Now' below.

Windows			
Windows XP/Vista/2000/2003 Online *	filesize: ~ 7 MB	Instructions	Verify Now
Windows XP/Vista/2000/2003 Offline	filesize: 10.50 MB	Instructions	Verify Java has been installed correctly.

\* Typical download size is 7.1 MB, which is the minimum download. The size may increase if additional features are selected.

Solaris			
Solaris (32-bit)	filesize: 23.41 MB	Instructions	Verify Now
Solaris (64-bit)*	filesize: 9.82 MB + 23.41 MB 32-bit Solaris	Instructions	After installing Java, restart your browser and verify Java has been installed correctly.
Solaris x86	filesize: 17.55 MB	Instructions	
Solaris x64 *	filesize: 0.24 MB	Instructions	

\* Please use the 32-bit version for Java applet and Java Web Start support.

Linux			
Linux RPM (self-extracting file)	filesize: 18.06 MB	Instructions	Verify Now
Linux (self-extracting file)	filesize: 19.18 MB	Instructions	After installing Java, restart your browser and verify Java has been installed correctly.
Linux x84 *	filesize: 17.56 MB	Instructions	
Linux x64 RPM *	filesize: 17.14 MB	Instructions	

\* Please use the 32-bit version for Java applet and Java Web Start support.

Apple (OS X)			
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Use the Software Update feature (available on the Apple menu) to check that you have the most up-to-date version of Java for your Mac.

**Click on the appropriate system environment for your system**

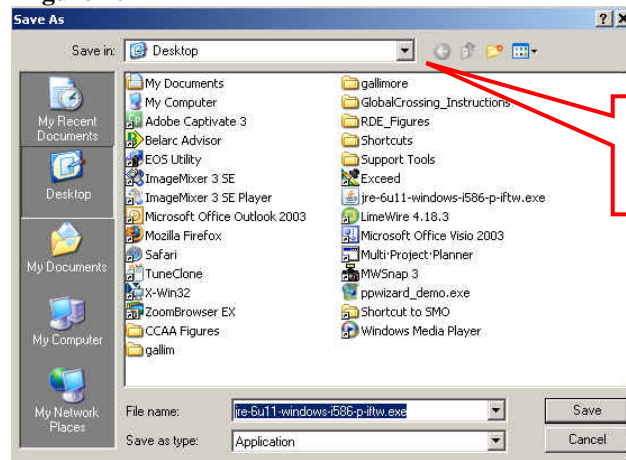
- The “File Download – Security” window will appear. Click on the “Save” button.

**Figure 9**



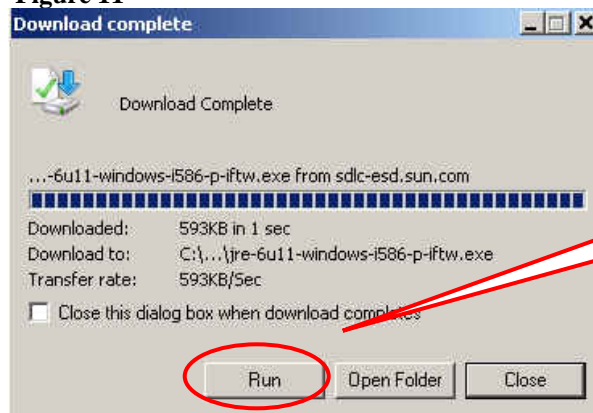
- The “Save As” window will appear. Save the file to your desktop.

**Figure 10**



- The “Download complete” window will appear. Click on the “Run” button to initiate the Java installation.

**Figure 11**



- The installation process starts and the “Java Setup – Welcome” window will appear. The installer presents an option to view the License Agreement. After reading the agreement, click the “Accept” button to accept its terms and to continue with the installation. If you’d like to change the installation directory, or customize other features, place a check in the “Change destination folder”.

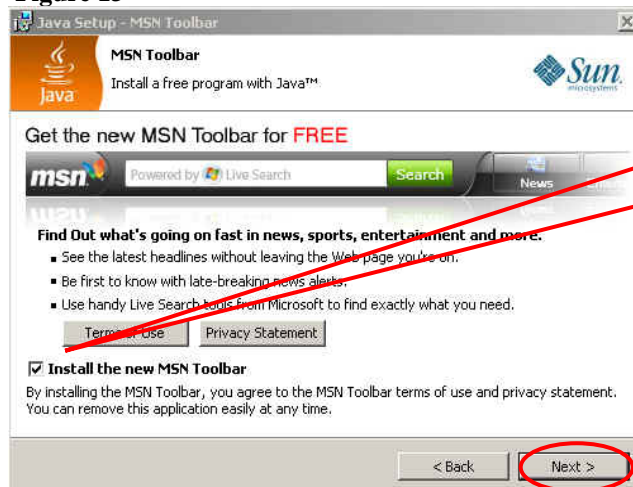
**Figure 12**



**Click on the ‘Accept’ button to accept the Java License Agreement and continue the Java installation**

- The “Java Setup - MSN Toolbar “ window is displayed. By default the “Install the new MSN Toolbar” box is checked. If you do not want this installed, you will need to remove the check mark by clicking the box to remove the check mark. Then click on the “Next” button to continue the Java installation.

**Figure 13**



**If you choose not to have the MSN Toolbar installed, click in the box to remove the check mark**

**Then click the ‘Next’ box to continue the Java installation**

- The “Java Setup - Progress” window will appear and Java will be installed.

**Figure 14**



- After the Java installation is completed you will see the “Java Setup – Complete” window that indicates that you have successfully installed Java. Click on the “Finish” button to complete and close the Java installation window.

**Figure 15**



**Click on the ‘Finish’ button to complete the Java installation and close the window**

- Once the installation is successfully completed, you may need to restart (close and re-open) your browser to enable the Java installation.

## Installing the Remote Registration Application

This section will walk you through installing the Remote Registration application. As previously mentioned you must have Java 1.5.0\_02 or later installed on your system to run this application.

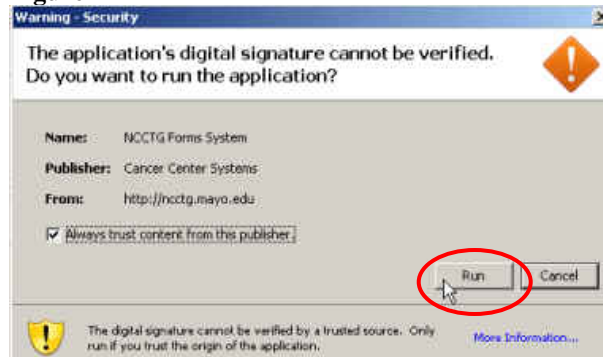
- You will click on the link provided on your Cooperative Group Web site for the [Remote Registration](#) application. **NOTE:** If you are a Mayo employee you will need to refer to the internal Mayo Web site provided for the [JCCS Registration](#).
- You will click on the Remote Data Entry link. The “Java starting...” pop-up window will automatically appear.

