

NHG ROAM

Research Online Administration & Management

General Guidebook for Researchers

Version 1

Table of Contents

1	ACCESSING THE PI USER ACCOUNT	4
1.1	User Interface Functions	4
1.2	User Profile	10
1.2.1	Account Information	10
1.2.2	Personal Information	11
1.2.3	Contact Information	13
1.2.4	Research Profile	14
1.2.5	Publications	15
1.3	Notifications	17
2	SUBMITTING NEW STUDIES	20
2.1	Ethics Submission	20
2.2	Display Form	21
2.2.1	For Section B Question B2,	22
2.2.2	Section C	25
2.2.3	For Section D Question D1;	25
2.2.4	For Section E Question E2;	27
2.2.5	For Section F Question F18;	28
2.2.6	For Section H Question H1;	29
2.2.7	For Section I Question I2;	32
2.2.8	For Section K Question K4;	32
2.2.9	For Section Q;	34
2.2.10	For Section R Question R1;	36
2.2.11	Section S Question S1;	38
2.2.12	For Section U;	40
2.2.13	Section V;	41

2.3	Finding and Editing Drafts	42
3	ACTIONS AFTER SUBMISSION	44
3.1	After Submission	44
3.2	The Submission Status Diagram:	44
3.3	The Details Panel:	44
3.4	Study Details Panel	45
3.5	Attachments Panel	48
3.6	Endorsements Panel	49
3.7	History Panel	50
3.8	DSRB Attachments Panel	52
4	AMENDMENTS	53
4.1	Amendment Panels	53
4.1.1	Study Summary	53
4.1.2	Document Library	55
4.1.3	Amendments	56
4.2	Creating a New Amendment	58
	Creating a Study Status Report	64
4.3	Creating a Non-Compliance Report (NCR)	68
4.4	Creating an UPIRTSO Report	70
4.5	Creating Other Study Notifications	72
5	EVENTS	74

1 ACCESSING THE PI USER ACCOUNT

- User Interface Functions
- Submitting New Studies
 - Ethics Submission
 - Events
 - Meetings
 - Standing Database Submission

1.1 User Interface Functions

1. The login page that user should come to after clicking “Login” at the homepage at www.research.nhg.com.sg

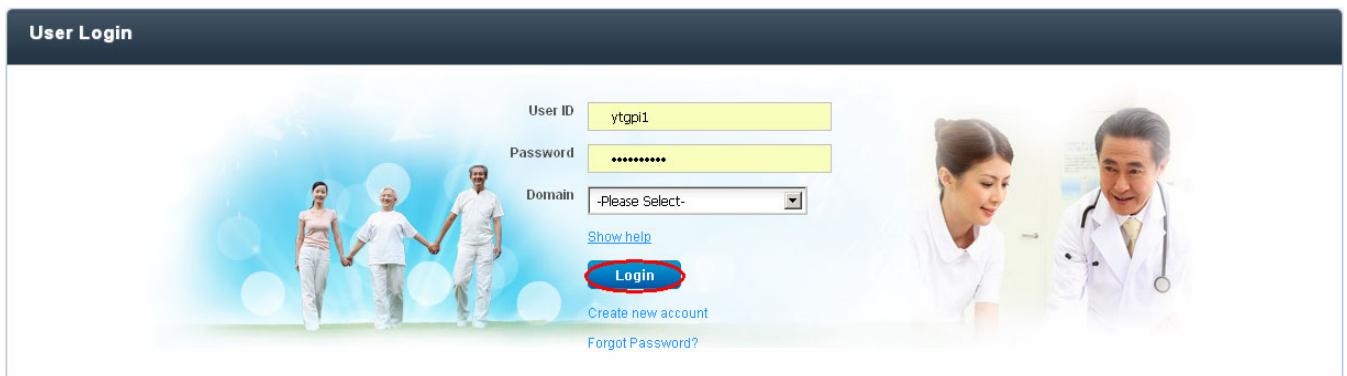


Figure 1 - Login Page

2. Enter the PI name and password.
3. Click on the “Login” button.
4. Once the SOP authentication is successful, the user will be redirected to the User Homepage as shown on Figure 2.
5. Click on the ‘Workspace’ at the side column and user would see the following; Home; Profile; Tasks; Logout.
 - 5.1 Home – View homepage
 - 5.2 Profile – Editing and changing of user profile.
 - 5.3 Tasks – List of tasks user have yet to done.
 - 5.4 Logout – Logging out of user account.

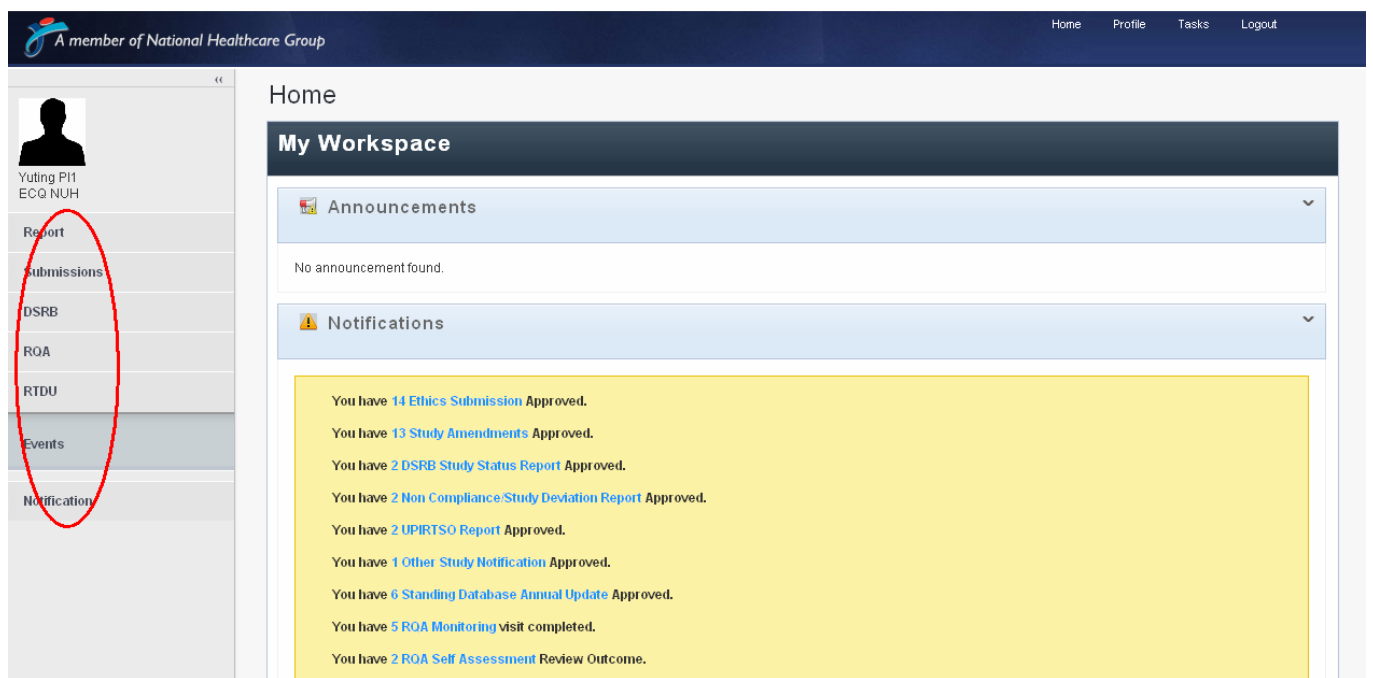



Figure 2 - User Homepage

5.2 Editing and changing of user profile.

1. User could update their profile by clicking on the 'Profile' button
2. Edit the User Account Info.

Update User Profile

Account Info **Personal Info** Contact Info Research Profile Publications

User Picture: 

Salutation: * Mr Ms Mrs Mdm Dr Prof A/Prof

Surname: *

Given Name: *

NRIC/FIN: *

Profession

What is your Profession? *

What is your professional specialty?

3. Edit the Personal Info.

Update User Profile

Account Info Personal Info **Contact Info** Research Profile Publications

Account Email Address: * @

Correspondence Email: *
 Please enter preferred email address that you would like to use for correspondence.
 Would you like your Correspondence Email address to be publicly shared on our website?
 Yes No

Telephone (Work): *
 Would you like your Telephone number (Work) to be publicly shared on our website?
 Yes No

Mobile No.:

Fax:

Mailing Address

Block / House No:

Street Name:

Postal Code:

4. Edit the Contact Info.

Update User Profile

Account Info | Personal Info | Contact Info | **Research Profile** | Publications

We strongly encourage Investigators to complete these sections so that their public profile will appear to be more complete.

