

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  button.

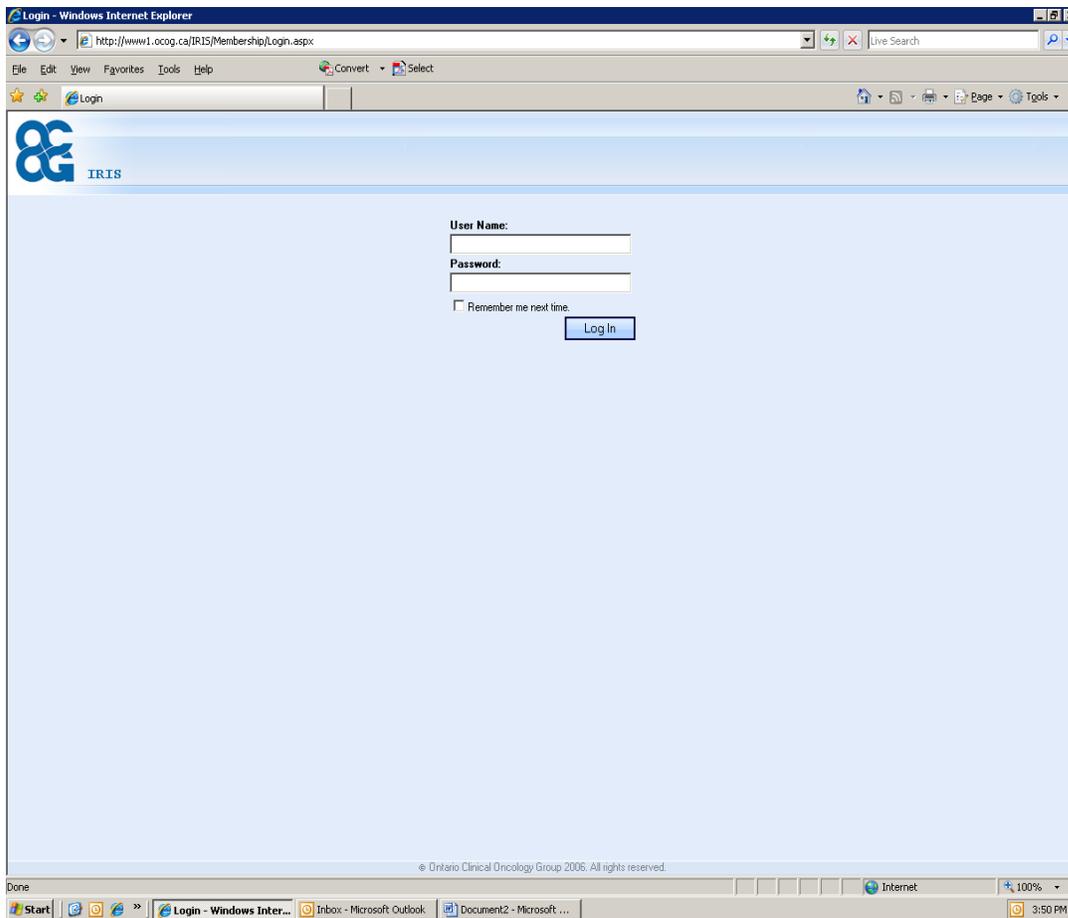


Figure 1, Login screen

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.