Figure 16



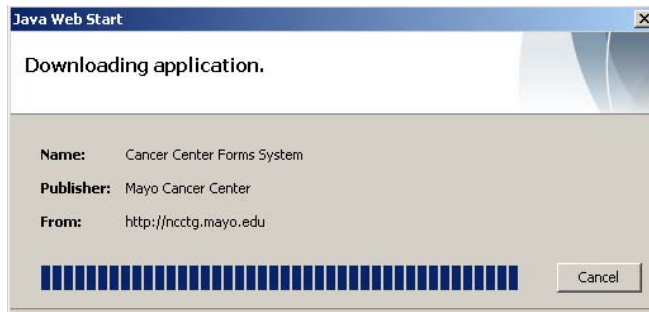
- The first time that you access the Remote Registration application, the Warning –Security pop-up window may appear. If you place a check-mark in the box next to the statement “Always trust content from this publisher”, the message will not appear in the future.
- You will then click the “Run” button to continue installing and launching the application.

Figure 17



- Then the “Java Web Start” pop-up window will quickly flash on the screen as the application is downloaded onto your system. You may also see another pop-up window flash by briefly, indicating that the application is installing.

Figure 18



- After the application has completed the installation, the Login pop-up window is displayed.

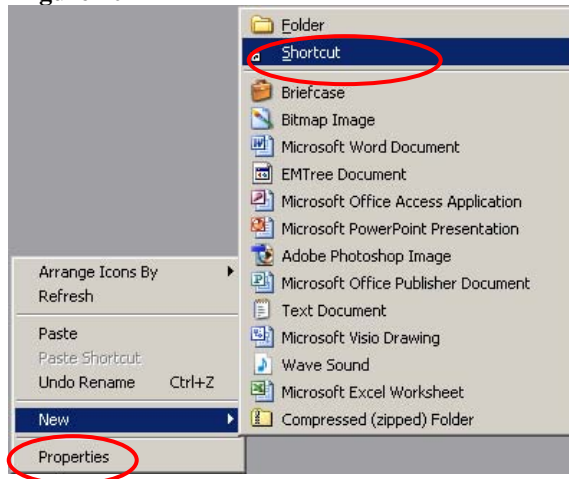
**Figure 19**



## Create a Desktop Shortcut to Remote Data Entry Application

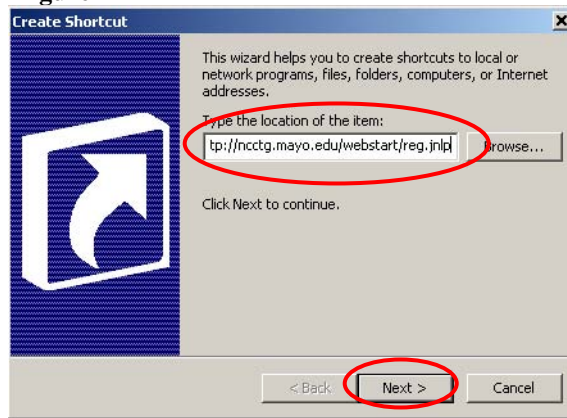
- Right click with mouse on your desktop and select **New** and then select **Shortcut**

**Figure 20**



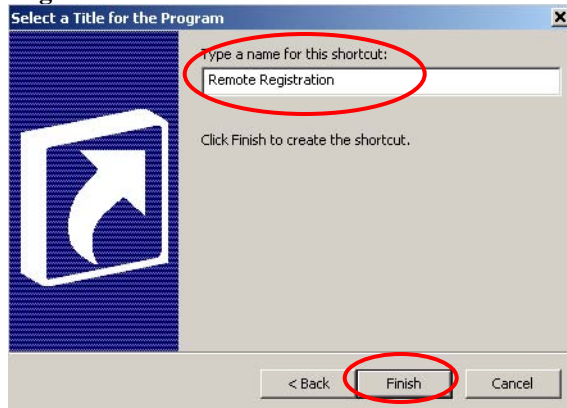
- Enter the following URL (<http://ncctg.mayo.edu/webstart/reg.jnlp>) into the space provided and click on the **Next** button. **NOTE:** If you are a Mayo employee enter the following URL in place of the one listed above (<http://hsrwww.mayo.edu/ccs/jweb/reg.jnlp> ).

**Figure 21**



- Enter “Remote Registration” in box provided for the name of the shortcut and click on the **Finish** button. **NOTE:** Mayo employees should enter JCCS Registration.

**Figure 22**



- The shortcut is created and placed on your desktop.

**Figure 23**



Congratulations, you have now completed the installation process of the Remote Registration (Mayo employees – JCCS Registration) and are ready to start using the application.

## Start Using the Remote Registration Application

This section will demonstrate how to launch the application, navigate within the application, login to the application and enter Registration form, enter Eligibility Checklist Form, register a subject, save & close a form, and print a form.

### How to Launch the Application

In order to use the Remote Registration application, you must have a valid User Name and Password, as the application will prompt you for this information. If you do not have a User Name and Password or you are unable to login successfully, please contact the Operations Office at (507) 284-5999.

- Click on the Remote Data Entry application desktop shortcut to launch the application. If you do not have a desktop shortcut, go to the link provided on your Cooperative Group Web site for the [Remote Registration](#) application. **NOTE:** If you are a Mayo employee you will need to refer to the internal Mayo Web site provided for the [JCCS Registration](#).
- The “Login” pop-up window is displayed.

Figure 24

A screenshot of a Windows-style dialog box. The title bar is blue with a close button (X) on the right. The text inside the dialog reads "Please enter your user name and password:". Below this text are two input fields: "User Name:" followed by a text box, and "Password:" followed by a text box. At the bottom center of the dialog is a button labeled "OK".

### How to Navigate within the Application

This section will demonstrate how to navigate within the form and explain why it is very **important** to use the navigation rules provided. In addition it will walk you through the different types of data entry fields and the data entry options.

#### Movement from Data Field to Data Field

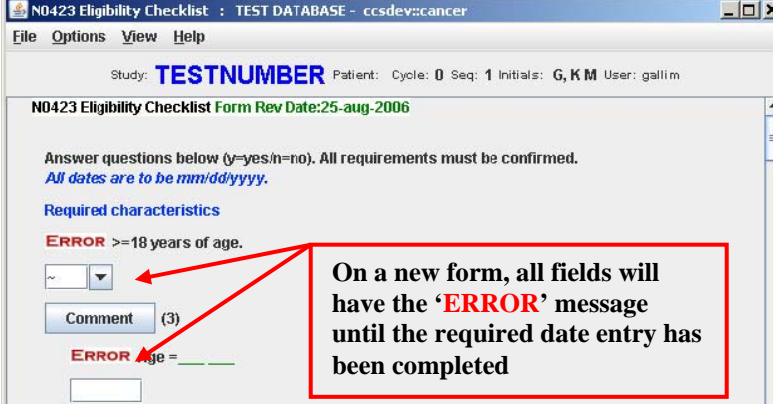
The **TAB** key must be used to move from data field to data field; to ensure that the programming rules and validation procedures are activated within the form. By using the mouse to navigate within the data entry screen the required data fields may be missed. Using the **TAB** key will ensure that the application correctly evaluates whether or not the answer you entered within the data field, should generate an Error message. Additionally, some data fields may be shown or hidden based on how you answer the questions, so using the **TAB** key will help ensure that this is done correctly.



