Interactive Registration System (IRIS)
Subject Registration + Randomization Instructions

1. In your web browser navigate to https://www.ocog.ca/IRIS or use OCOG web site (www.ocog.ca) as a gateway to access IRIS.

2. Enter provided User Name and Password, and click on the Log In button.

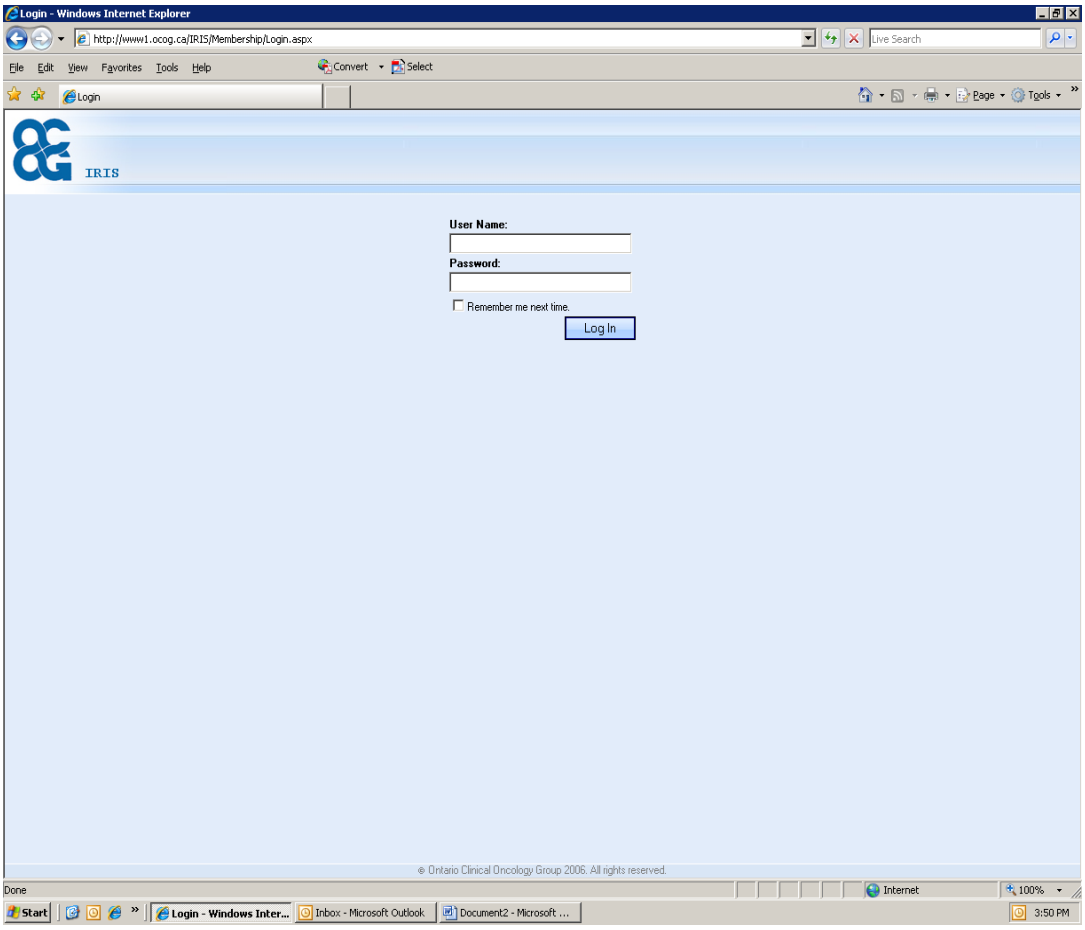

Figure 1, Login screen

STAGE 1: Subject Registration

After successful login, **Subject screen** will be shown (***Figure 2***)
This screen lists all previously registered Subjects for user's assigned centre.

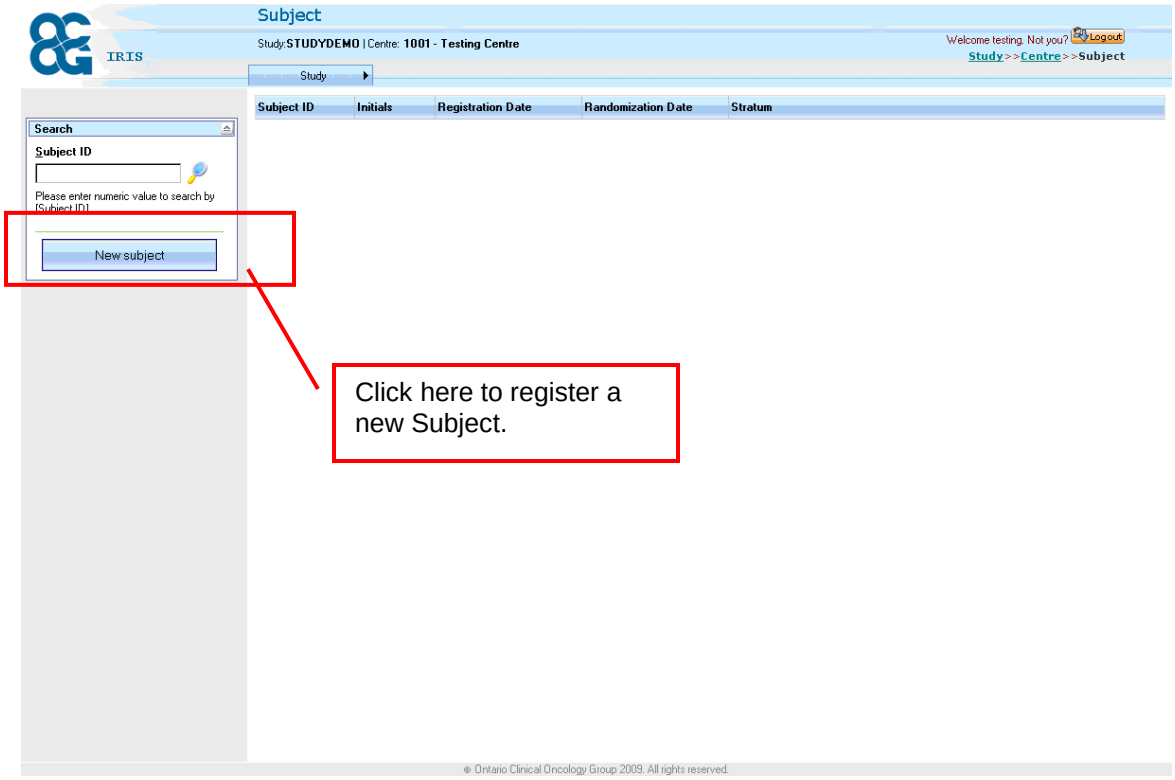

Figure 2, Subject screen I

For Randomizing studies there is Randomization date and stratum columns in the list as well.