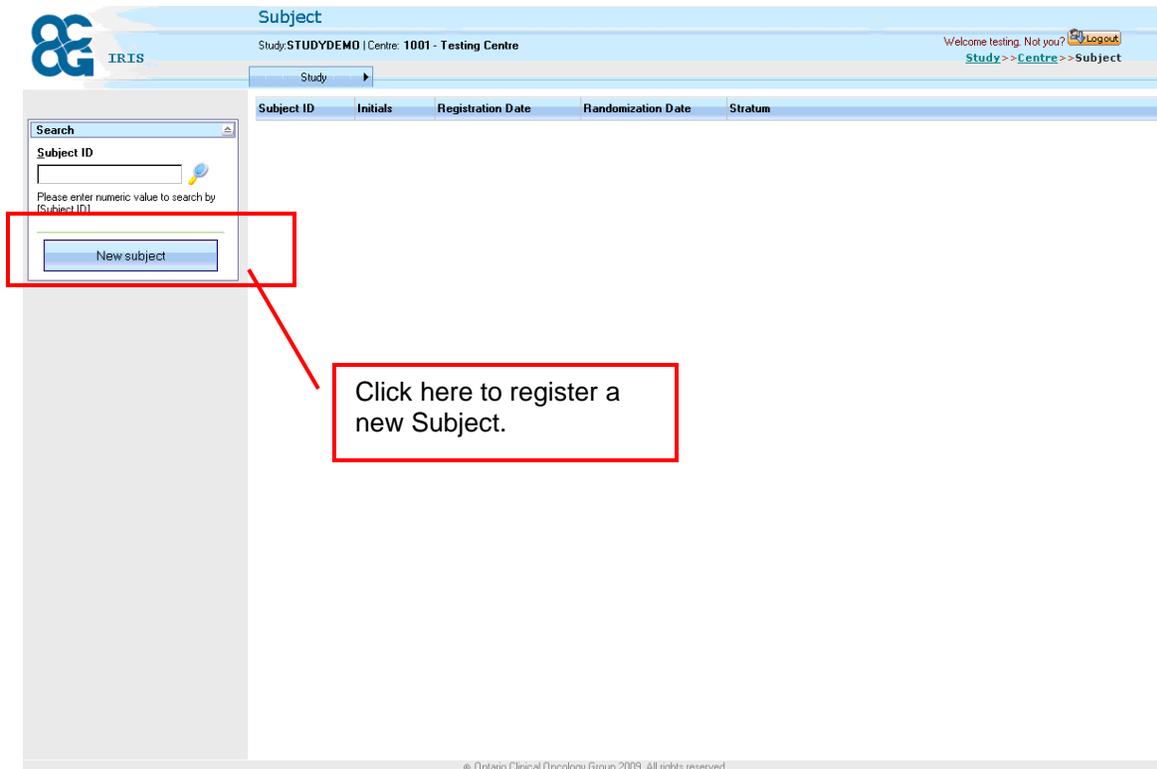


Figure 2, Subject screen I

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.