Specify the areas of research interest

Area of Research Interest

Specify your research, technical, IT, Statistical skills relating to research

Research Skills

Add your academic/corporate research projects and awards

5. Edit the Research Profile.

Update User Profile

Account Info | Personal Info | Contact Info | Research Profile | **Publications**

Journal articles

Yes No

Have you published any Journal articles? *

Citation	Journal Title	Publication Year	Journal Impact Factor
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

[Show help](#)

Conference proceedings/articles

Yes No

Do you have any research conferences you attended or will attend? *

Citation	Conference Name	Conference Year
<input type="text"/>	<input type="text"/>	<input type="text"/>

[Show help](#)

Book articles or chapters

Yes No

Do you have any published Book

Citation	Book Name	Publication Year
<input type="text"/>	<input type="text"/>	<input type="text"/>

6. Edit the Publications.



7. Click on the 'Save' button to complete the updating of profile.

5.3 Tasks – List of tasks user have yet to done.

1. User will see the list of tasks they have yet done with, on the homepage upon logging into account. Or they can click on the 'Tasks' link in the top right corner.



6. Studies approved/completed or only requires PI to review, would be shown on the 'Notifications' column. Refer to Figure 2.

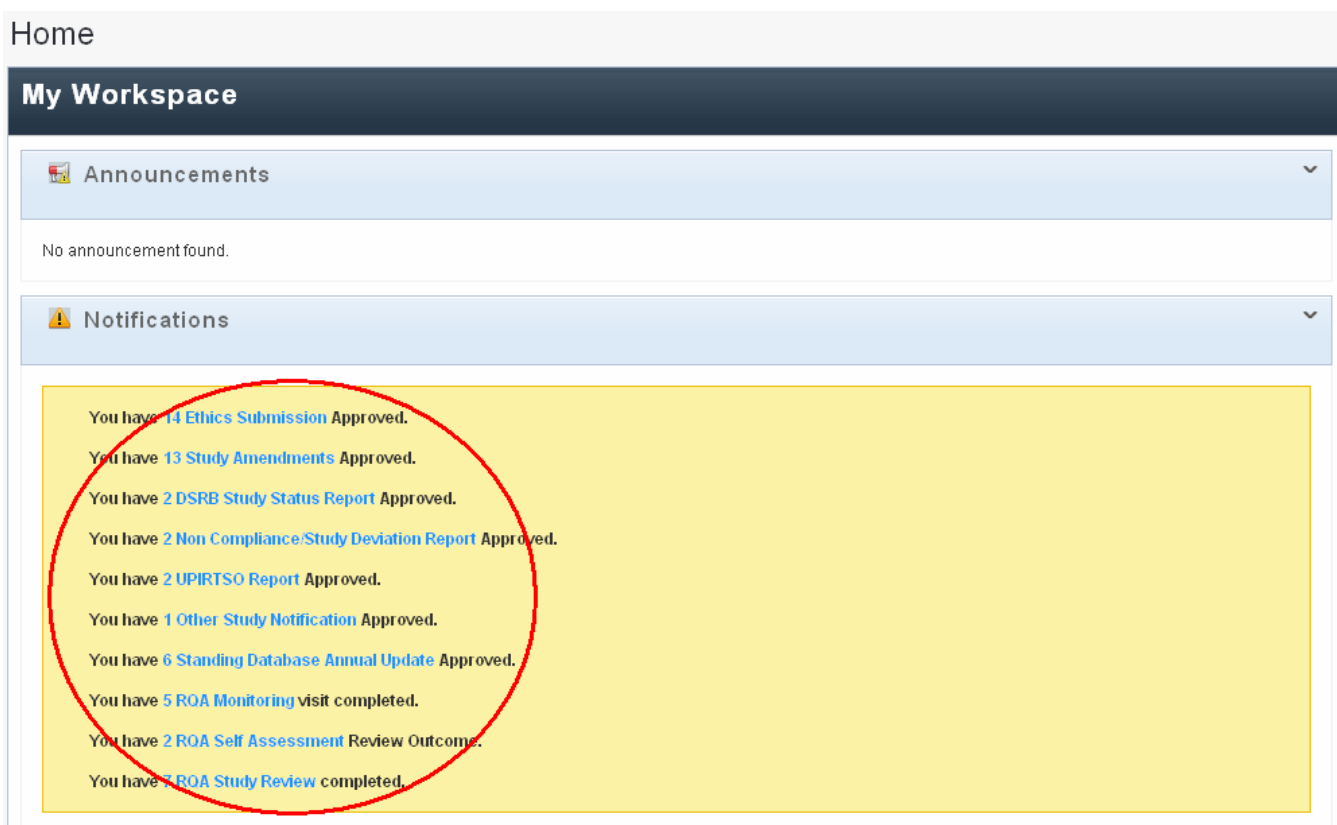


Figure 2 - PI User Homepage_Notification

7. Ongoing studies that requires any approval or steps for PI to access would be shown under the 'Tasks' column. Refer to Figure 3.

Tasks

PI

- You have [2 Submission](#) Pending DR Endorsement (DR Queried)
- You have [1 Submission](#) Pending Reviewer Assignment (DSRB Queried)
- You have [1 Submission](#) Pending DSRB Review Outcome (DSRB Queried)
- You have [1 Study Amendments](#) Pending IR Endorsement (IR Queried)
- You have [1 Study Amendments](#) Pending Reviewer Assignment (DSRB Queried)
- You have [1 UPIRTSO Report](#) Pending Reviewer Assignment (DSRB Queried)
- You have [2 Standing Database Application](#) Pending Reviewer Assignment (DSRB Queried)

Figure 3 - PI User Homepage_Tasks

1.2 User Profile

1. This groups of screens allow the PI to fill out the professional details of his or her account. However this does not replace the need to upload the CV.

1.2.1 Account Information

1. This section allows the PI to change his or her account related information like name to be displayed in ROAM, and login password, etc.