Subject ID	Initials	Registration Date	Randomization Date	Stratum
1023001	KKK	22 May 2009		

Figure 3, Randomizing studies

3. To register a new Subject click on *New subject* button located on the left hand side of the screen (***Figure2)***

This will navigate you to the “Register subject” screen.
Screen has entry box for subject’s initials and lists all eligibility criteria.

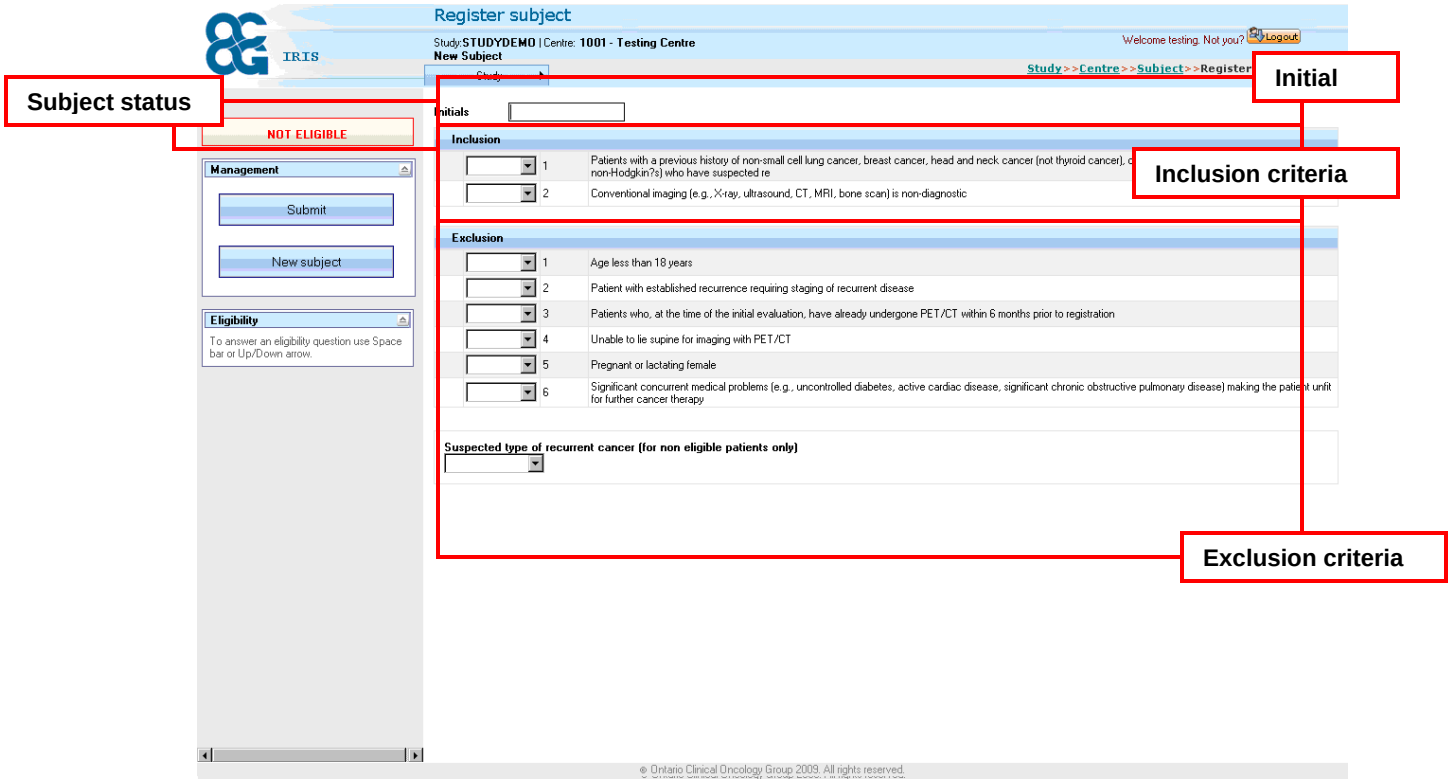

Figure 4, Register Subject screen I

4. Type subject's initials in Initials box, then answer all eligibility criteria.
Use Tab key to navigate between questions. To go back to a previous question you can hold Shift key and press Tab key. Alternative method is using a mouse.
Type Y to answer Yes or N to answer No. Mouse can be used to choose Yes/ No answer from dropdown.

In order to register a subject all inclusion criteria must be answered **Yes** and all exclusion criteria must be answered **No.**

System checks Subject eligibility status based on provided answers.
When subject status becomes **Eligible,** additional questions will be presented to confirm eligibility status and date (***Figure 5)***

Accepted date format is dd-mmm-yyyy.
In order to enter 4 Feb 2009 - type 040209 and system will format it to 4-Feb-2009.
In all dropdowns you can use mouse to select necessary answer or simply type first letter of the value (y for Yes, n for No, etc.)