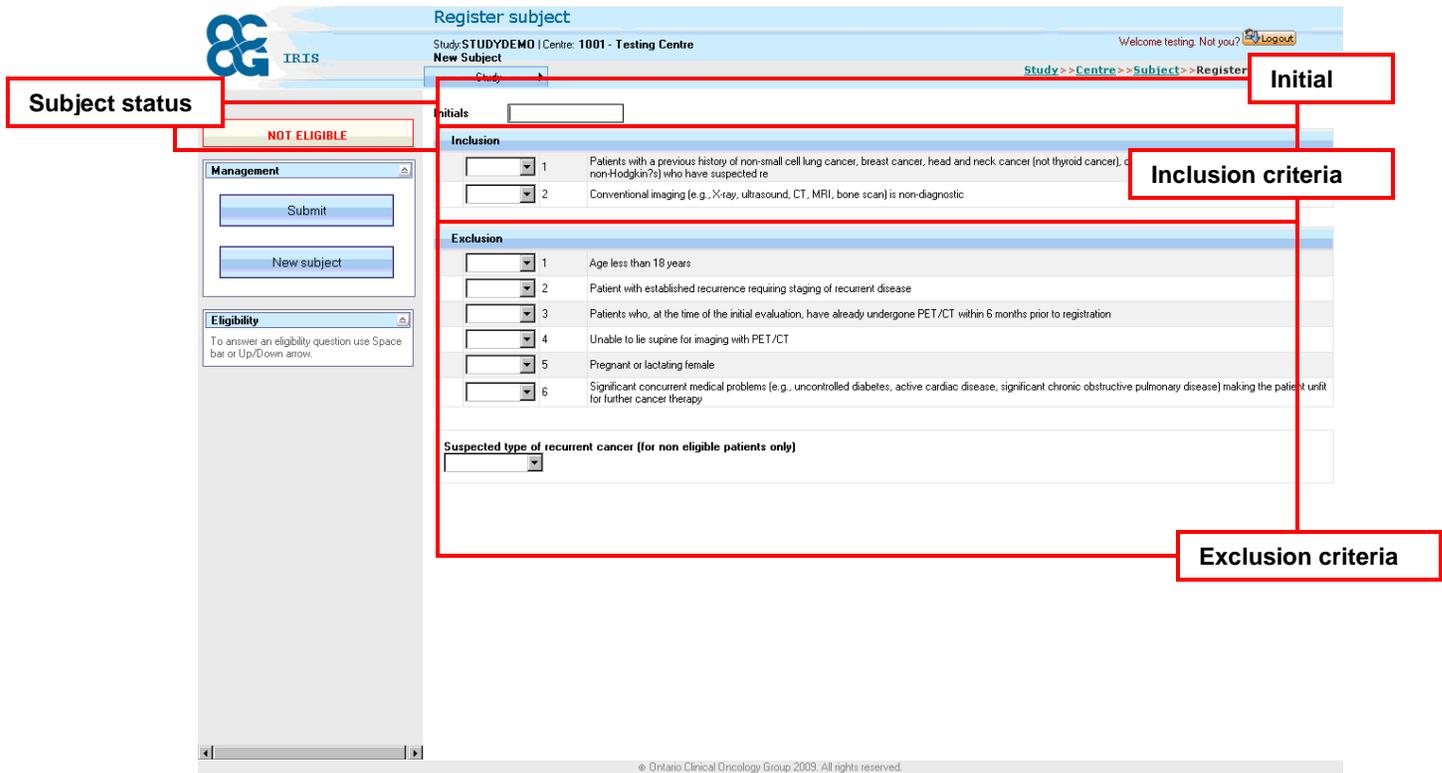


Figure 4, Register Subject screen I

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.)

Subject status

ELIGIBLE

Management

Submit

New subject

Eligibility

To answer an eligibility question use Space bar or Up/Down arrow.

Confirmation of Eligibility

1. Date eligibility status confirmed: [Date Picker]

2. Has this subject provided written, informed consent? [Yes/No]

2.1. Date approved study consent form signed by subject: [Date Picker]

2.2. Informed Consent form Version date: [Date Picker]

3. Study Investigator: [Dropdown]

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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*).

6. Blood pressure Systolic (mmHg):	<input type="text" value="40"/>	Validation Warning
Warning: the value should be >= 90		
6.1. Blood Pressure Diastolic (mmHg)	<input type="text"/>	Validation Error
Mandatory		

Figure 6: Validation Error & Validation Warning

Warning
 ⚠ There are warnings

ELIGIBLE

Management
 Submit with warnings
 New subject

Eligibility
 To answer an eligibility question use Space bar or Up/Down arrow.

Register Subject
 Study: STUDYDEMO | Centre: 1001 - Testing Centre
 New Subject

Study | Drugs | Admin

Initials: JDH

Inclusion

Yes	1	Patients with a previous history of non-small cell lung cancer, breast or non-Hodgkin?s) who have suspected re
Yes	2	Conventional imaging (e.g., X-ray, ultrasound, CT, MRI, bone sca

Exclusion

No	1	Age less than 18 years
No	2	Patient with established recurrence requiring staging of recurrent
No	3	Patients who, at the time of the initial evaluation, have already ur
No	4	Unable to lie supine for imaging with PET/CT

regnant or lactating female
 significant concurrent medical problems (e.g., uncontrolled diabe
 unfit for further cancer therapy

Suspected type of recurrent cancer (for non eligible patients only)
 NSCLC

Confirmation of Eligibility

- Date eligibility status confirmed
- Blood pressure Systolic (mmHg):
 Warning: the value should be >= 90
 - Blood Pressure Diastolic (mmHg)
 Warning: the value should be >= 50

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)

Randomize subject

Study: STUDYDEMO | Centre: 1001 - Testing Centre
 Subject: 1001001 | Initials: GGG | Registered: 29 May 2009 11:11:00 AM

Welcome testing. Not you? [Logout](#)

Study >> Centre >> Subject >> Randomize subject

Process result

This Subject has been Registered/Randomized into the STUDYDEMO study. Assigned Subject ID Number is 100101

Initials:

Inclusion

Yes 1 Patients with a previous history of non-small cell lung cancer, breast cancer, head and neck cancer (not thyroid cancer), ovarian cancer, or lymphoma (Hodgkin's or non-Hodgkin's) who have suspected re

Yes 2 [unclear] (ultrasound, CT, MRI, bone scan) is non-diagnostic

Exclusion

No 3 [unclear] requiring staging of recurrent disease

No 4 Patients who, at the time of the initial evaluation, have already undergone PET/CT within 6 months prior to registration

No 5 Unable to lie supine for imaging with PET/CT

No 6 Pregnant or lactating female

No 7 Significant concurrent medical problems (e.g., uncontrolled diabetes, active cardiac disease, significant chronic obstructive pulmonary disease) making the patient unfit for further cancer therapy

Suspected type of recurrent cancer (for non eligible patients only)

Confirmation of Eligibility

1. Date eligibility status confirmed

2. Has this subject provided written, informed consent?

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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.