## Error Messages

When you open a new form, all of the fields will have an 'ERROR' message; this message will go away after you complete the data entry required within that field.

Figure 25



The screenshot shows a web browser window titled "N0423 Eligibility Checklist : TEST DATABASE - ccsdev:cancer". The form header includes "Study: TESTNUMBER", "Patient: Cycle: 0 Seq: 1 Initials: G, K M User: gallim", and "Form Rev Date: 25-aug-2006". Below the header, there are instructions: "Answer questions below (y=yes/n=no). All requirements must be confirmed. All dates are to be mm/dd/yyyy." Under the heading "Required characteristics", the first requirement is ">=18 years of age." This requirement has a dropdown menu with "y" selected and a "Comment (3)" button. Below this, there is an "ERROR" message: "ERROR >=18 years of age." followed by "Age = \_\_\_\_\_" and an empty input field. A red box highlights the "ERROR" message and the "Comment (3)" button, with a red arrow pointing to the dropdown menu. A text box next to the arrow contains the text: "On a new form, all fields will have the 'ERROR' message until the required date entry has been completed".

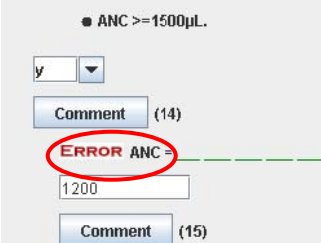
Figure 26



This close-up shows the ">=18 years of age." requirement. The dropdown menu now shows "y" and the "Comment (3)" button is visible. The "ERROR" message is no longer present. A red box highlights the "ERROR" message area, with a red arrow pointing to the dropdown menu. A text box next to the arrow contains the text: "'ERROR' message is removed after data is entered in field".

When you **TAB** to the next field, the application validates the data entered and if the data does not meet the required criteria the **ERROR** message is triggered.

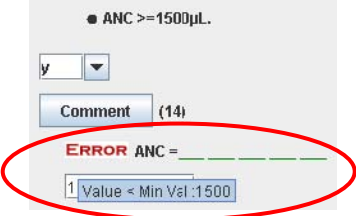
Figure 27



The screenshot shows a requirement for "ANC >=1500µL.". There is a dropdown menu with "y" selected and a "Comment (14)" button. Below this, there is an "ERROR" message: "ERROR ANC = \_\_\_\_\_" followed by an input field containing "1200" and a "Comment (15)" button. The "ERROR" message is circled in red.

If you place the mouse over the 'ERROR' message, a pop-up will display the reason for the 'ERROR' message, which may assist you in resolving the error.

Figure 28



This close-up shows the "ERROR ANC = \_\_\_\_\_" message with the input field containing "1200". A red box highlights the "ERROR" message and the input field. A tooltip is displayed over the "ERROR" message, containing the text: "1 Value < Min Val: 1500".

You will not be able to save the form and register the subject until all fields are completed and no 'ERROR' messages are present.

The subject is deemed ineligible until all 'ERROR' messages are resolved. If you are unable to resolve an 'ERROR' message, please contact the Registration Office at (507) 284-4130.

## Field Types

**Date** – you are not required to put any dashes or slashes in between the month, day, and year (e.g. 041808). You are only required to type in the last two digits of the year. After you have entered the date, the system will automatically reformat the date to the format of mm/dd/yyyy.

Figure 29

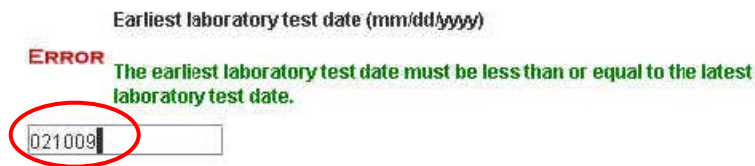
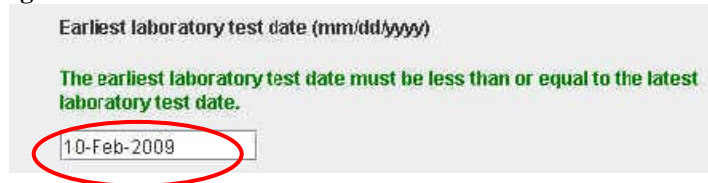


Figure 30



**Drop-down Menu** – with the mouse click on the downward arrow and then click on the appropriate answer. The drop-down menu can also be used by clicking on the down arrow with the mouse and scrolling until the appropriate selection is reached and then release the mouse clicker to select and display it in the field.

**Text Field** – text fields are fields that do not allow you to choose between one or more answers (e.g. non-multiple-choice fields). When you tab to a text field that has existing data, it will be highlighted and you can simply type over and replace the existing text information. You can also use the arrow keys to change part or all of the answer in the text field.

## Field Options

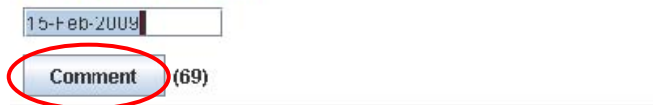
**Comment Box** – the **Comment Box** may be used to provide additional information or clarification. At any point in time, if you need to change the comment in the comment box, simply click on the **Comment** button to open the comment box and make the necessary changes.

### How to Use the “Comment” Option

- Click on the **Comment** button

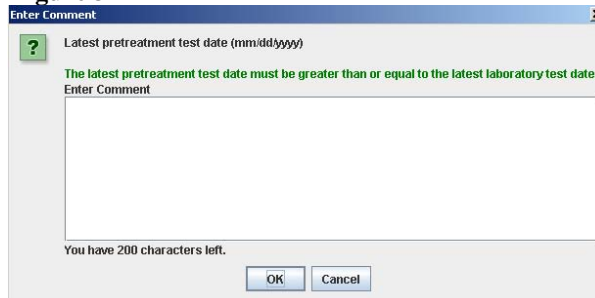
**Figure 31**

The latest pretreatment test date must be greater than or equal to the latest laboratory test date.



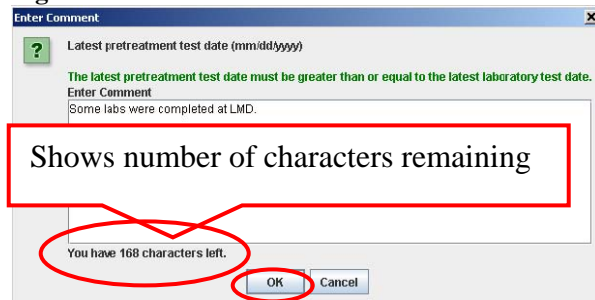
- The Enter Comment pop-up window will be displayed.