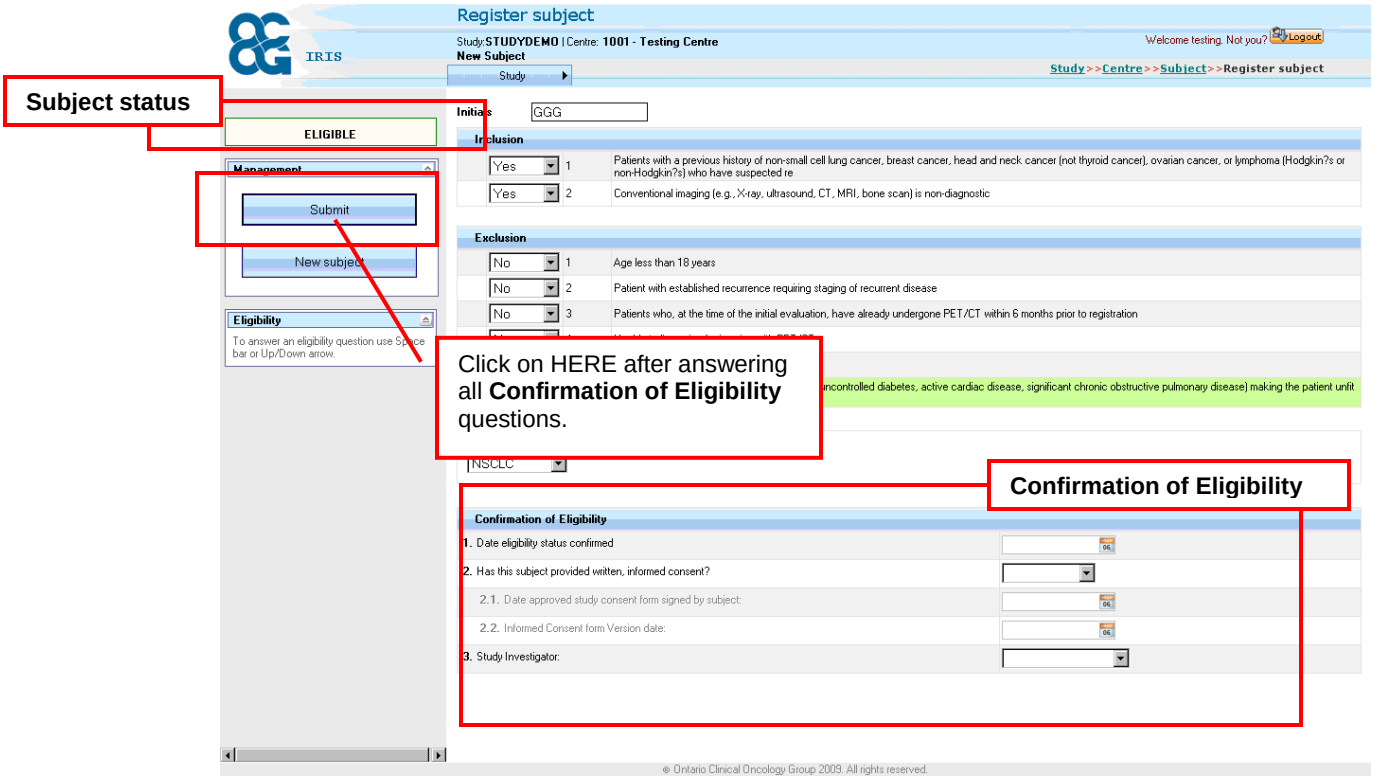

Figure 5, Register Subject screen II – Confirmation of Eligibility and Submit

5. After answering all **Confirmation of Eligibility** questions click on Submit button to register subject and save entered information.

Prior to submit, the System will validate data (ranges, mandatory fields).
If entered data has passed validation subject's ID will be assigned and shown above subject's initials. If validation has failed – the System will mark the field that hasn't passed validation (validation error) in the colour red, and the field that passed with warning (validation warning) in the colour of light yellow (***Figure 6***). User cannot submit the data with validation error, but user is able to submit with warning by clicking on the Submit with warning button (***Figure 7***).