Randomize subject

Study: STUDYDEMO | Centre: 1001 - Testing Centre
 Subject: 1001001 | Initials: GGG | Registered: 29 May 2009 11:11:00 AM

Welcome testing. Not you? [Logout](#)

[Study](#) >> [Centre](#) >> [Subject](#) >> Randomize subject

Process result

This Subject has been Registered/Randomized into the STUDYDEMO study. Assigned Subject ID Number is 100101

Initials:

Inclusion

<input checked="" type="checkbox"/> Yes	1	Patients with a previous history of non-small cell lung cancer, breast cancer, head and neck cancer (not thyroid cancer), ovarian cancer, or lymphoma (Hodgkin's or non-Hodgkin's) who have suspected recurrence
<input checked="" type="checkbox"/> Yes	2	Conventional imaging (e.g., X-ray, ultrasound, CT, MRI, bone scan) is non-diagnostic

Exclusion

<input checked="" type="checkbox"/> No	1	Age less than 18 years
<input checked="" type="checkbox"/> No	2	Patient with established recurrence requiring staging of recurrent disease
<input checked="" type="checkbox"/> No	3	Patients who, at the time of the initial evaluation, have already undergone PET/CT within 6 months prior to registration
<input checked="" type="checkbox"/> No	4	Unable to lie supine for imaging with PET/CT
<input checked="" type="checkbox"/> No	5	Pregnant or lactating female
<input checked="" type="checkbox"/> No	6	Significant concurrent medical problems (e.g., uncontrolled diabetes, active cardiac disease, significant chronic obstructive pulmonary disease) making the patient unfit for further cancer therapy

Suspected type of recurrent cancer (for non eligible patients only)

Confirmation of Eligibility

1. Date eligibility status confirmed:

2. Has this subject provided written, informed consent? Yes

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Live Search

Welcome hang. Not you? [Logout](#)