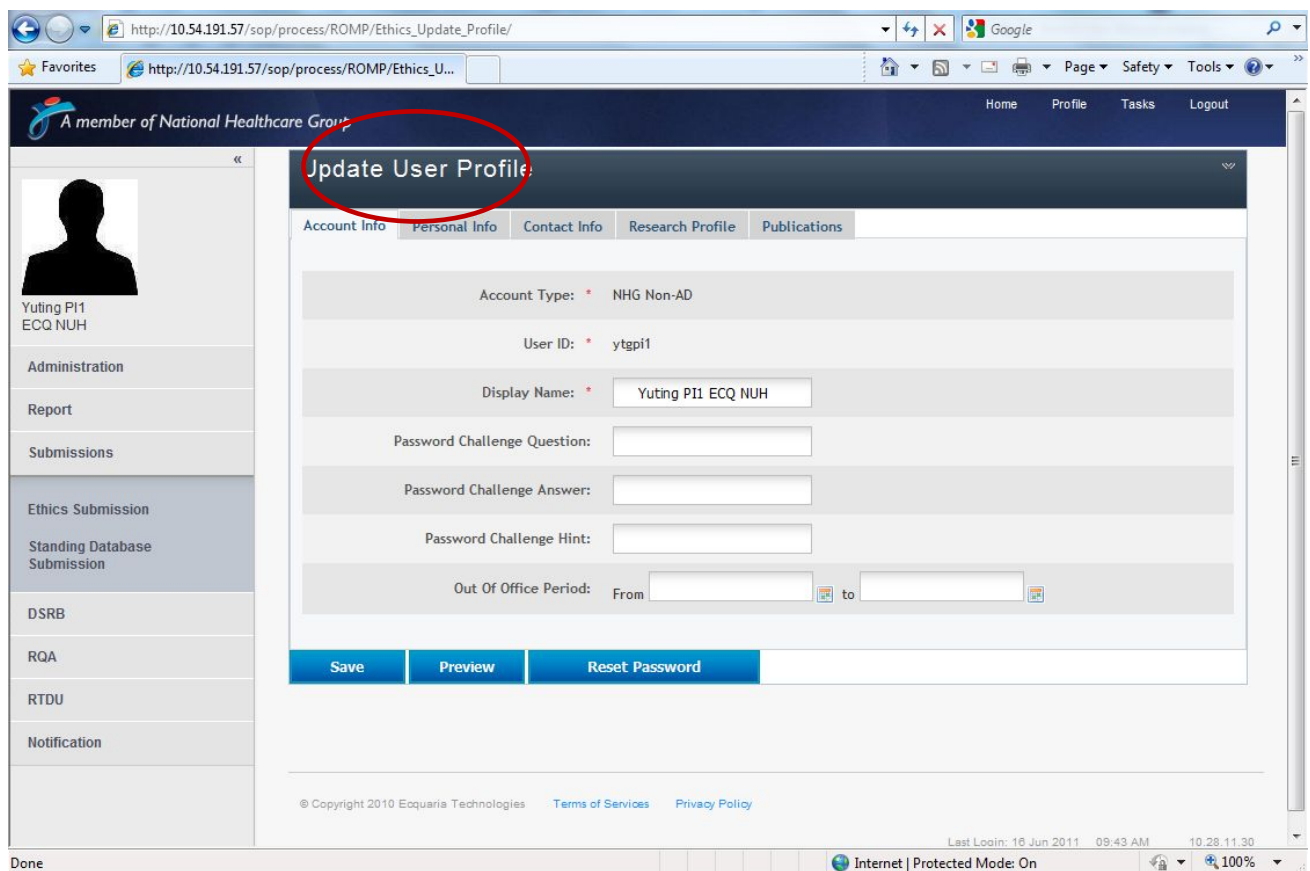


Figure 3 User Profile: Account Info

1.2.2 Personal Information

2. This section allows the PI to describe himself or herself with a summarised version of the CV.

The screenshot shows a web browser window displaying the 'Update User Profile' page. The browser's address bar shows the URL: http://10.54.191.57/sop/process/ROMP/Ethics_Update_Profile/. The page header includes the National Healthcare Group logo and navigation links: Home, Profile, Tasks, Logout. The main content area is titled 'Update User Profile' and has several tabs: Account Info, Personal Info (selected), Contact Info, Research Profile, and Publications. On the left, there is a sidebar menu with options: Administration, Report, Submissions, Ethics Submission, Standing Database Submission, DSRB, RQA, RTDU, and Notification. The 'Personal Info' tab is active, showing a 'User Picture' field with a silhouette and a 'Change' button. Below this are fields for 'Salutation' (radio buttons for Mr, Ms, Mrs, Mdm, Dr, Prof, A/Prof), 'Surname' (text input: ECQ NUH), 'Given Name' (text input: Yuting P11), and 'NRIC/FIN' (text input: S0002137G). The 'Profession' section has two dropdown menus: 'What is your Profession?' (selected: Dental Officer) and 'What is your professional specialty?' (selected: Cornea). At the bottom, there is a 'What is your Registration' field. The browser's status bar at the bottom indicates 'Internet | Protected Mode: On' and a zoom level of 100%.

Figure 4 User Profile : Personal Info I

specialty? _____

What is your Registration Number? * (For registered Doctors, Nurses and Allied only)

Primary Appointment

Organization/Cluster (Primary) *

Institution (Primary) *

Department (Primary) *

Appointment (Primary) *

Do you hold any other concurrent appointments? Yes No

Additional Appointment

Organization/Cluster (Additional)	Institution (Additional)	Department (Additional)	Appointment (Additional)
<input type="text" value="-Please Select-"/>	<input type="text" value="-Please Select-"/>	<input type="text" value="-Please Select-"/>	<input type="text" value="-Please Select-"/>

[NHG-ROMP-06-002 Search Events.doc](#) ✖

Resume: *

Internet | Protected Mode: On

Figure 5 User Profile : Personal Info II

[NHG-ROMP-06-002 Search Events.doc](#) ✖

Resume: *

[Show help](#)

Would you like your resume to be publicly shared on our website? Yes No

Minimum Training Requirement for Principal Investigators(PI) in NHG

Since 1 August 2004, all Principal Investigators who conduct research within NHG have to submit proof of research ethics training to the DSRB. The PI's Minimum Training requirement is to complete the CITI Modules. To update your training status, or to apply for a waiver of this requirement, please contact the DSRB, or visit our website for more information. You can upload proof of your minimum training status below for verification by the DSRB. Your Minimum training Status will be updated once it has been verified by the DSRB. Your current Minimum Training Status is:

Upload Minimum Training Status Proof:

Figure 6 User Profile : Personal Info III

1.2.3 Contact Information

3. This section allows the PI to list out official contact information for correspondence.

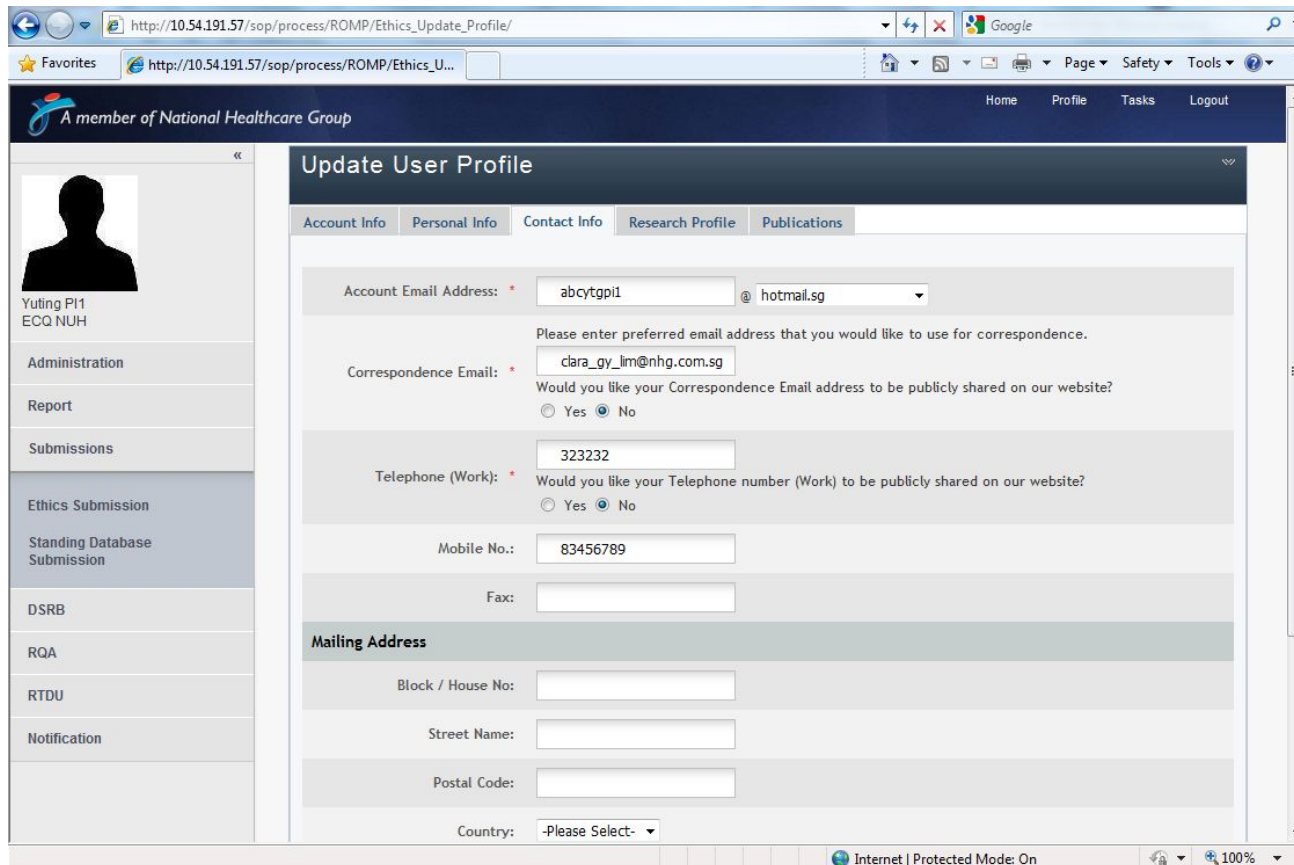


Figure 7 User Profile: Contact Info

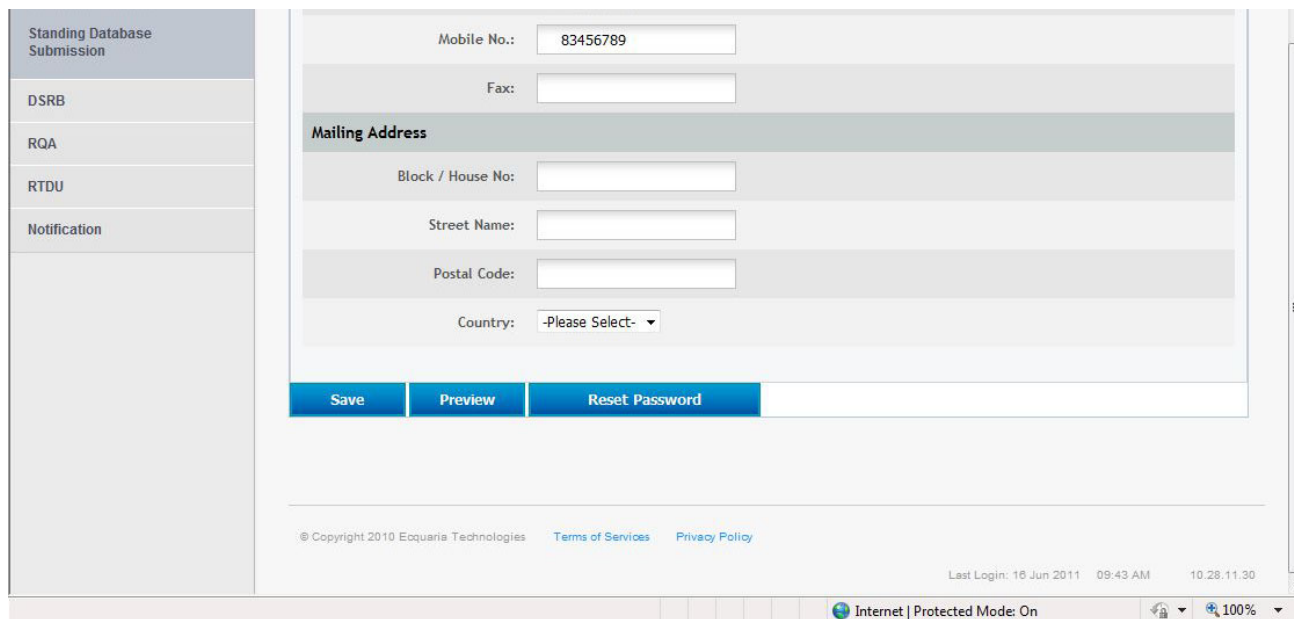


Figure 8 User Profile: Contact Info II

1.2.4 Research Profile

4. This section allows the PI to describe the list of specific areas and skills relevant to this field of research.

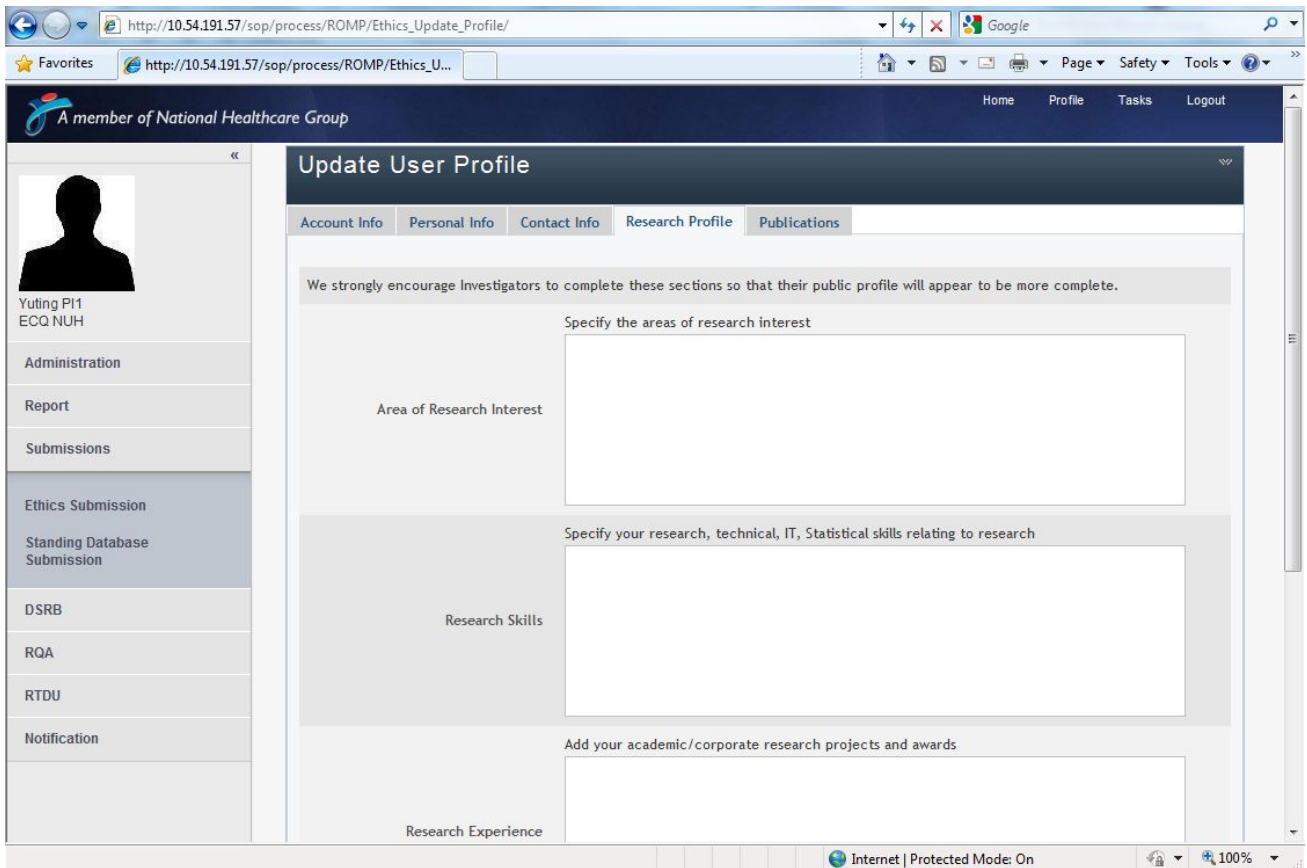


Figure 9 User Profile: Research Profile

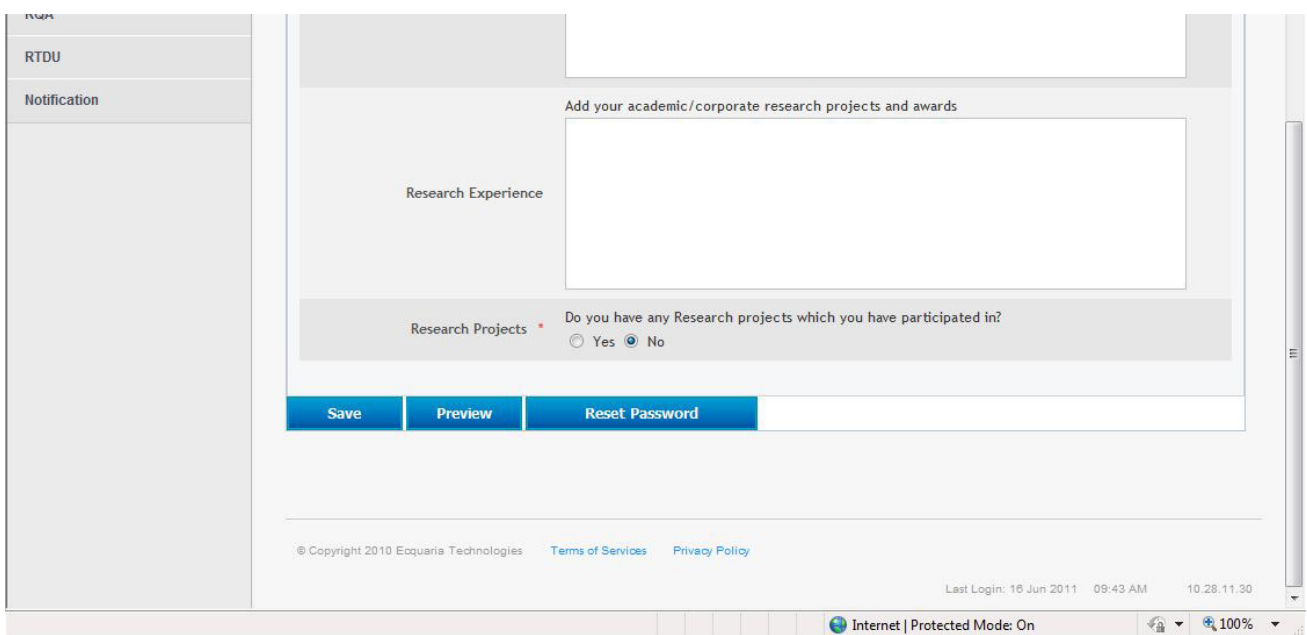


Figure 10 User Profile: Research Profile

1.2.5 Publications

5. This section allows the PI to describe the list of publications that he or she has made in the relevant field of research.