**Figure 32**



- You are allowed to enter up to 200 characters. As you enter the comment, the number of characters remaining is shown below the text box provided.

**Figure 33**



- Click the **OK** button to save and close the Comment Box pop-up window. You will be automatically returned to the data entry form.
- **NOTE:** when a comment is entered, the Comment option changes color from grey to red.

**Figure 34**

The latest pretreatment test date must be greater than or equal to the latest laboratory test date.

A screenshot showing a date input field containing '15-Feb-2009'. Below it is a red button labeled 'Comment' with '(69)' next to it. The button and its label are circled in red.

## How to Login to the Application and Enter the Registration Form

The first form to be loaded is the Registration/Randomization form; this consists of participation and demographic information necessary to register a subject onto the protocol. The information collected varies somewhat from protocol to protocol, so some forms may look different than those in another study.

The words in parenthesis behind the fields denote whether the items are required or optional. Before attempting to register a subject, **all** required fields must be completed. Some of the participation information may be pre-filled for you (e.g. “Participant Sponsor” – main participant and member).

- Enter your User Name and Password and then click on the **OK** button.

**Figure 35**

A screenshot of a login dialog box titled 'Please enter your user name and password.'. It contains fields for 'User Name:' (with 'gallim' entered) and 'Password:' (with masked characters). An 'OK' button is at the bottom. Red arrows point from a red-bordered box on the right to the 'User Name' field, the 'Password' field, and the 'OK' button. The 'OK' button is also circled in red.

- The following “Reminder” pop-up message will appear, reminding the user **NOT** to use the form to register a patient if there is any kind of deviation for timing of tests. To continue to register subject, click the **OK** button to close the message.

**Figure 36**

A screenshot of a reminder pop-up message window titled 'Reminder!!!'. It features an information icon and the text: 'Important!!! Do not use this form to register a patient if you have received any kind of deviation for timing of tests. The registration must be done by the Randomization Office.' An 'OK' button is at the bottom right, circled in red. A red-bordered box on the right contains the text 'Click on the ‘OK’ button to continue' with an arrow pointing to the 'OK' button.

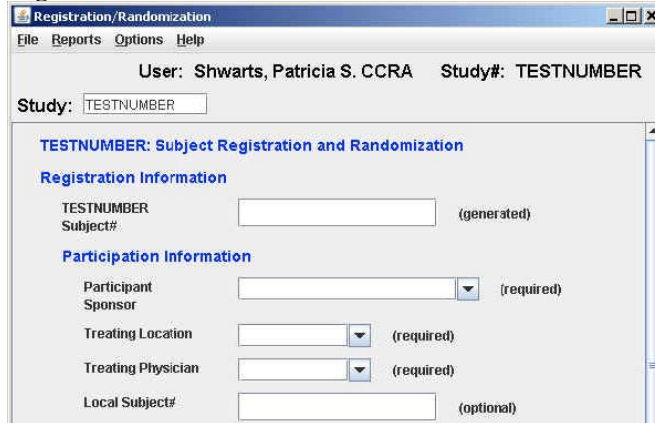
- The Registration/Randomization window is displayed.

**Figure 37**



- Enter the protocol "Study" number in the box provided and press the **Enter** key on your keyboard.
- The screen is refreshed and the registration form is displayed. **NOTE:** Mayo employees will see a form like the one shown below in **Figure 38** and external remote users will see a form like the one displayed in **Figure 39**.

**Figure 38**



**Figure 39**



- Mayo employees – for Mayo studies you will enter the subject’s Mayo Clinic number (excluding the dashes) and for CPN studies you will enter the appropriate subject number provided in the “Subject#” field and then press the keyboard **TAB** key.

**Figure 40**

**Registration Information**

TESTNUMBER Subject# 01237658

Mayo studies – enter subject’s MC # and CPN studies – enter subject # provided; do not include any dashes

- You will be taken to the “Participant Sponsor” field.
- If you have multiple treating locations you will need to select the appropriate “Participant Sponsor” from the drop-down menu. If you only have one treating location, this field will be automatically pre-filled for you.
- Press the keyboard **TAB** key to navigate to the “Treating Physician” field.

**Figure 41**

**Participation Information**

Participant Sponsor (required)

Treating Location (required)

Florida (FL080) through NCCTG

Mayo (MNO26) through NCCTG

Select Participant Sponsor from drop-down menu

- The screen is automatically refreshed and the “Participant Sponsor” field is updated, the “Treating Location field” is auto-filled with the appropriate information, and the cursor is moved to the “Treating Physician” field.

**Figure 42**

**Participation Information**

Participant Sponsor Florida (FL080) through NCCTG (required)

Treating Location Mayo Clinic Florida (FL080) (required)

Treating Physician (required)

- **NOTE:** If there is no IRB approval or the IRB approval has expired for the Treating Location selected for the study defined, a pop-up window will be displayed and you will not be able to register subject until this is resolved.

**Figure 43**

The screenshot shows the 'Participation Information' form. Fields include: Participant Sponsor (Alleghehy WP (PA009) through NCCTG), Treating Location (Alleghehy Cancer Center Network (PA009)), Treating Physician (None), and Secondary Treating Location. A pop-up window titled 'Information' is overlaid on the form, displaying the message 'Unable to find a current IRB.' with an 'OK' button.

- Select the appropriate Treating Physician from the drop-down menu.

**Figure 44**

The screenshot shows the 'Treating Physician' drop-down menu. The menu is open, showing a list of names: Ahlquist, David Alan M.D., Aksamit, Allen J. M.D., and Alberts, Steven R. M.D. A red arrow points to the first name, and a red callout box contains the text 'Select Treating Physician from drop-down menu'.

- **NOTE:** If the Treating Physician selected does not have a current 1572 on file, a pop-up window will appear and you will not be allowed to register the subject until this has been resolved.

**Figure 45**

The screenshot shows the 'Treating Physician' field with 'Solfelt, Mark L. M.D.' selected. A pop-up window titled 'Information' is overlaid, displaying the message 'No current form 1572 on file for the selected physician.' with an 'OK' button.

- Press on the keyboard **TAB** key to navigate to the "Local Subject#" field. This is an optional field; for Mayo studies the subject's MC # should be entered here.

**Figure 46**

The screenshot shows the 'Treating Physician' field with 'Ahlquist, David Alan M.D.' selected and the 'Local Subject#' field with the value '01237658' entered.

- Mayo Employees Only – Press on the keyboard **TAB** key to navigate to the “Patient ID” field. This field is optional; it is used to enter external Patient ID information. Then press on the keyboard **TAB** key to navigate to the “Org Abbrev” field. This field is optional; it is used to enter the organization’s abbreviation.

**Figure 47**

Additional Patient ID (e.g. Patient ID: ex106305, Org: extref)

Patient ID  (optional)

Org Abbrev  (optional)

Used by Mayo only and is option- to be used to enter external PT Id & Org Abbrev

- Press on the keyboard **TAB** key to navigate to the “Initials” fields. Enter the subject’s Last, First, and Middle initials in the appropriate boxes.