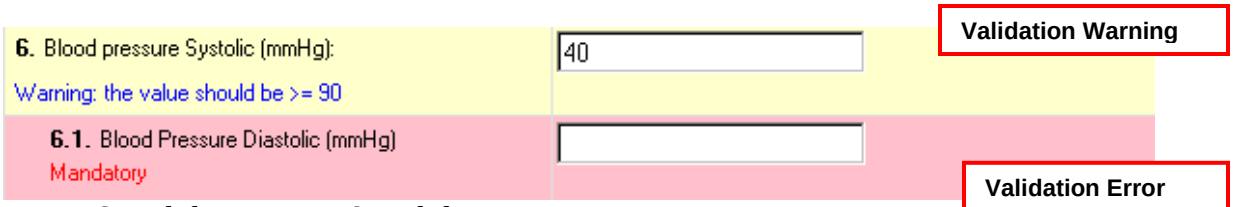

Figure 6: Validation Error & Validation Warning

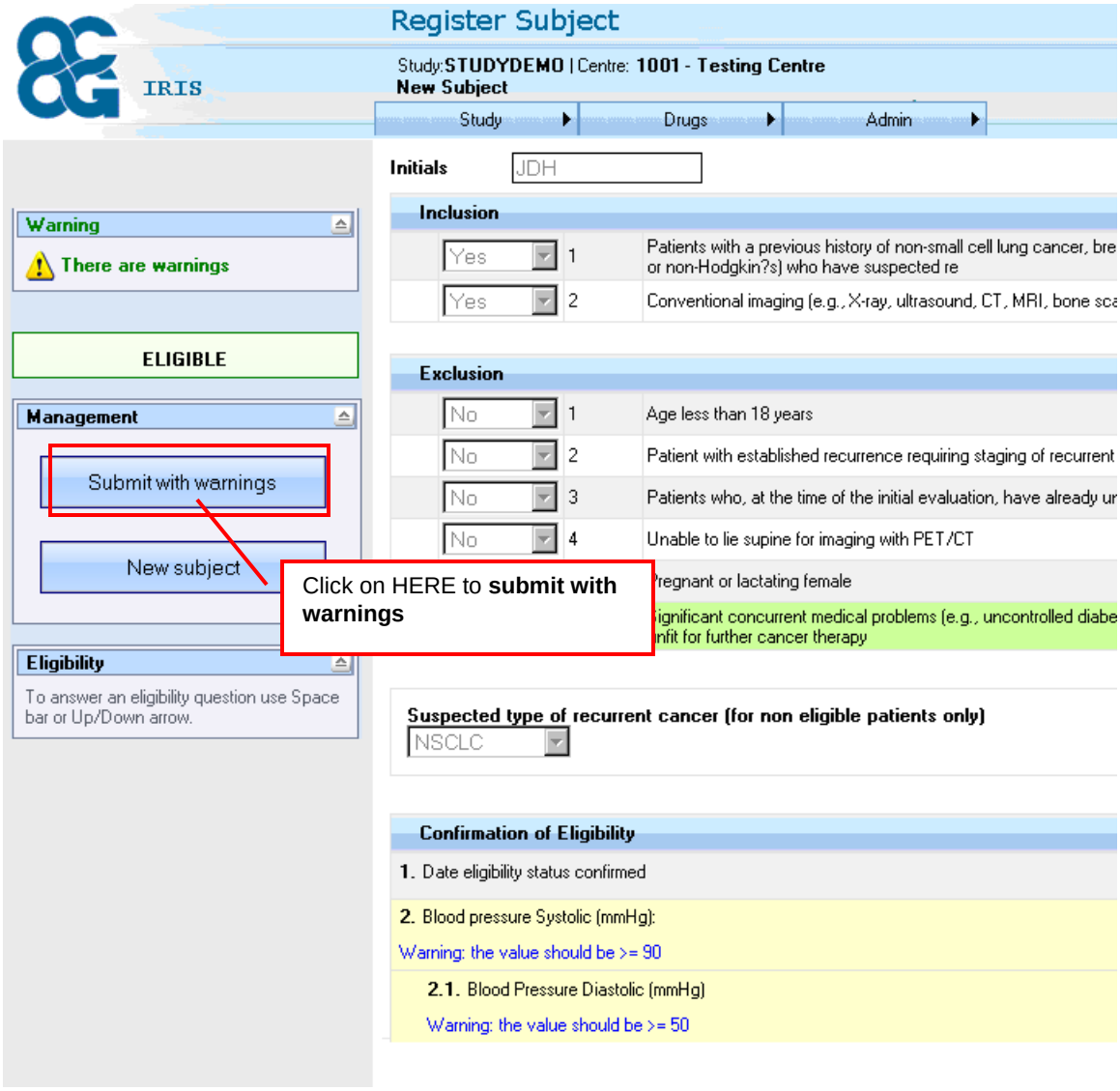

Figure 7: Submit with warnings

IMPORTANT! You will not be able to change or complete any answers after submitting data. Make sure all your answers are correct before clicking Submit button.

At this point you can print confirmation of eligibility form by clicking on *Print Form* button (***Figure 8***)

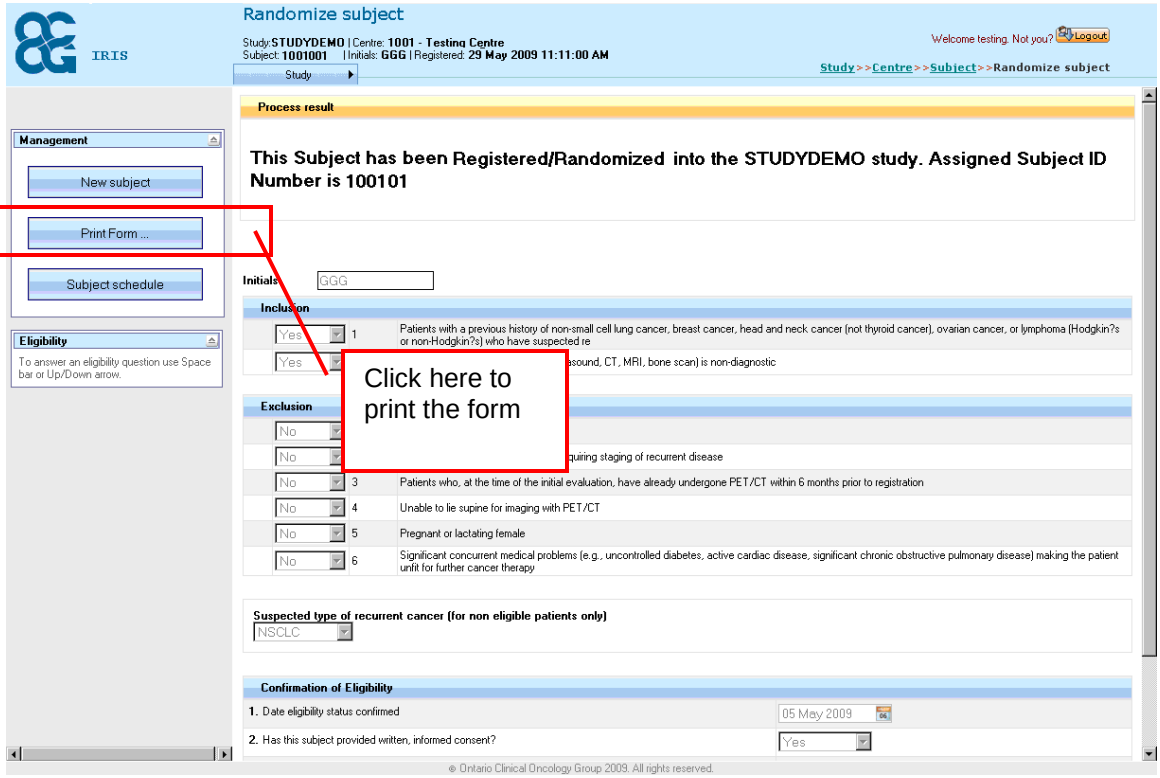

Figure 8, Register Subject screen III – Printing

To register a new subject click *New Subject* button.

By clicking on a Subject>> button in a top right corner you will navigate back to a Subject screen, which will show just registered Subject.