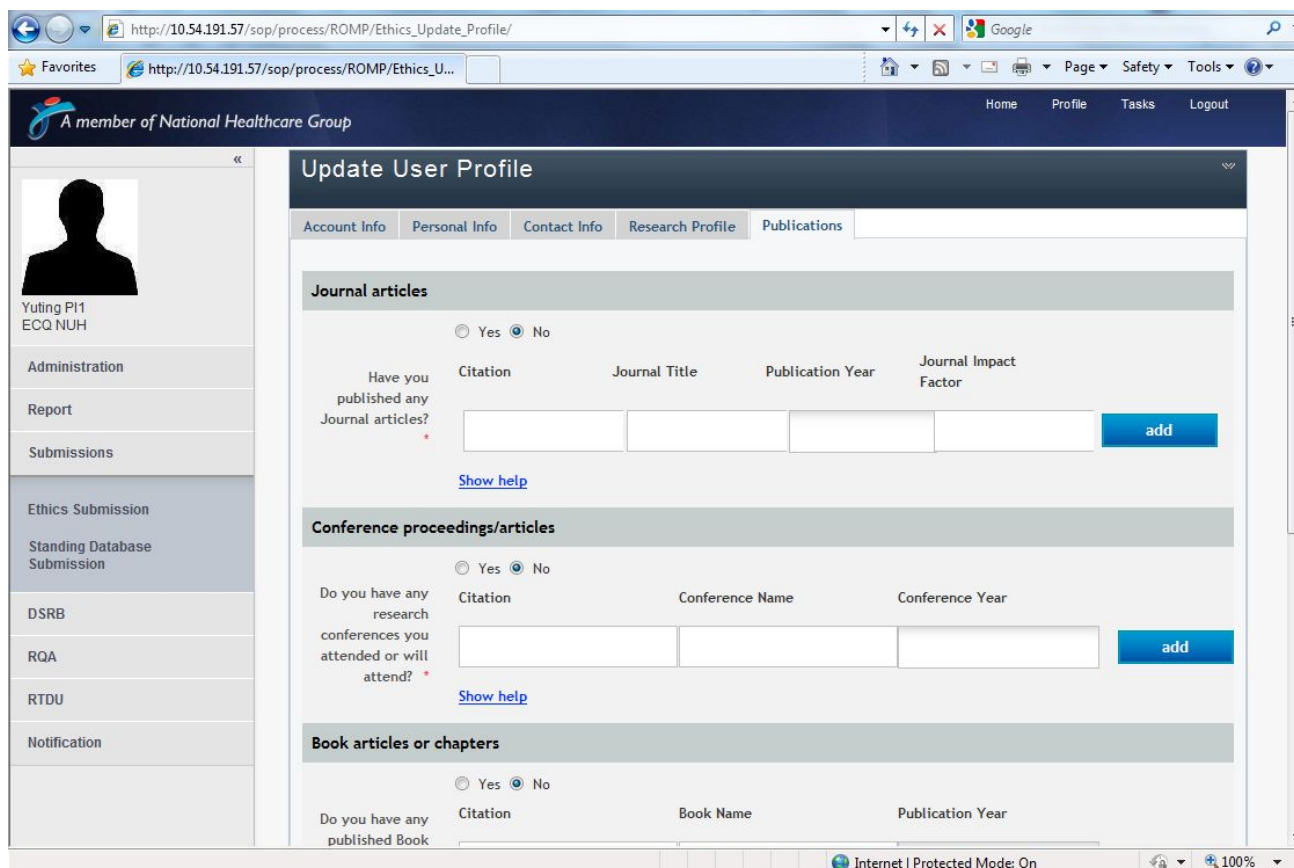


Figure 11 User Profile: Publications

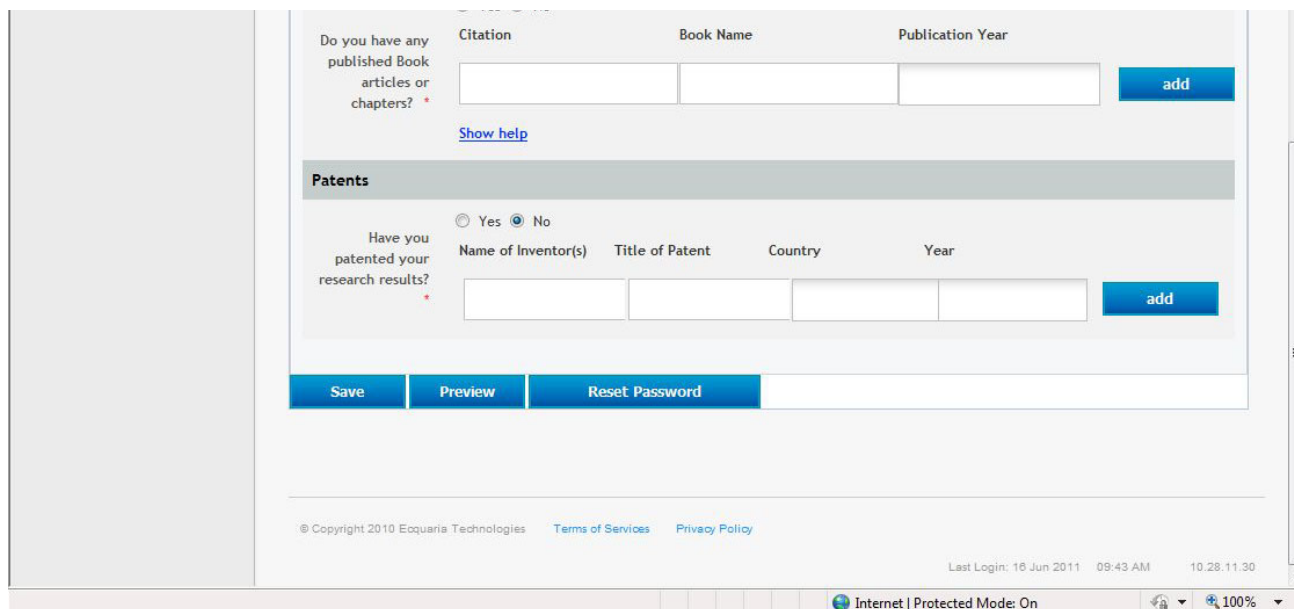


Figure 12 User Profile: Publications

1.3 Notifications

1. The Notifications screen is a complete list of notifications received, unlike the list on the Home screen which shows a most-recent set only.
2. It consists of a Search portion for filtering certain notifications, and the filtering options below.
3. Below the Search panel is the standard list of all the exiting notifications received.