[Home](#) >> [Study](#) >> [Centre](#) >> [Subject](#) >> Register subject

Click here to navigate to the **subject** screen

Figure 9, Navigation to Subject screen

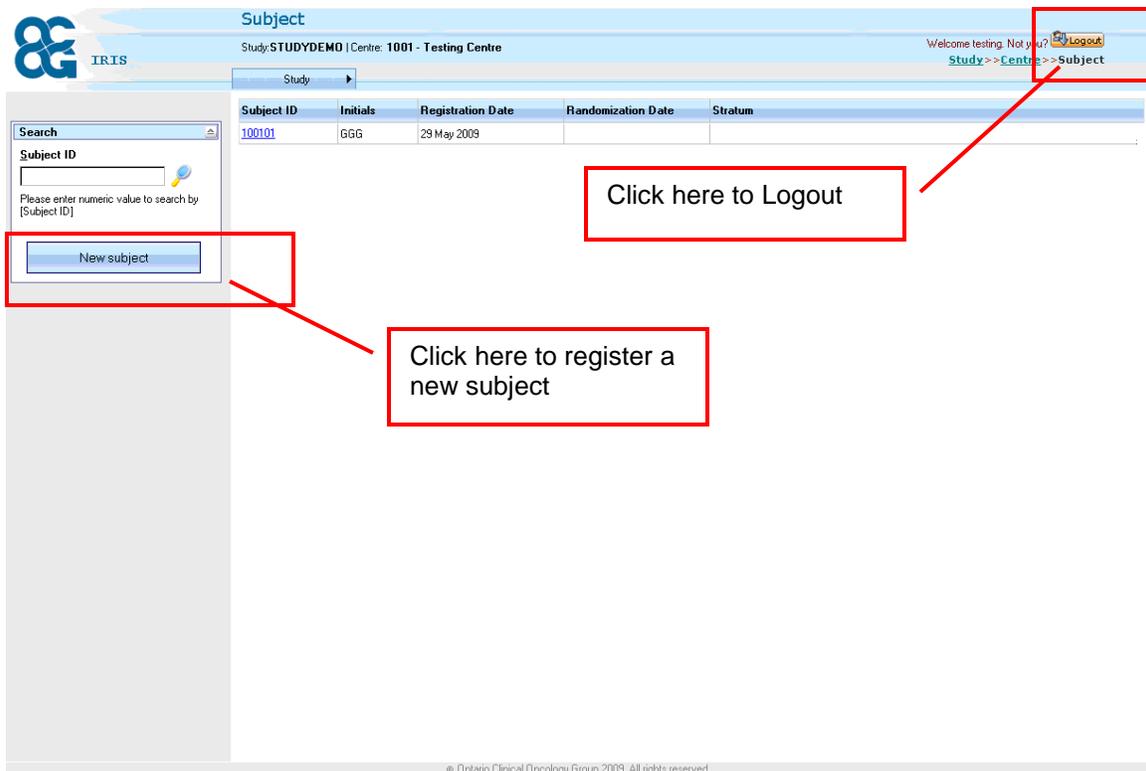


Figure 10, Subject screen II

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).