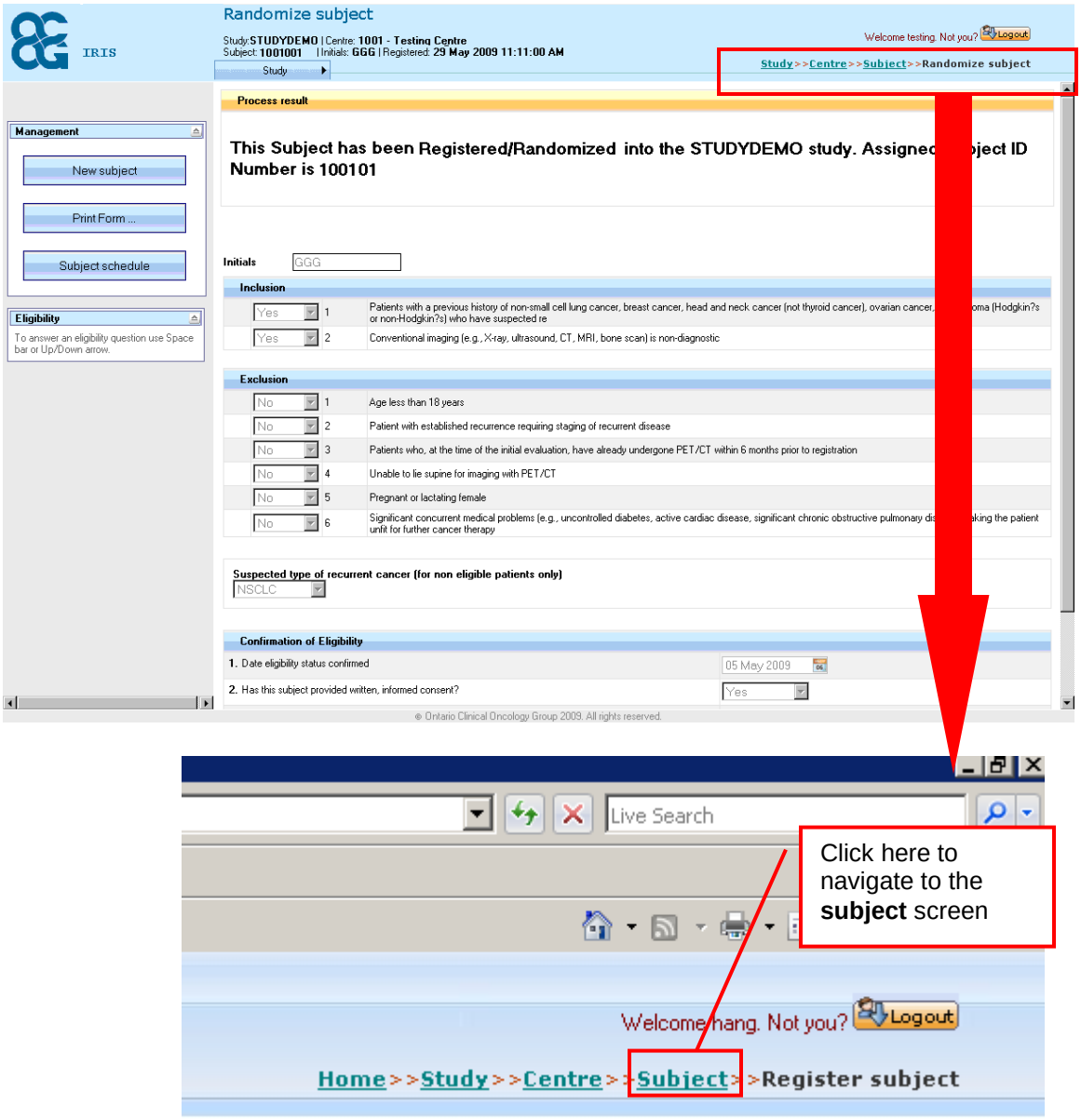

Figure 9, Navigation to Subject screen

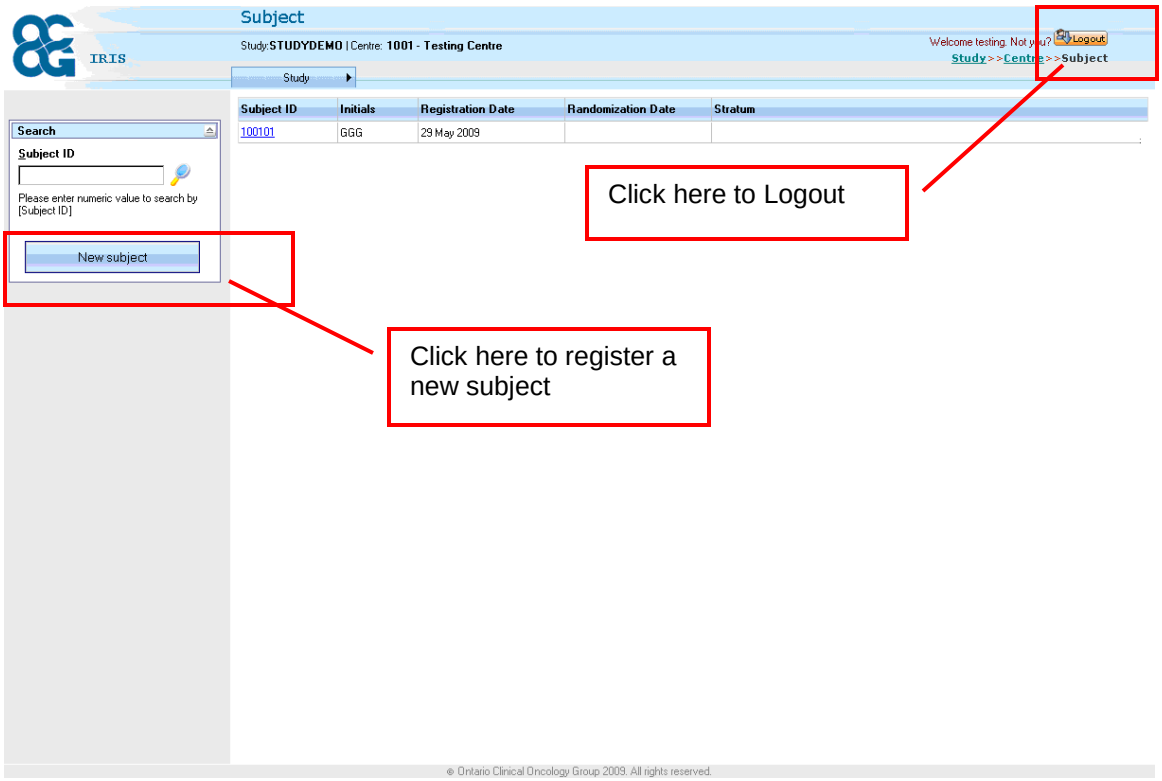

Figure 10, Subject screen II

From this screen you can logout by clicking Logout button at the top right corner, or register a new subject, or look at the entered data for previously registered subject by clicking on Subject ID link from the list. You may want to do it to reprint eligibility confirmation form.

This system is also used for entering screening log data and not consenting patients data. Only patients meeting all inclusion criteria can be entered into screening log.

Screening log and not consenting patients will be assigned Study ID 0 (zero).

This completes the steps of registration.

STAGE 2a: Randomizing Subject with Pre-registration

Subject has to be fully registered in IRIS in order to start the randomization stage. Please refer to the section of ***STAGE1: Subject Registration*** as a guideline for subject registration.

Login to the IRIS, click on a Subject Id link to proceed to “Randomize subject” screen (see figure 11). After the subject has been successfully registered in IRIS, a set of randomization questions are shown. User has to complete these questions before clicking on the Randomize Subject button located on the left hand side of your screen (see Figure 12).