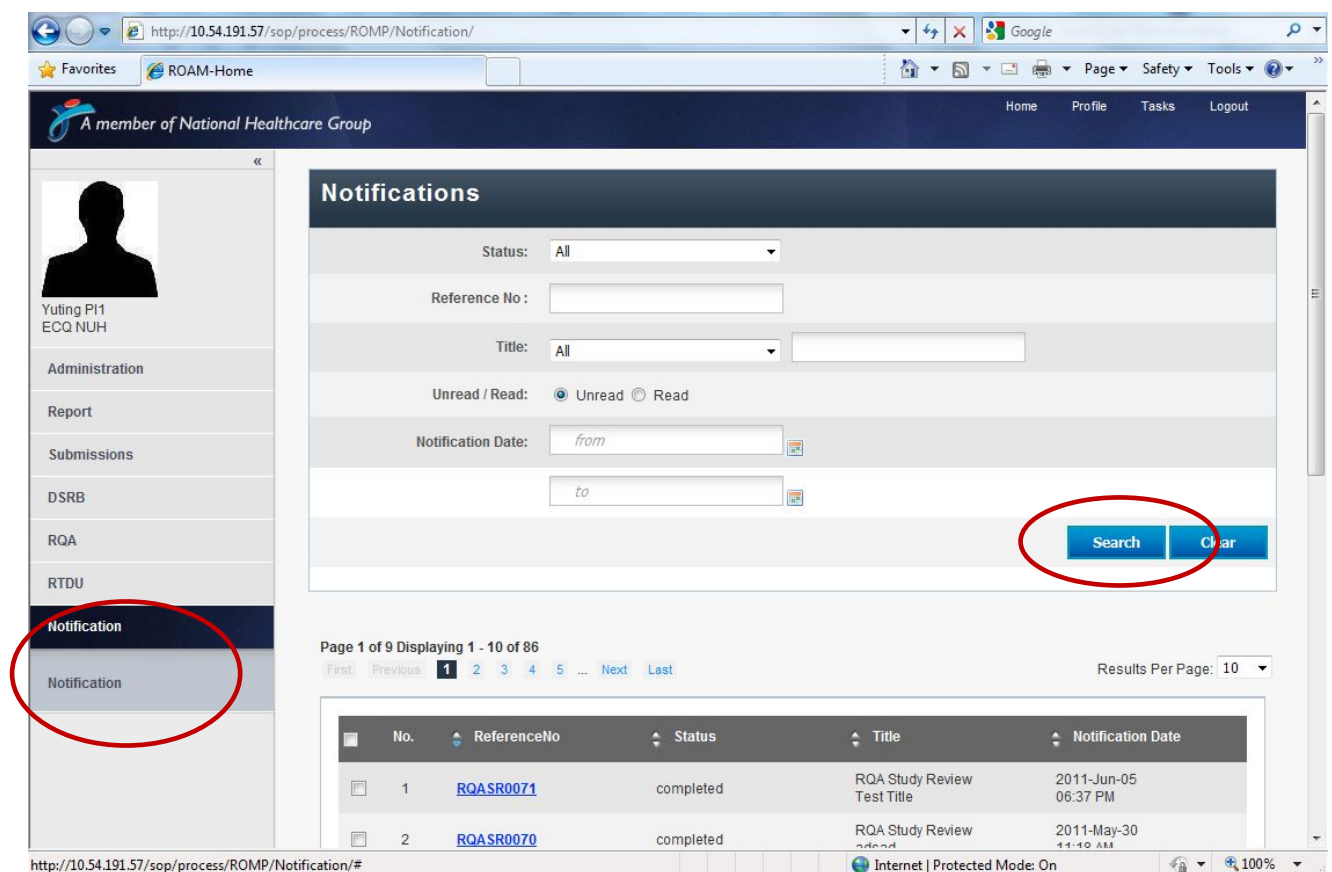


Figure 13 Notifications screen : Search

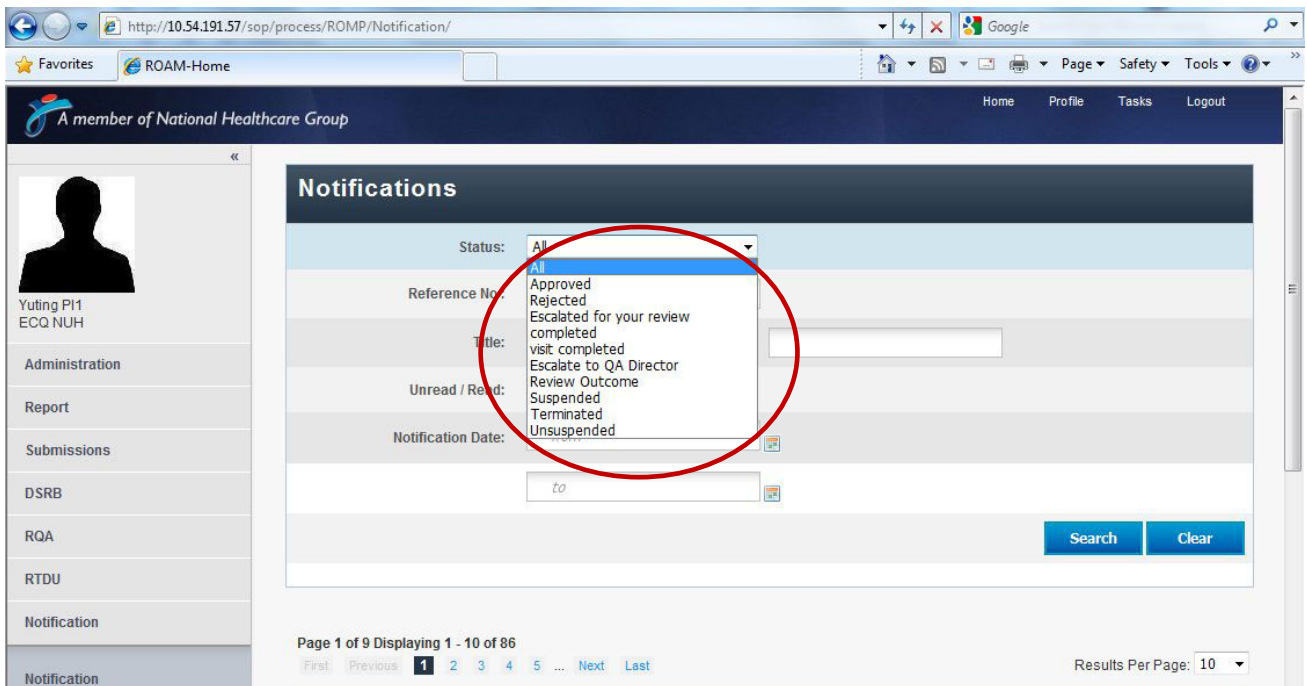


Figure 14 Notifications screen : Search II

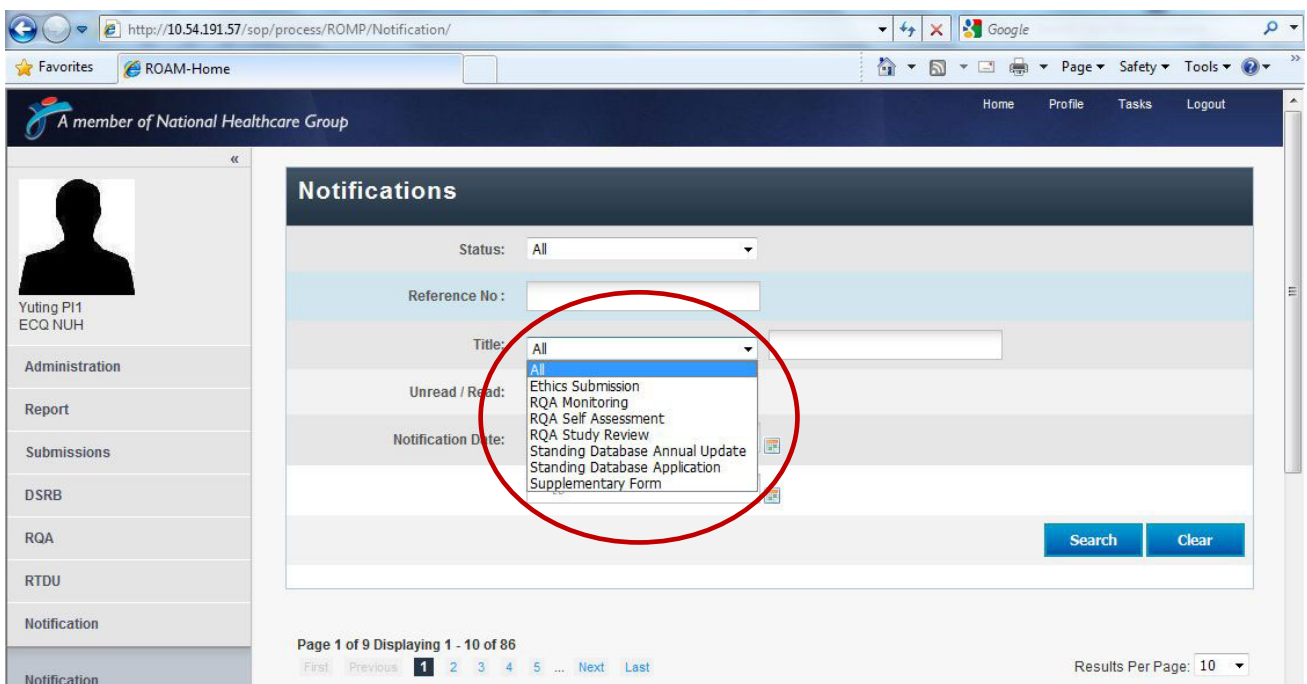


Figure 15 Notifications screen : Search III

RQA

RTDU

Notification

Notification

[Search](#) [Clear](#)

Page 1 of 9 Displaying 1 - 10 of 86

First Previous **1** 2 3 4 5 ... Next Last Results Per Page: 10

No.	ReferenceNo	Status	Title	Notification Date
1	RQASR0071	completed	RQA Study Review Test Title	2011-Jun-05 06:37 PM
2	RQASR0070	completed	RQA Study Review adsad	2011-May-30 11:18 AM
3	RQASR0068	completed	RQA Study Review test05-24	2011-May-25 03:05 PM
4	RQASR0066	completed	RQA Study Review 4th May smoke test	2011-May-19 11:39 AM
5	RQASR0063	completed	RQA Study Review Smoke test 7 Mar 2011	2011-May-06 03:11 PM
6	RQASR0062	completed	RQA Study Review abbbbbbbbbbbCCCCC	2011-Apr-21 12:17 PM
7	RQASR0061	completed	RQA Study Review GGGG	2011-Apr-12 03:53 PM
8	RQASR0056	completed	RQA Study Review Smoke test 7 Mar 2011	2011-Mar-07 01:21 PM
9	RQASA0016	Review Outcome	RQA Self Assessment UAT Scenario Yuting Testing	2011-May-19 02:52 PM
10	RQAM0035	visit completed	RQA Monitoring Test Title	2011-Jun-05 06:51 PM

[Mark as read](#) [Mark as unread](#)

Page 1 of 9 Displaying 1 - 10 of 86

First Previous **1** 2 3 4 5 ... Next Last Results Per Page: 10

© Copyright 2010 Equaria Technologies [Terms of Services](#) [Privacy Policy](#)

Last Login: 16 Jun 2011 09:51 AM 10.28.11.30

http://10.54.191.57/sop/process/ROMP/Notification/# Internet | Protected Mode: On 100%

Figure 16 Notifications screen : Listing

2 SUBMITTING NEW STUDIES

2.1 Ethics Submission

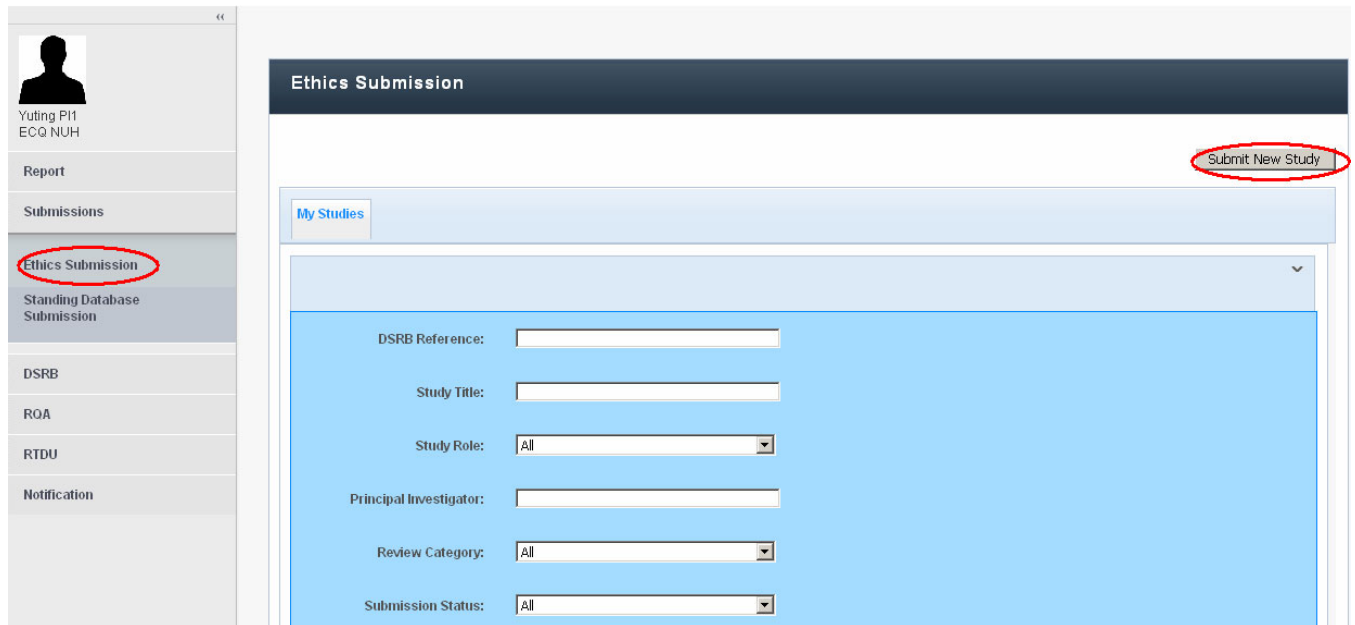


Figure 17

1. Click 'Ethics Submission' under Submission in left menu
2. Click 'Submit New Study' button
3. System redirects to 'Select Study Form' as shown in Figure 6