**Figure 48**

Initials

Last  First  Middle  (required)

- Press on the keyboard **TAB** key to navigate to the “Gender” field and select the appropriate gender from the drop-down menu.

**Figure 49**

Gender  (required)

Race

Date of Birth

Female

Male

Unknown

- Press on the keyboard **TAB** key to navigate to the “Race” field and select the appropriate race from the drop-down menu. **NOTE:** You can select multiple races by holding down the Ctrl key while you select the appropriate races.

**Figure 50**

Race  (required)

Date of Birth  (required)

Zip Code  (required)

Country

blank

Asian

Black

Hispanic

- Press on the keyboard **TAB** key to navigate to the “Date of Birth” field and enter the subject’s birth date using the following format: mm/dd/yyyy. **NOTE:** The Age field will be automatically calculated and displayed on the form.

**Figure 51**

Date of Birth  Age: (required)



- Press on the keyboard **TAB** key to navigate to the “Zip Code” field and enter the subject’s zip code, if unknown; enter ‘unk’ in the field.

Figure 52



Zip Code  If unknown, enter 'unk' (required)

- The “Country” field is defaulted to United States; if the subject that you are entering does not reside in the United States; use the drop-down menu to select the appropriate country.

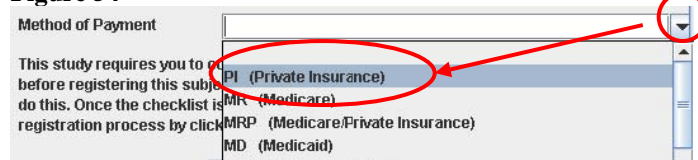
Figure 53



Country  (required)

- Press on the keyboard **TAB** key to navigate to the “Method of Payment” field, using the drop-down menu select the appropriate payment method.

Figure 54

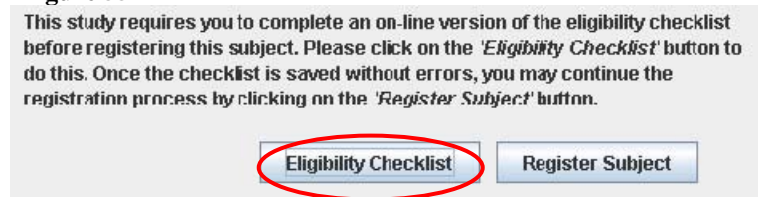


Method of Payment  (required)

This study requires you to complete an on-line version of the eligibility checklist before registering this subject. Please click on the 'Eligibility Checklist' button to do this. Once the checklist is saved without errors, you may continue the registration process by clicking on the 'Register Subject' button.

- Press on the keyboard **TAB** key, you are taken to the **Eligibility Checklist** button.

Figure 55



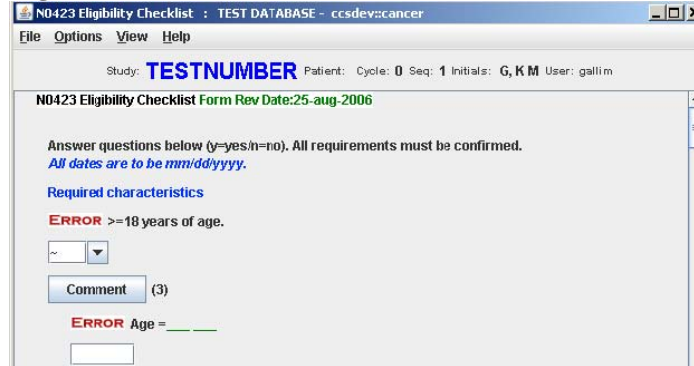
This study requires you to complete an on-line version of the eligibility checklist before registering this subject. Please click on the 'Eligibility Checklist' button to do this. Once the checklist is saved without errors, you may continue the registration process by clicking on the 'Register Subject' button.

## How to Enter the Eligibility Checklist Form

Most protocols require you to complete an Eligibility checklist before registering a subject. An exception to this would be an Industry protocol. This section will walk-thru entering an Eligibility Checklist Form.

- Click on the **Eligibility Checklist** button. The Eligibility Checklist form is displayed.

Figure 56

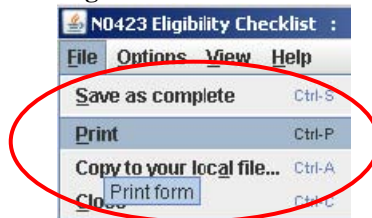


- Complete the checklist by answering the question and then navigate to the next question by using the keyboard **TAB** key.
- It is very important that you answer the questions accurately to ensure that an ineligible patient is not registered to the study. If you believe there is an error on the checklist, please contact the Registration Office at (507) 284-4130.
- Print a copy of the checklist for your records.

## How to Print a Form

- Go to the **File Menu**, located on the top of the data entry form.

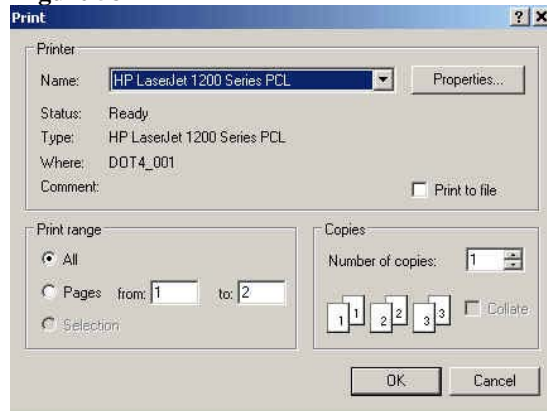
Figure 57



- Click on **Print**

- You may also use the keyboard shortcut by clicking on the **Ctrl & P** keys at the same time.
- The **Print** window will be automatically displayed.

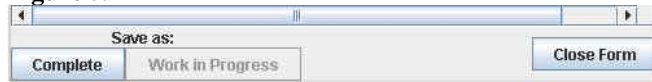
**Figure 58**



### How to Save & Close Form

When exiting a form you have two options: 1) **Save as: Complete** or 2) **Close Form** without saving.

**Figure 59**



### How to Close Form

- If you choose to **Close Form**, the form will not be saved. To close the form you simple click on the **Close Form** button.

**Figure 60**



- The **Unsaved Changes** pop-up window will appear. Click the **Continue** button to close the window.

**Figure 61**



- The **Unsaved Changes** pop-up window and form will automatically close and you will be redirected back to the Cancer Center Forms System window.

### How to Save As: Complete

- Click on the **Save as: Complete** button.

Figure 62



- The Save Form box will automatically appear.

Figure 63



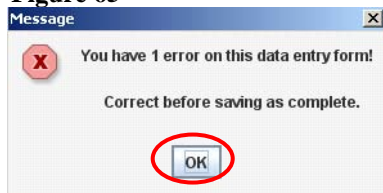
- If no error(s) are found, the Save Successful pop-up message will appear. Click on the **OK** button and the message and form will be closed automatically.