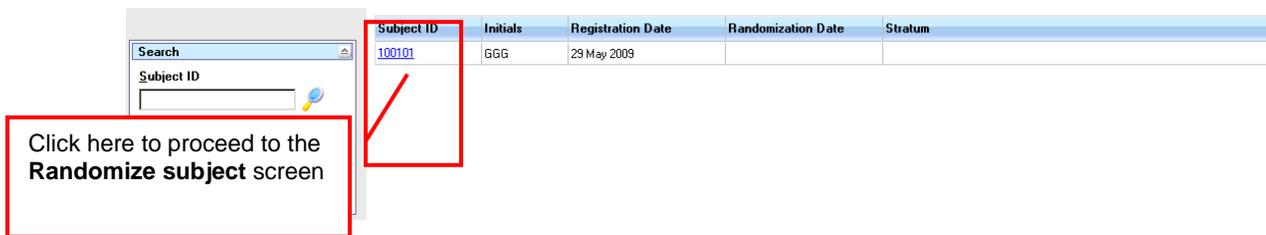


Figure 11, Subject screen with pre-registration

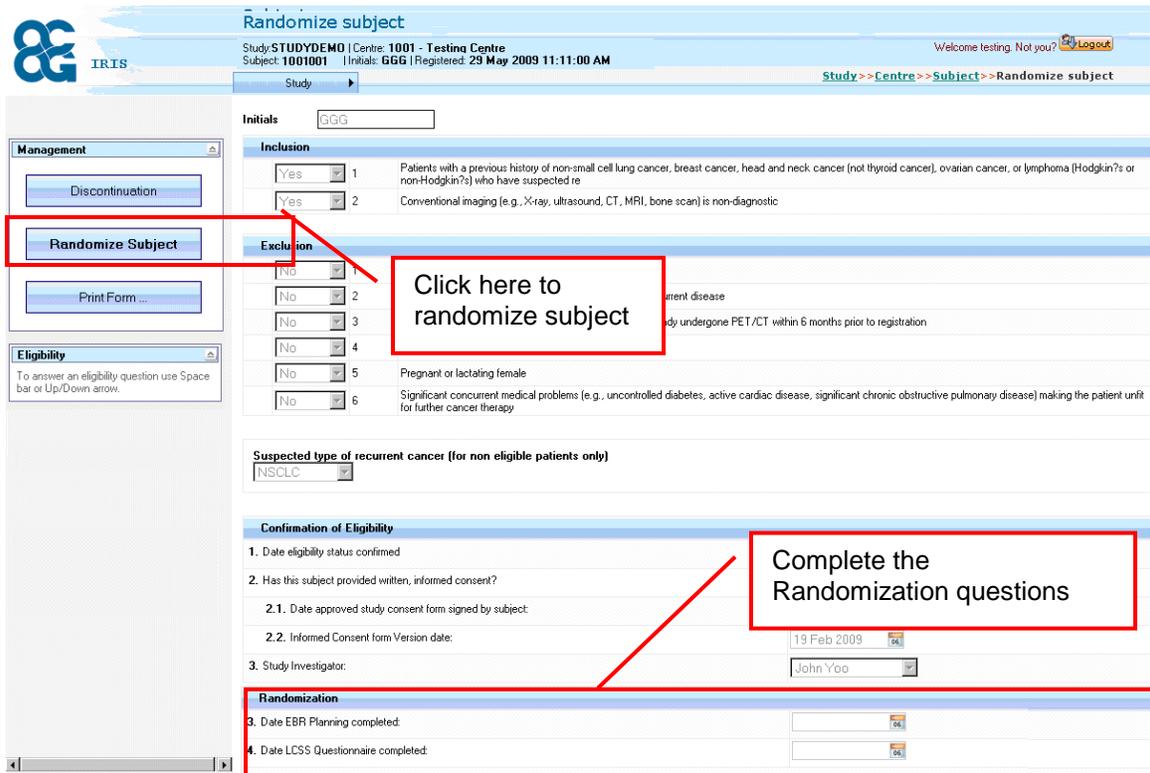


Figure 12, Randomize Subject screen

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

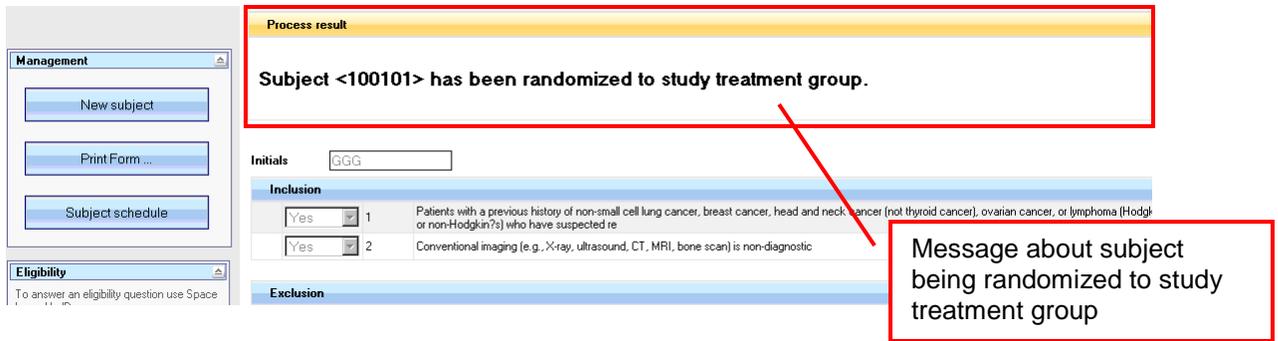


Figure 13, Randomized message

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

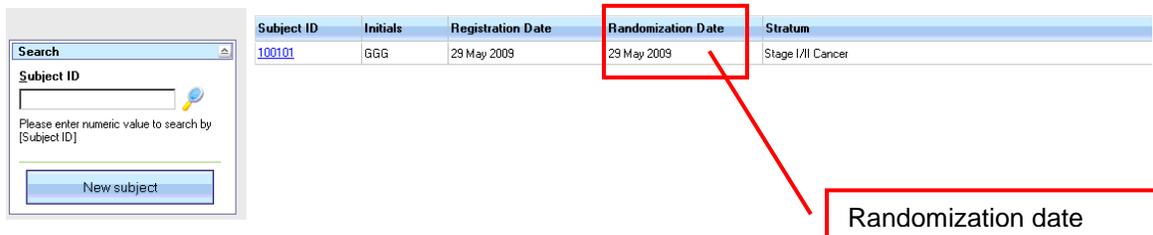


Figure 14, Randomization date on Subject screen

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).

Randomize subject

Study: STUDYDEMO | Centre: 1001 - Testing Centre
 Subject: 1001001 | Initials: GGG | Registered: 29 May 2009 11:11:00 AM

Welcome testing. Not you? [Logout](#)

Study >> Centre >> Subject >> Randomize subject

Initials: GGG

Inclusion

<input type="checkbox"/>	Yes	1	Patients with a previous history of non-small cell lung cancer, breast cancer, head and neck cancer (not thyroid cancer), ovarian cancer, or lymphoma (Hodgkin's or non-Hodgkin's) who have suspected re
<input type="checkbox"/>	Yes	2	Conventional imaging (e.g., X-ray, ultrasound, CT, MRI, bone scan) is non-diagnostic

Exclusion

<input type="checkbox"/>	No	1	Age less than 18 years
<input type="checkbox"/>	No	2	Patient with established recurrence requiring staging of recurrent disease
<input type="checkbox"/>	No	3	Patients who, at the time of the initial evaluation, have already undergone PET/CT within 6 months prior to registration
<input type="checkbox"/>	No	4	Unable to lie supine for imaging with PET/CT
<input type="checkbox"/>	No	5	Pregnant or lactating female (e.g., uncontrolled diabetes, active cardiac disease, significant chronic obstructive pulmonary disease) making the patient unfit

Confirmation of Eligibility

1. Date eligibility status confirmed:	05 May 2009
2. Has this subject provided written, informed consent?:	Yes
2.1. Date approved study consent form signed by subject:	05 May 2009
2.2. Informed Consent form Version date:	19 Feb 2009
3. Study Investigator:	John Yoo

Randomization

3. Date EBR Planning completed:	
4. Date LCSS Questionnaire completed:	

Management

- Discontinuation
- Randomize Subject
- Print Form ...