Figure 18

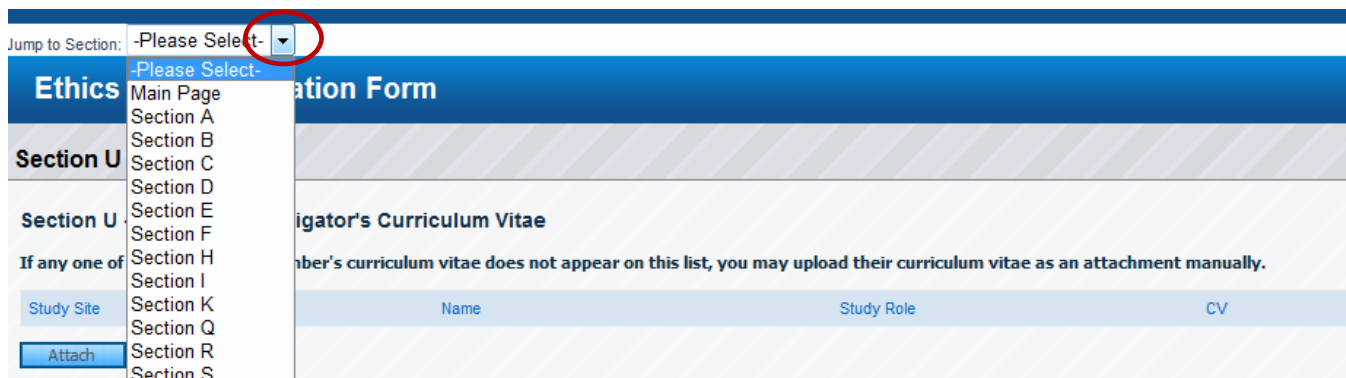
4. Tick "Biomedical Study (Domain A-E) radio button.
5. Click "Create" button
6. A "Display Form" pops up

2.2 Display Form

Steps/Procedures



1. User can click 'Save Draft' button to save their current data any time to store changes;
2. User is allowed to re-open submission form with the data latest saved.



3. Click on the arrow beside Jump to Section;
4. A list of sections available will be shown;
5. User can click on the Section where they edited recently.

Jump to Section:

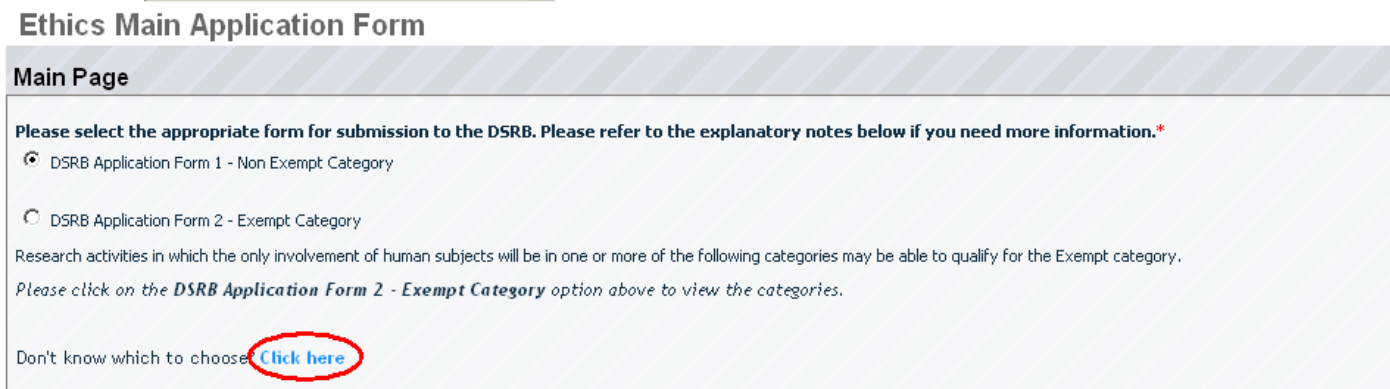


Figure 19 – Display Form’s Main Page

6. If User is not sure of which selection to choose; click 'Click here' button for seeking helps.

Don't know which to choose? [Click here to hide](#)

- DSRB Application Form 1 - Non Exempt Category
Principal Investigators should use Application Form 1 if their research activity does not qualify under the Exempt Category. Application Form 1 should be used for submissions for the Full Board Review and Expedited Review.
- DSRB Application Form 2 - Exempt Category
Research activities in which the only involvement of human subjects will be in one or more of the following categories may be able to qualify for the Exempt category.

IMPORTANT: The criteria for the Exempt category do not apply when the research activity:-

- (i) involves prisoners
- (ii) involves children, when the research involves survey or interview procedures or observations of public behavior, except when the investigator(s) do not participate in the activities being observed
- (iii) is a US FDA-regulated research activity.

Figure 20

B2 External Study Site (for Institutions NOT under the oversight of NHG DSRB)

(i) Are there any other independent study sites by another PI which are conducting the same study?*

Yes

SingHealth

Other Local Sites

Overseas Sites

No

Figure 21 – Section B Question B2

2.2.1 For Section B Question B2,

1. If user selects 'Yes' button, then a list of sites would be shown.
2. If 'SingHealth' is selected; a list of SingHealth hospitals would be shown as well.

B2 External Study Site (for Institutions NOT under the oversight of NHG DSRB)

(i) Are there any other independent study sites by another PI which are conducting the same study?*

Yes

SingHealth

Changi General Hospital

KK Woman's and Children's Hospital

National Cancer Centre Singapore

National Dental Centre Singapore

National Heart Centre

National Neuroscience Institute

Singapore General Hospital

Singapore National Eye Centre

SingHealth Polyclinics

Other Local Sites

Overseas Sites

No

3. If 'Other Local Sites' is selected; user is required to add in the local site.

Other Local Sites

No.	Other Local Study Site
1	<input type="text"/>

4. If 'Overseas Sites' is selected; it requires user to specify the number of sites.

Overseas Sites

Please specify number of overseas sites:

B4

i. Which Domain Specific Review Board (DSRB) is this application being submitted to?*

Doreen Domain A

-Please Select-

D

Danny Domain A

Domain F

Doreen Domain A

DSRB Domain A

DSRB Domain B

DSRB Domain C

DSRB Domain D

DSRB Domain E

ECQ Domain A

submitted to another IRB?*

previously rejected by any IRB? (Including NHG-DSRB)*

Yes

Figure 22 - Section B Question B4 Part I

5. For Section B Question B4 Part I, it requires user to select a correct domain.
6. Click dropdown list and a list of names will be shown.
7. Select the DSRB Staff for the application to be submitted to.
 - o If a wrong DSRB staff is selected, the DSRB staff of the application would not be able to view or receive tasks to view the application.

B4

i. Which Domain Specific Review Board (DSRB) is this application being submitted to?*

Doreen Domain A

ii. Has the study been submitted to another IRB?*

No

Yes

a. The study has been submitted to which IRB?

SingHealth

Other

Figure 23 - Section B Question B4 Part II

8. For Section B Question B4 Part II;
9. If 'Yes' is selected, a question will appear; user is required to select the correct IRB.

a. The study has been submitted to which IRB?

SingHealth

Please specify:

-Please Select-

CIRB A

CIRB B

CIRB C

CIRB D

CIRB E

iii. Has the application been previously rejected by any IRB? (Including NHG-DSRB)

Figure 24 - Section B Question B4 Part II Question a

- 10. Section B Question B4 Part II Question a;
- 11. If 'SingHealth' is selected; user will be required to select which CIRB.

iii. Has the application been previously rejected by any IRB? (Including NHG-DSRB)*

No

Yes

iv. Please state which IRB rejected the study and provide reasons for the rejection.

Figure 25 - Section B Question B4 Part III

- 12. Section B Question B4 Part III
- 13. If 'Yes' is selected; user will be required to state and provide reasons for rejection.

2.2.2 Section C

Section C - Conflict of Interest Declaration

The Conflict of Interest Declaration section must be completed by the PI on behalf of the Study Team if any member of the Study Team has any potential conflicting interest while conducting the research. Any such member(s) must complete and submit their Declarations when this application is submitted.