Figure 64



- If potential error(s) are found, the Message window will automatically appear indicating the number of error(s) found and you will be given the option to correct the potential error(s) before saving as complete.
- Click the **OK** button and you will automatically be redirected to the data entry form and taken to the first potential error found on the form.

Figure 65



- Once you have resolved all fields with 'Error' messages, you can click on the **Save as: Complete** button. If no additional errors are detected the 'Save Successful' pop-up message will appear. Click on the **OK** button and the message and form will be closed automatically.

### How to Register a Subject

Once all of the information on the registration form has been filled out and the Eligibility V2.1

Checklist is completed (if required) you may attempt to register the subject. This section will walk-thru that process.

- Click the **Register Subject** button.

**Figure 66**



- The pop-up window “Registering ....Please wait” will flash by. At this time the information you entered on the Registration\Randomization form will be validated, IRB approval for the study as well as physician certifications will be checked. This process is somewhat time-consuming and can take up to a minute or so to complete. If any of this information is missing, a pop-up window will alert you of this fact and prevent you from registering the subject until all issues have been resolved.

**Figure 67**



- If everything is validated, the patient is registered and the Registration Confirmation Screen is displayed. **NOTE:** The subject is not registered until you see the registration confirmation screen.

**Figure 68**

TESTNUMBER Registration Confirmation	
<b>Registration Information</b>	
TESTNUMBER	01237658
Subject#	
Date On	16-feb-2009 13:05:51
Arm	A - ALIMTA + CBDCA
<b>Participation Information</b>	
Participant Sponsor	Mayo through NCCTG
Treating Location	Mayo Clinic Rochester
Treating Physician	Alberts, Steven R. M.D.
Local Subject#	01237658
<b>Existing Reference Numbers</b>	
NCCTG	01237658
Rochester	01237658
<b>Demographic Information</b>	
Initials	G, K M
Gender	Female
Race	Asian
Date of Birth	01-jun-1962
Zip Code	55920
Country	United States
Method of Payment	Private Insurance
Who Randomized: Kim M Gallimore (gallim)	
CCS Pocock-Simon(); Version 2.0.0, 31 March 2006	

- **NOTE:** In the event that the patient is being registered to a double-blinded study, the Arm will not be displayed on the confirmation screen. Instead, a list of bottle numbers and the pharmacy location where the

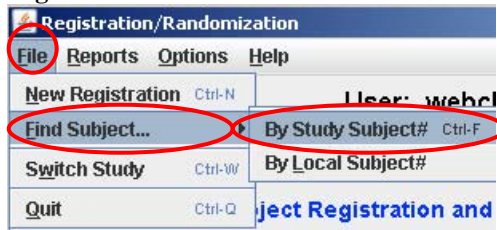
bottles may be obtained from will be displayed.

- Print a copy of the screen displaying the list of bottle numbers and the pharmacy location that the bottles may be obtained from for your records by pressing the **Print** button.

### How to Find/Display Information about a Registered Subject

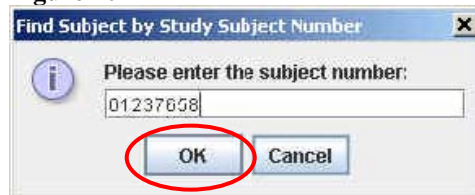
- When a subject is registered to the protocol, you will be able to find this subject either through the study assigned subject number or through the local Patient ID.
- Go to the **File** menu and select the **Find Subject** and then select **By Study Subject#**

Figure 69



- The Find Subject by Study Subject Number pop-up will be displayed; enter the subject's number and then click on the **OK** button.

Figure 70



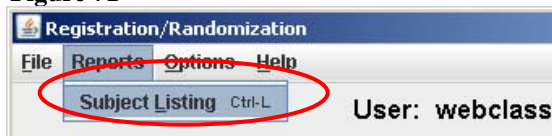
- If you are searching by Local Subject# and are able to register subjects for multiple locations, you will also be prompted for the location.  
**NOTE:** If you forgot to print a confirmation at the time of registration, you can print it from here.

## How to create a Subject Listing Report

You can create and print a listing of all Subjects for a Particular Membership/Location.

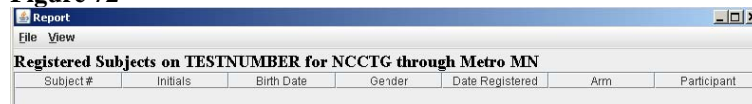
- Go to the Report menu and select Subject Listing or by simultaneously pressing the Ctrl-L keys.

Figure 71



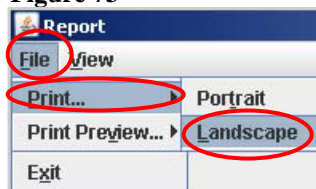
- You may have to specify the location for which you want this listing, unless the treating location is pre-filled in your registration form.
- The report is created and displayed in a separate pop-up window with information about the currently registered subjects for the site defined.  
**NOTE:** This is a great way to determine if a certain subject is on a study. The report will also give you all of the subject numbers, which can be used for displaying further information about the subject as indicated above.

Figure 72



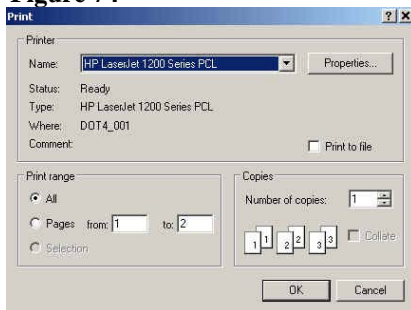
- If you want to print this report, you can resize the columns as necessary and then use the 'Landscape' printing option under the **File** menu and **Print** menu located at the top of the report screen.

Figure 73



- The **Print** window will be automatically displayed.

Figure 74



## How to Switch to another Study Protocol

You may need to register patients onto a protocol other than the one that is currently displayed.

- There are two ways that you can switch to another protocol. You can enter the protocol study number into the **Study** field and press the **Enter** key on the keyboard or by going to the **File** menu and select **Switch Study**.

Figure 75



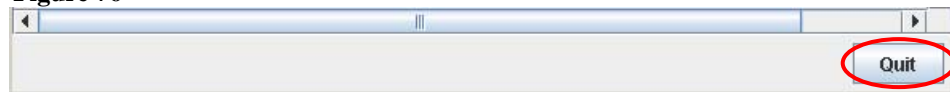
- Once the new protocol number has been validated to be available both for remote registration and to your location, a new registration form will be loaded for the study defined.

## How to Exit the Application

There are four ways to exit the application and each way is displayed in this section.

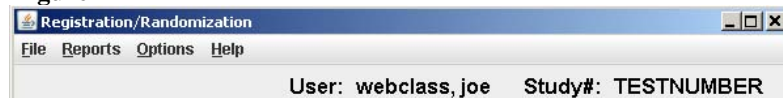
- Option #1 – click on the **Quit** button in the lower right-hand corner of application.