Eligibility

To answer an eligibility question use Space bar or Up/Down arrow.

Click here to discontinue a subject

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)

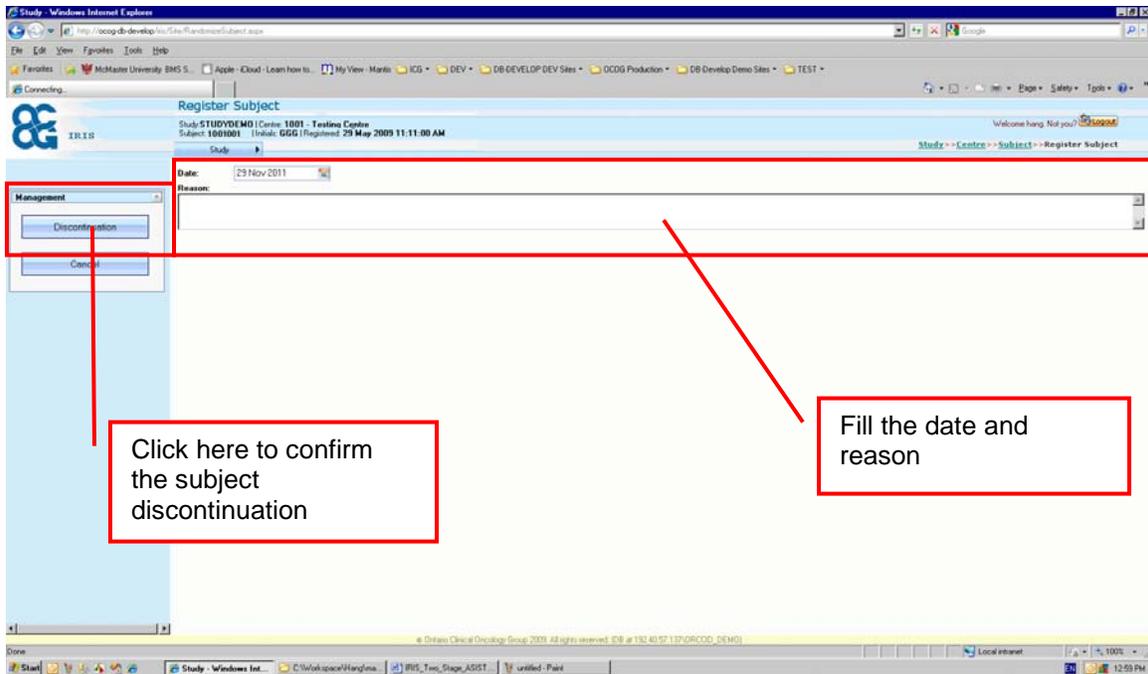


Figure 16, Confirm discontinuation

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).