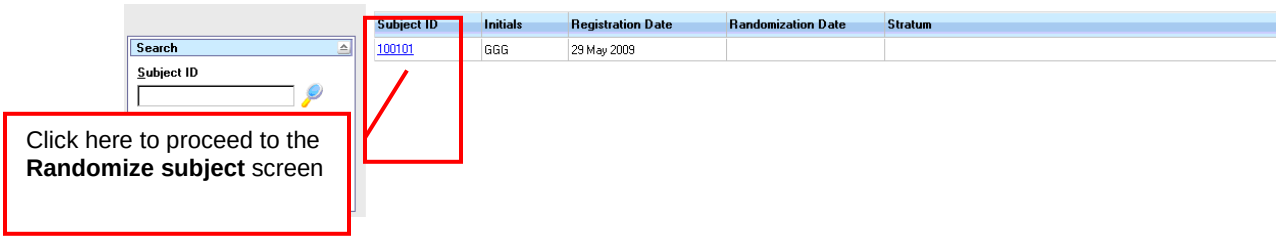

Figure11, Subject screen with pre-registration

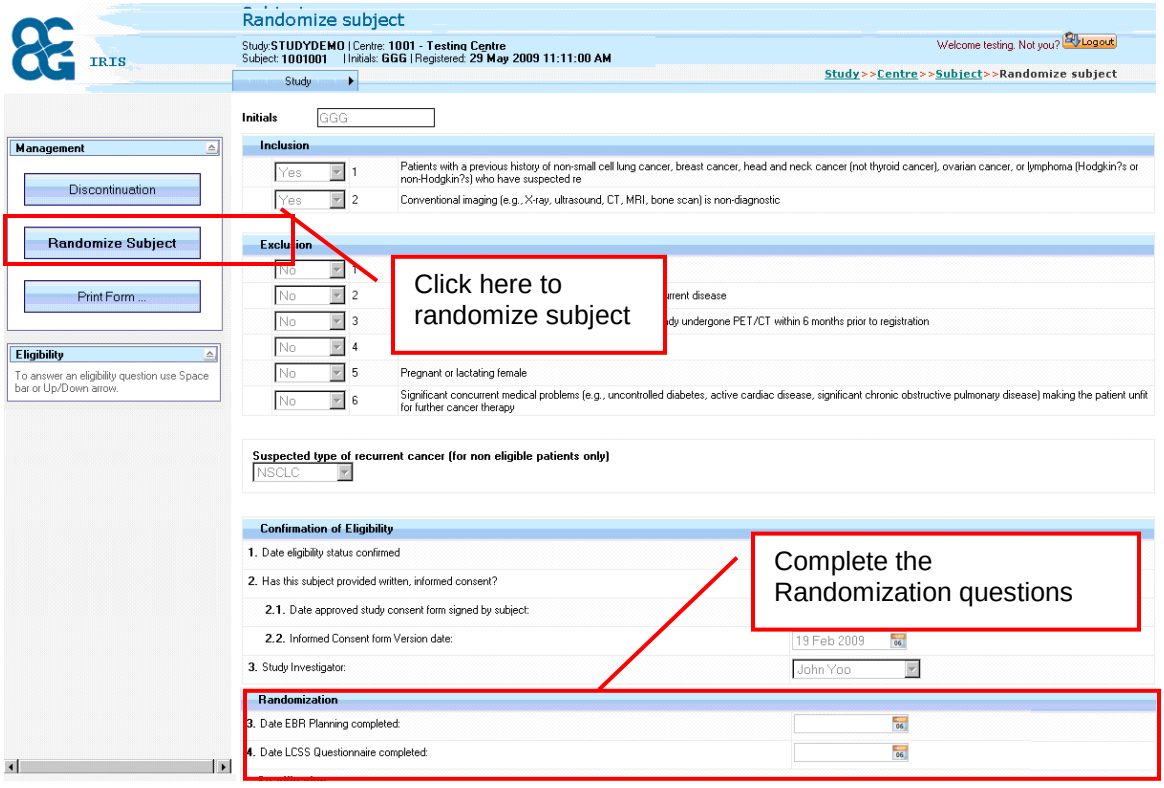

Figure 12, Randomize Subject screen

Message about subject being randomized to study treatment group will be shown.

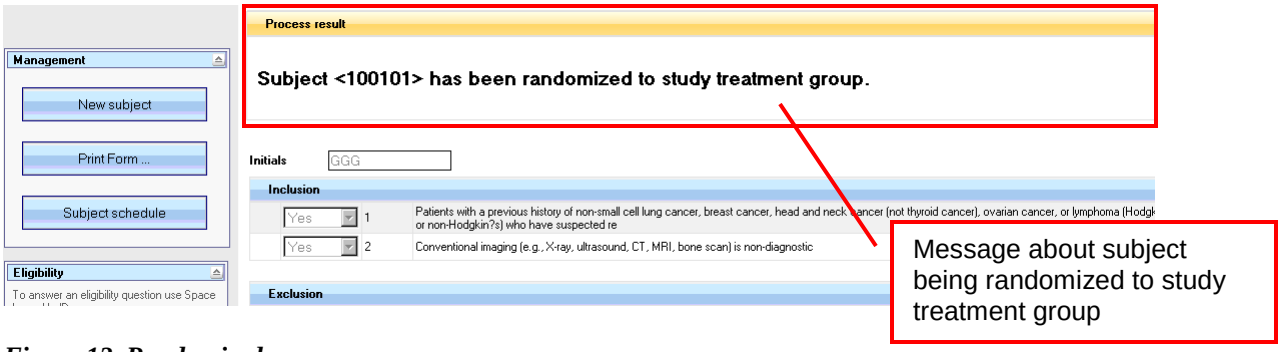

Figure 13, Randomized message

Randomized Subject will have Randomization date listed on a Subject screen (***Figure 14***)

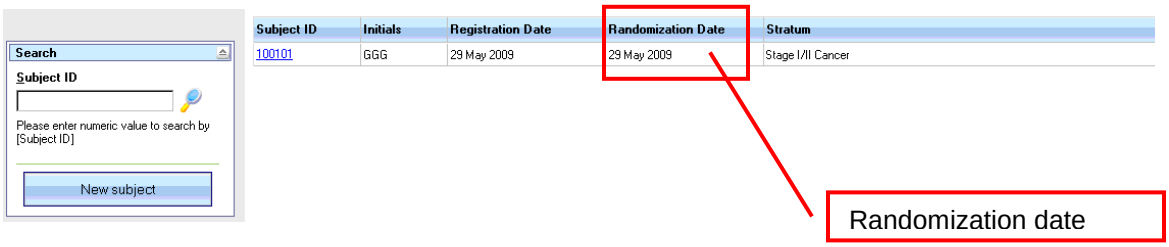

Figure 14, Randomization date on Subject screen

STAGE 2b: Discontinuing Subject with Pre-registration

A subject may be discontinued in IRIS if the subject becomes ineligible after registration but has not yet been randomized. Please refer to the section ***STAGE 1: Subject Registration*** as a guideline for subject registration.