Figure 76



- Option #2 – click on the **X** button in the upper right-hand corner of application.

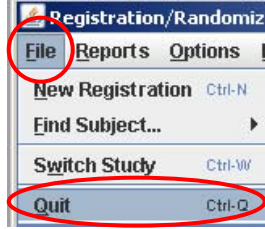
Figure 77





- Option #3 – click on the **File** menu in then click on **Quit**.

**Figure 78**



- Options #4 – simultaneously press the Ctrl-Q keys.

## How to Pre-Register a Subject

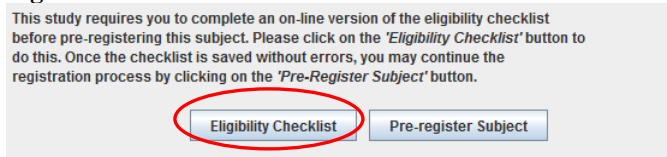
Some studies utilize Pre-Registration components to allow the data center the time to evaluate tissue samples or verify that the subject meets additional criteria prior to being registered to the study. In this case, there are a few changes to the process for registering a subject to a study.

In the instance that the study you are registering the subject to has a pre-registration component, then the first time you load the study you should see the initial screen specify 'Pre-Registration' in several key spots.

**Figure 79**

- Complete the Participation Information and Demographic Information sections
- Then click on the 'Eligibility Checklist' button located at the bottom of the screen

**Figure 80**



- The Eligibility Checklist form is displayed; complete data entry for all fields and then click on the 'Complete' button located in the lower left corner of the screen

**Figure 81**

MAYO TESTNUMBER Eligibility Checklist Form Rev Date:26-feb-2009

Person Completing Form:

Last Name: (25 available characters)  
Gallimore  
Comment (2)

First Name: (25 available characters)  
Kim  
Comment (3)

Phone: (20 available characters)  
(507) 538-1459  
Comment (4)

Fax: (20 available characters)  
(507) 222-2222  
Comment (5)

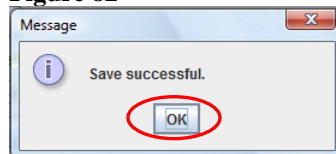
Email: (50 available characters)  
gallimore.kim@mayo.edu  
Comment (6)

Email (verification): 50 available characters  
gallimore.kim@mayo.edu

Save as: Complete Work in Progress Close Form

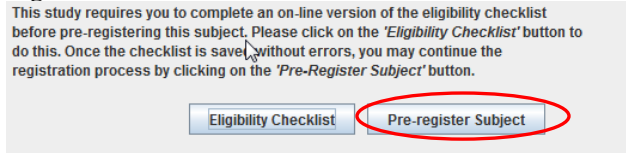
- The "Save successful" pop-up message is displayed, click on the 'OK' button

**Figure 82**



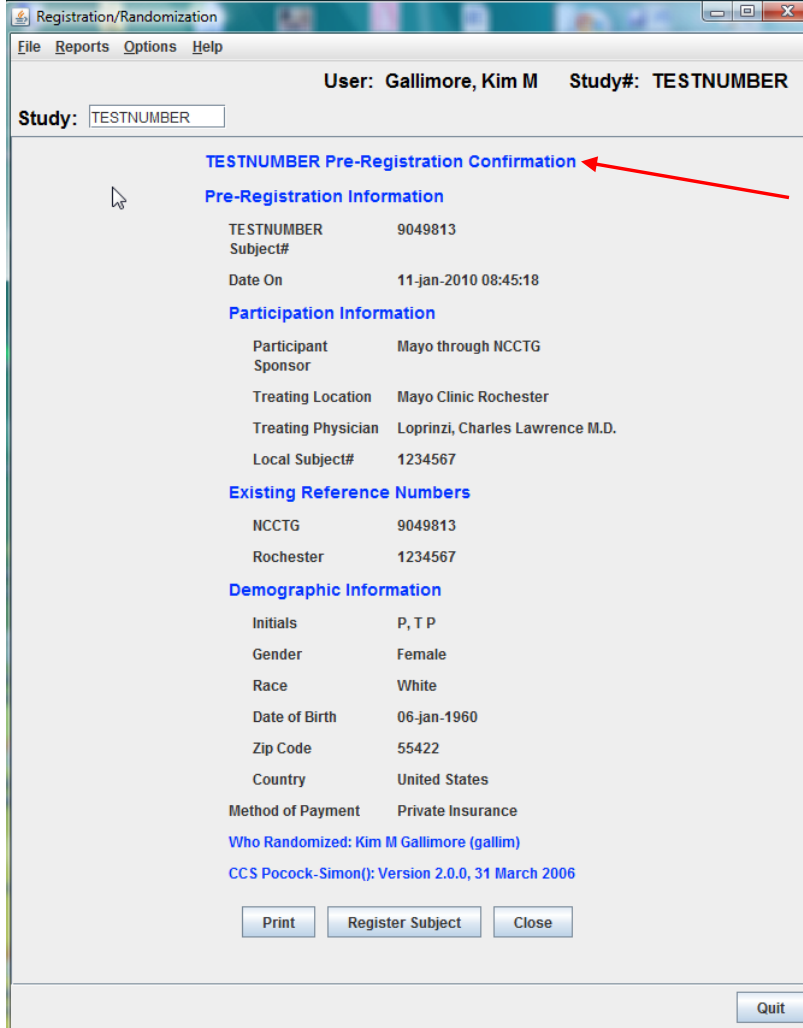
- The pop-up message box is closed and you are taken back to the “Subject Pre-Registration and Randomization” screen, click on the ‘Pre-register Subject’ button to complete the pre-registration process

**Figure 83**



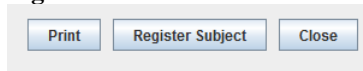
- The Pre-Registration Confirmation page will appear; this is a confirmation for a Pre-Registration **only**  
 Note: The subject is not actually on the protocol and any specimens defined by the protocol should be submitted as outlined in the protocol. An internal approval process will take place to verify that the subject can be registered to the study, at which point the registering location can register the subject to the study.