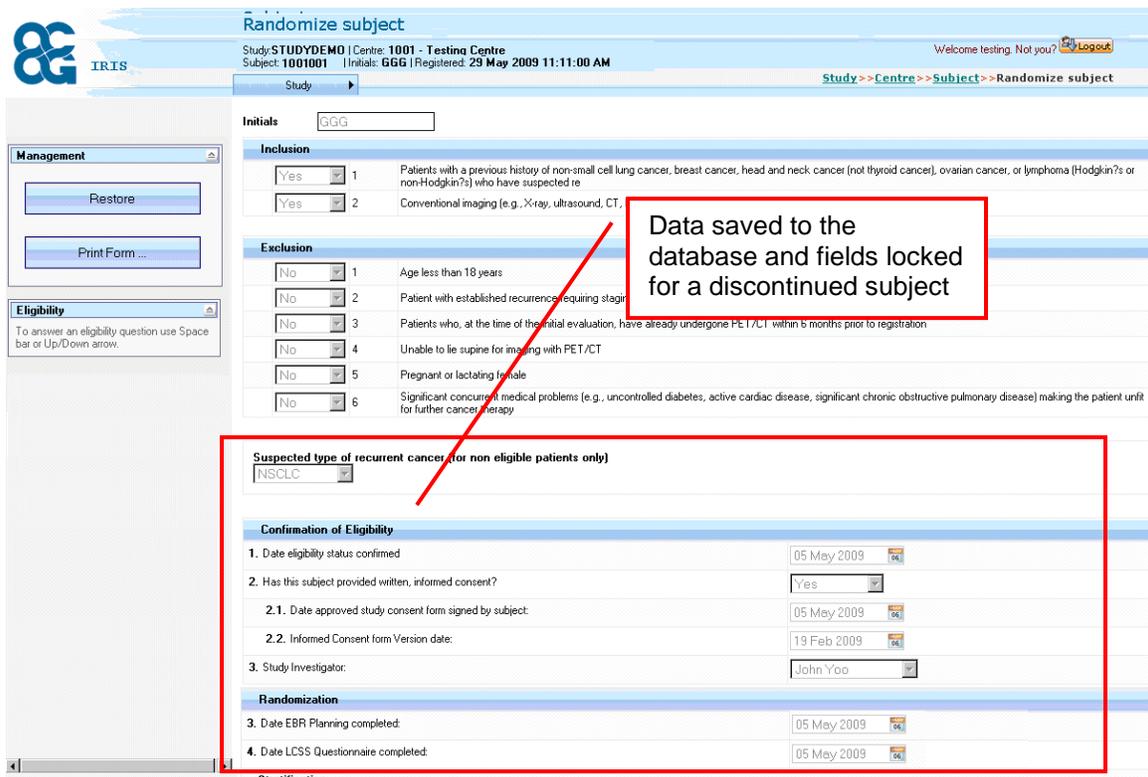


Figure 17, Randomization screen after discontinued

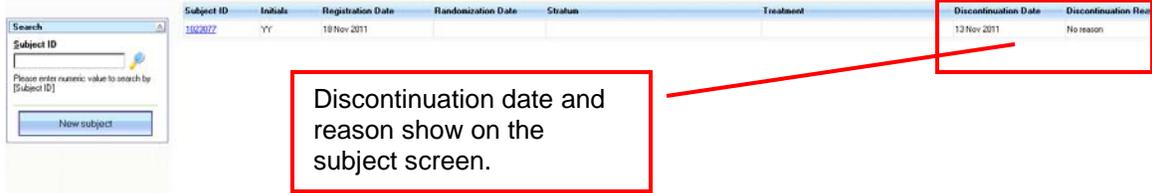


Figure 18, Discontinuation Date and Reason show on the subject screen

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).

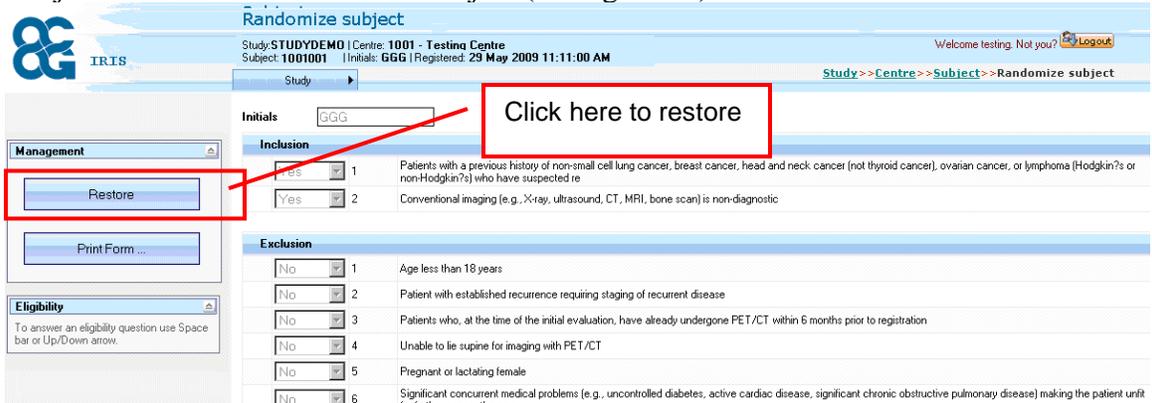


Figure 19, Restore subject