Login to IRIS, click on a Subject ID link to proceed to the 'Randomize subject' screen (see figure 11). After the subject has been successfully registered in IRIS, a set of randomization questions are shown. We recommend completing these questions as much as possible before clicking on the 'Discontinuation' button located on the left hand side of your screen (see Figure 15).

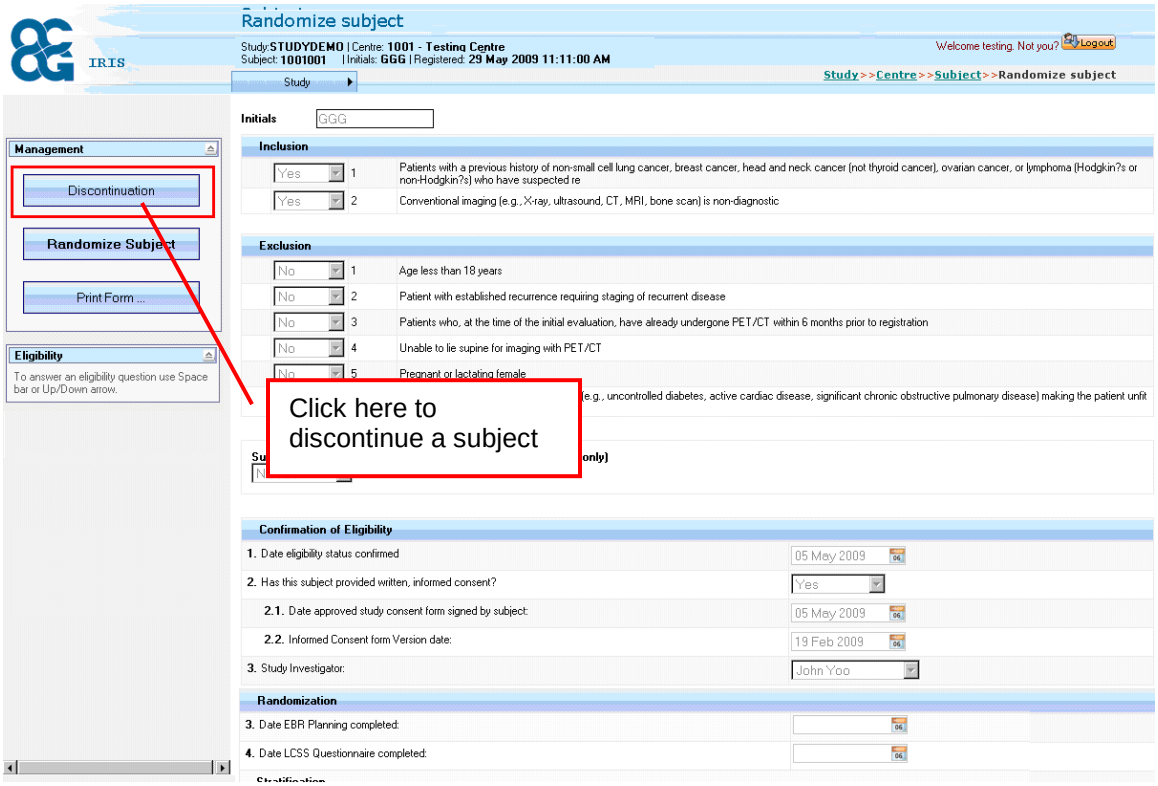

Figure 15, Discontinuation button on the Randomize Subject screen.

The System navigates to the Discontinued screen once the ‘Discontinuation’ button has been clicked. The User needs to provide the Date of Discontinuation, which should be on or after the subject registration date, but not in the future and the Reason for Discontinuation. These two fields are mandatory for discontinuing a subject. Click the ‘Discontinuation’ button again to confirm the action. (See Figure 16)

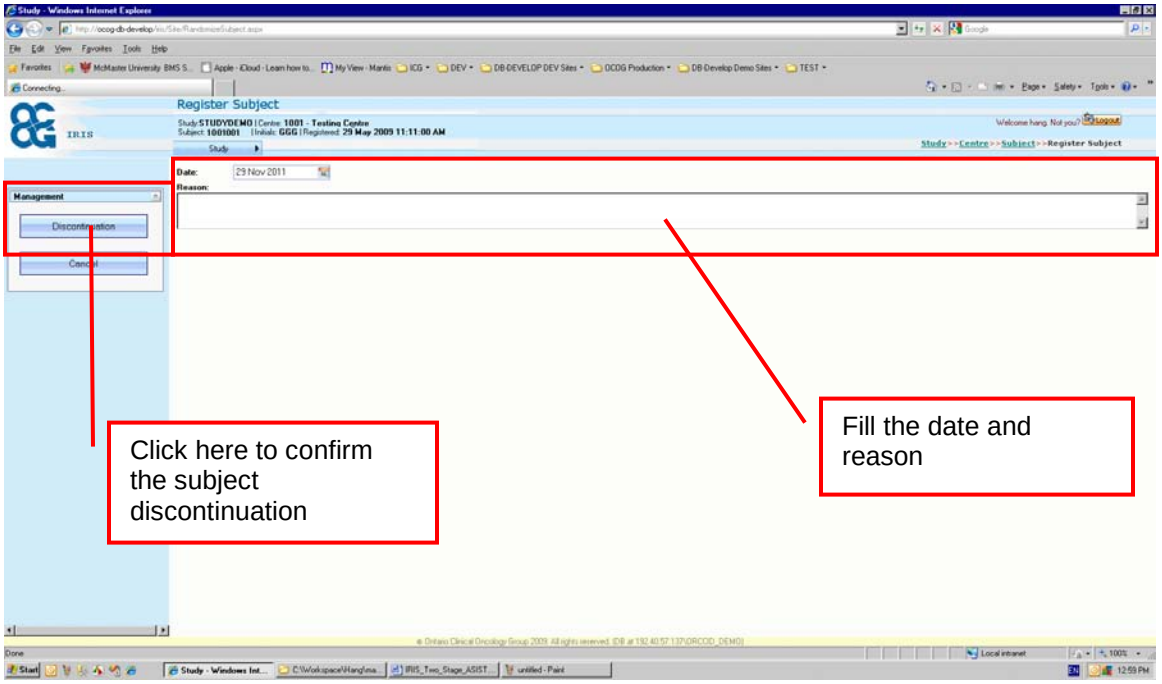

Figure 16, Confirm discontinuation

All the data saved in the database and the fields on the Randomization screen become locked once the discontinuation process is performed (see figure 17). Also, the Discontinuation Date and Discontinuation Reason are shown on the subject screen (see figure 18).