**Figure 84**



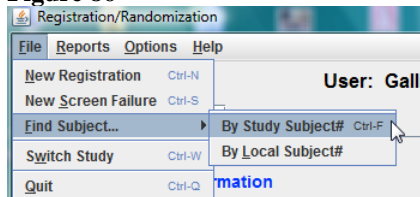
- Click on the 'Print' button located at the bottom of the screen, to print a copy of the Pre-Registration Confirmation and then click the 'Register Subject' button to complete the Pre-Registration process

**Figure 85**



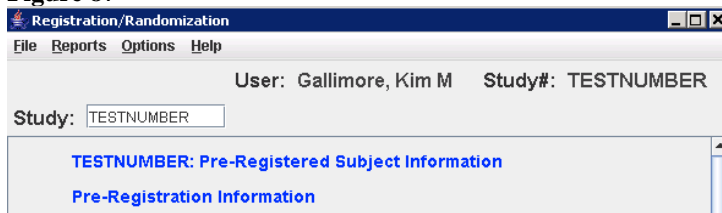
- The "Subject Pre-Registration and Randomization" screen is closed and the Subject Registration and Randomization screen is displayed with the data fields pre-filled with patient's pre-registration information
  - Note: You will not be able to complete the protocol registration until all approvals have been met for the subject, the original registrar will be notified via email that the subject is ready for registration to the protocol
- When this occurs, the user must launch the registration application as referenced in the "How to register a subject" section of the training manual – enter the protocol reference number
- Then go to the "File" menu and click on the "Find Subject" and then select the "By Study Subject #"

**Figure 86**

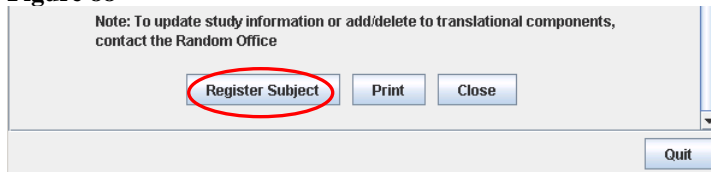


- The Pre-Registration Subject Information screen is displayed, click on the 'Register Subject' button located at the bottom of the screen

**Figure 87**



**Figure 88**



- The “Subject Registration and Randomization screen is displayed (looks similar to the screen that what displayed after you completed the “Subject Pre-Registration” process), make any necessary additions or changes and then click on the ‘Eligibility Checklist’ button located at the bottom of the screen

**Figure 89**

The screenshot shows a web application window titled "Registration/Randomization". At the top, it displays "User: Gallimore, Kim M" and "Study#: TESTNUMBER". Below this, there is a "Study:" field with the value "TESTNUMBER". The main section is titled "Participation Information" and contains several fields: "Participant Sponsor" (Mayo (MN026) through NCCTG (required)), "Treating Location" (Mayo Clinic Rochester (MN026) (required)), "Treating Physician" (Loprinzi, Charles Lawrence M.D. (required)), and "Local Subject#" (1234567 (optional)).

**Figure 90**

The screenshot shows a text box with the following instructions: "This study requires you to complete an on-line version of the eligibility checklist before registering this subject. Please click on the 'Eligibility Checklist' button to do this. Once the checklist is saved without errors, you may continue the registration process by clicking on the 'Register Subject' button." Below the text are two buttons: "Eligibility Checklist" and "Register Subject". The "Eligibility Checklist" button is circled in red.

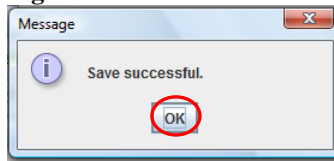
- The “Eligibility Checklist” form is displayed, complete all fields and click on the ‘Complete’ button located in lower left hand corner of screen

**Figure 91**

The screenshot shows the "MAYO TESTNUMBER Eligibility Checklist" form. At the top, it displays "Study: TESTNUMBER Patient: Cycle: 0 Seq: 1 Initials: P, T P User: gallim". The form title is "MAYO TESTNUMBER Eligibility Checklist Form Rev Date:26-feb-2009". The form contains several sections: "Person Completing Form:" with fields for "Last Name: (25 available characters)" (Gallimore), "First Name: (25 available characters)" (Kim), "Phone: (20 available characters)" ((507) 538-1459), "Fax: (20 available characters)" ((507) 222-2222), and "Email: (50 available characters)" (gallimore.kim@mayo.edu). There are also "Email (verification): 50 available characters" and "gallimore.kim@mayo.edu" fields. At the bottom, there are three buttons: "Complete", "Work in Progress", and "Close Form". The "Complete" button is circled in red.

- The form is validated, saved, and the “Save successful” pop-up message is displayed – click on the “OK” button

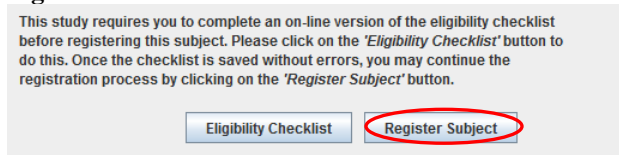
**Figure 92**



- The message pop-up box is closed and you are taken back to the “Subject Registration and Randomization screen – click on the ‘Register Subject’ button located at the bottom of the screen

Note: If not all of the approvals have been completed for the subject, you should receive an error message that will prevent you from completing the eligibility checklist or registering the subject. Once all approvals are met, you should be able to perform these functions and register the subject to the protocol.

**Figure 93**



- The Registration Confirmation screen is displayed, click on the ‘Print’ button located at the bottom of screen if you wish to have a printed copy and then click on the ‘Quit’ button located in the lower right corner of the screen or choose “Quit” from the “File” menu at the top of the screen, to exit the application

**Figure 94**

**TESTNUMBER Registration Confirmation**

Registration Information

TESTNUMBER Subject#	9049813
Date On	11-jan-2010 09:20:36
Arm	A - ALIMTA + CBDCA

Participation Information

Participant Sponsor	Mayo through NCCTG
Treating Location	Mayo Clinic Rochester
Treating Physician	Loprinzi, Charles Lawrence M.D.
Local Subject#	1234567

Existing Reference Numbers

NCCTG	9049813
Rochester	1234567

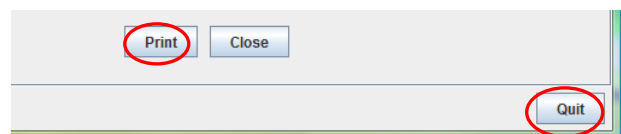
Demographic Information

Initials	P, T P
Gender	Female
Race	White
Date of Birth	06-jan-1960
Zip Code	55422
Country	United States
Method of Payment	Private Insurance

Who Randomized: Kim M Gallimore (gallim)

CCS Pocock-Simon(): Version 2.0.0, 31 March 2006

**Figure 95**



## Contact Information

Questions Regarding	Contact Person	Phone Number	E-mail
Installation & System Technical Support	Larry Esser	(507) 284-0083	<a href="mailto:lje09@mayo.edu">lje09@mayo.edu</a>
Security (User id & password)	Sheree Estes	(507) 284-5999	<a href="mailto:Estes@mayo.edu">Estes@mayo.edu</a>
Study Form Technical Support	Data Management Specialist Assigned to Study		
Registration/Randomization Issues IRB, 1572s etc.	Randomization Office	(507) 284-4130	
Questions on Study Specific Data Items	Quality Control Specialist Assigned to Study		
Protocol documents, Consent forms and Regulatory Issues	Protocol Development Coordinator Assigned to Study		

To report application issues please fill out the [CCS Help Request Form](#) .

To request changes to application please fill out the [Application/System Request Form](#) .

If unable to resolve an '**ERROR**' message, contact Registration Office at (507) 284-4130.