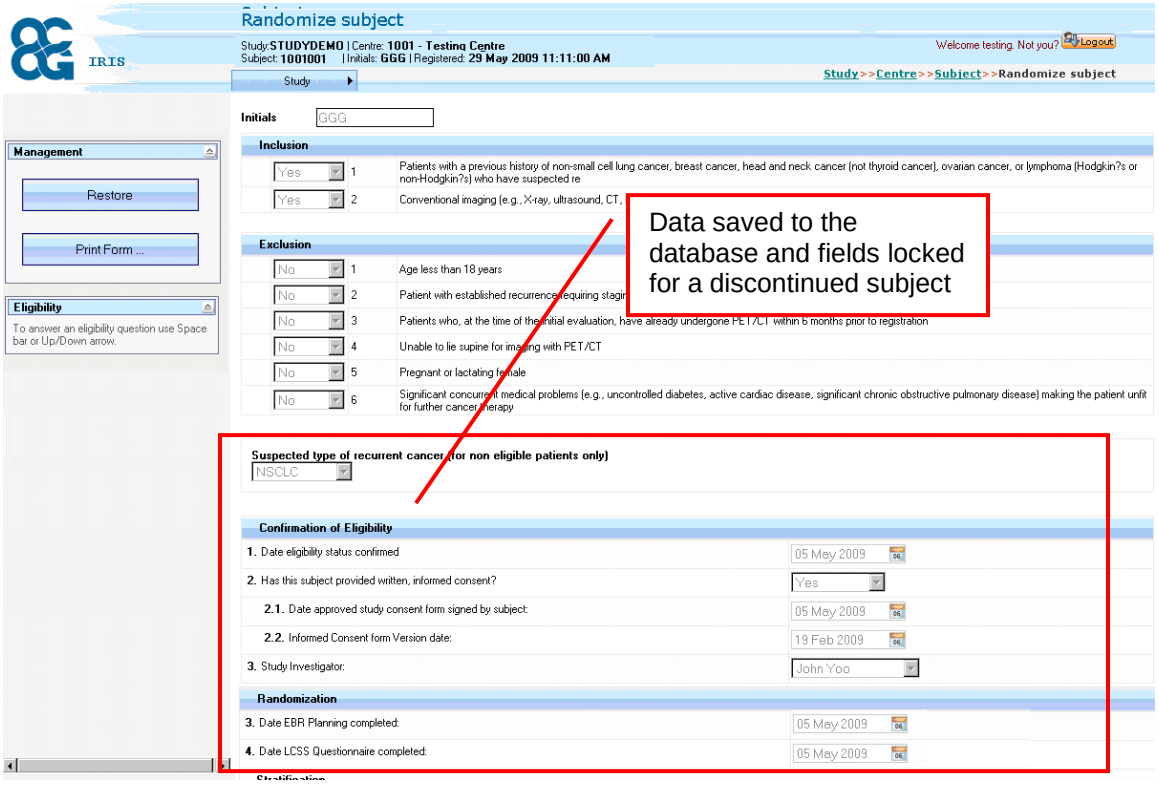

Figure 17, Randomization screen after discontinued

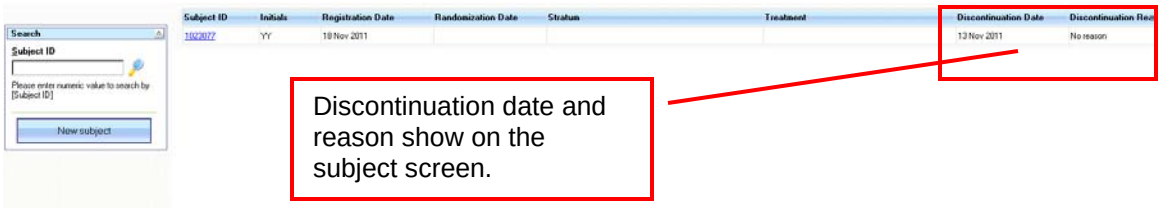

Figure 18, Discontinuation Date and Reason show on the subject screen

Additionally, if necessary, the discontinued subject can also be restored (for coordinators only), if the subject's condition changes, by clicking the 'Restore' button on the Register Subject screen of a discontinued subject (see figure 19).

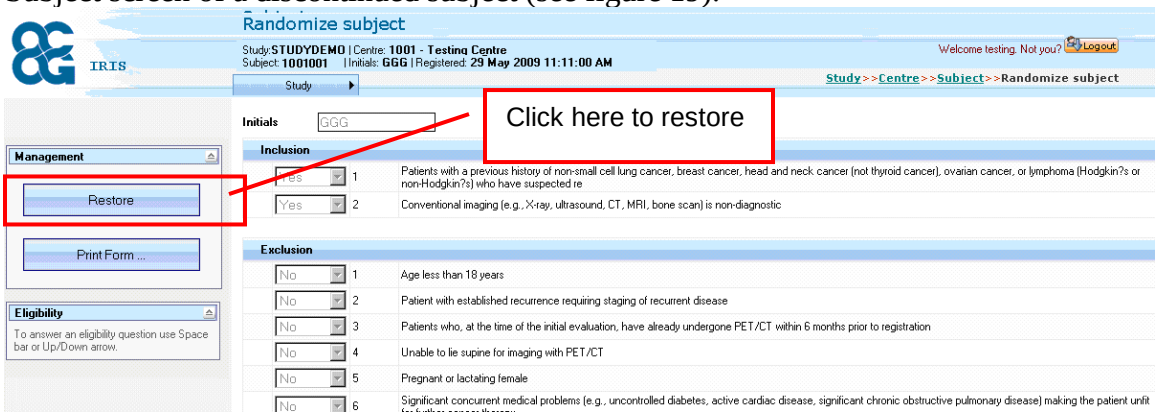

Figure 19, Restore subject