Conflicting Interest - A conflicting interest can be broadly defined to refer to any interest of the investigator that competes with the investigator's obligation to protect the rights and welfare of research subjects.

Financial Interest - Significant Financial Interest means anything of monetary value, including but not limited to, salary or payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g. patents, copyrights and royalties from such rights), and board or executive relationships.

The Conflict of Interest Declaration Section must be submitted to the DSRB via protocol amendments if any of the circumstances relevant described herein change during the conduct of the research.

C1 Does the Principal Investigator or any study team members have any potential conflict of interest? *

Mr Yuting P11 ECQ NUH (Principal Investigator):*

No

Yes

i. Please tick all the applicable boxes.*

- Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any organisation that may benefit from the research activity.
- Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any organisation that may benefit from the research activity.
- Employment or executive relationships with any organisation that may benefit from the research activity.
- Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.
- Options or other compensation arrangements that could be affected by the outcome of the research.
- The sponsor company supporting this study offers incentives connected with subject recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff.
- Others, to specify (financial/non-financial conflict).

ii. Please provide details of all of the above Conflict of Interest.*

iii. Please describe the plan to manage all of the above Conflict of Interest.*

Figure 26 - Section C Question C1

1. If 'Yes' is selected, a list of questions would pop up .
2. User is required to make selection and answer the following questions.

D1 Please select one category that best describes your research activities.*

- Clinical Trials (which includes Drug, Device and Surgical-Procedure Trials)
- Questionnaire/ Survey/ Interviews
- Medical Records Review
- Clinical Research

WARNING: Clinical Trial Certificate from Health Sciences Authority might be required if you are testing the safety and efficacy of the medicinal product. You should check with HSA if you are unsure.

D2 Is this a US FDA IND/IDE study or data is intended to be reported to FDA in support of a IND/IDE application?*

- Yes
- No

Figure 27 - Section D Question D1

2.2.3 For Section D Question D1;

1. If selection is 'Clinical Trials'; a list of study would be listed for user to choose.

D1 Please select one category that best describes your research activities.*

- Clinical Trials (which includes Drug, Device and Surgical-Procedure Trials)
- Questionnaire/ Survey/ Interviews
- Medical Records Review
- Clinical Research

What does the study involve?

- Drug/Biologic
- Device
- Surgical Procedure

Figure 28

2. If selection is 'Drug/Biologic'; a list of phases would be listed for user to choose.

D2 Is this a US FDA IND/IDE study or data is intended to be reported to FDA in support of a IND/IDE application?*

- Yes
- No

Please select the study type and give the number.

- IND
- IDE

Study number:

No

Figure 29 - Section D Question D2

3. If selection is 'Yes';
4. User is required to select the study type and enter the study number.

D3 Is this study subjected to any of the following regulations:

- No
- Yes

- US Code of Federal Regulations 45 CFR 46
- US Code of Federal Regulations 21 CFR 50
- US Code of Federal Regulations 21 CFR 56
- US Code of Federal Regulations 21 CFR 312
- US Code of Federal Regulations 21 CFR 812
- Others

Figure 30 - Section D Question D3

5. If selection is 'Yes'; a list of US Code of Federal Regulations for user to choose.

E2 Please give information regarding the study's Funding source or Sponsor information.*

No funding is required for this study to be carried out

Pharmaceutical / Industry Sponsored

i. Name of Sponsor Company*

-Please Select-

ii. Sponsor Company's Contact Person

Name *

Telephone *

Email Address *

Fax *

Address*

iii. Name of Clinical Research Organization (CRO) if applicable.

-Please Select-

iv. CRO's Contact Details

Name

Telephone

Email Address

Fax

Figure 31 - Section E Question E2

2.2.4 For Section E Question E2;

1. If selection is 'Pharmaceutical/Industry Sponsored'; user will be required to fill in the details.

E2 Please give information regarding the study's Funding source or Sponsor information.*

No funding is required for this study to be carried out

Pharmaceutical / Industry Sponsored

Grant

i. Name of Grant Agency and Grant Name*
-Please Select-

ii. Grant amount applied for *
S\$

iii. Date of Grant application deadline *
Calendar icon

iv. Has the Grant application been approved?*

Yes. Grant application successful.

No. Grant application is pending approval.

Figure 32 - Section E Question E2

2. For Section E Question E2;
3. If selection is 'Grant'; user will be required to fill in the details.

F18 Does this study have a Study Protocol?*

Yes

Please submit a copy of the Study Protocol. *

Attach

No

Figure 33 - Section F Question F18

2.2.5 For Section F Question F18;

1. If selection is 'Yes'; user will be required to attach a copy of Study Protocol.
2. Click on the 'Attach' button to submit a copy of the Study Protocol.

F19 The PI is responsible for ensuring that all Study Subjects give informed consent before enrolling into the study.

Please select all the applicable consent scenarios.*

- Informed Consent will be taken for all study subjects.
- Waiver of Informed Consent is requested for all study subjects.
- A combination of both Informed Consent and Waiver of Consent is required for different study populations.

Please elaborate:*

Figure 34 - Section F Question F19

3. For Section F Question F19;
4. If selection is 'A combination of both Informed Consent and Waiver of Consent is required for different study populations';
5. User will be required to elaborate more in the textbox provided.

Section H - Recruitment Details

H1 How will potential subjects be identified? (Please tick all the applicable boxes)*

- Referral by attending healthcare professional
- Patients of study team
- Databases

i. Which of the following databases will be used? (Please tick all the applicable boxes)*

- Laboratory Records
- Pharmacy Records
- Operating Theatre Records
- DRG Codes
- Standing databases/other department's databases
- Medical Records
- Other Data Sources

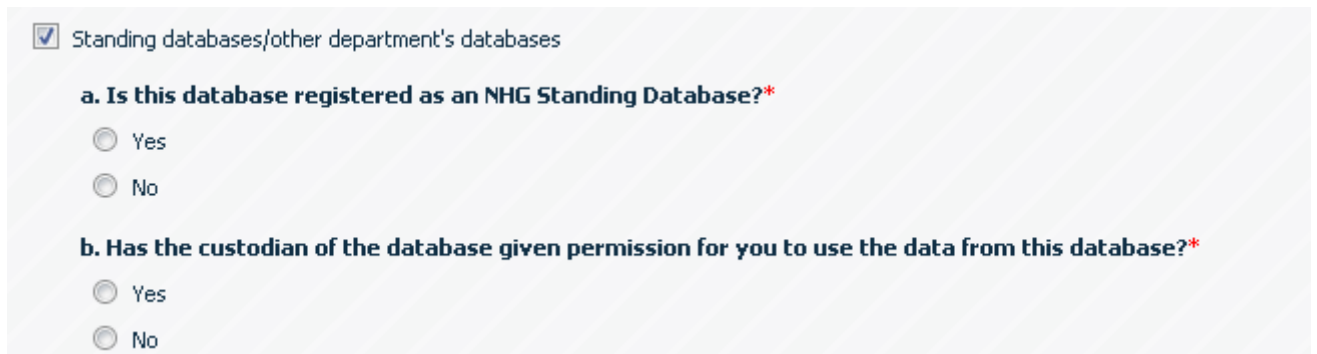
Other methods of subject identification

Figure 35 - Section H Question H1

2.2.6 For Section H Question H1;

6. If selection is 'Databases';

7. A list of checkboxes of the following databases that will be used will appear;
8. Click on the databases that will be used.



Standing databases/other department's databases

a. Is this database registered as an NHG Standing Database?*

Yes

No

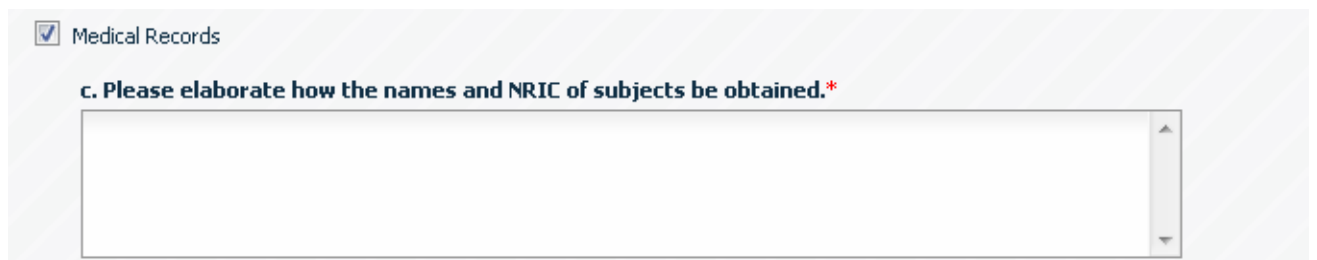
b. Has the custodian of the database given permission for you to use the data from this database?*

Yes

No

Figure 36 - Section H Question H1 Part I

9. For Section H Question H1 Part I;
10. If 'Standing databases/other department's databases' is checked;
11. User will need to answer the following questions; question A and B.

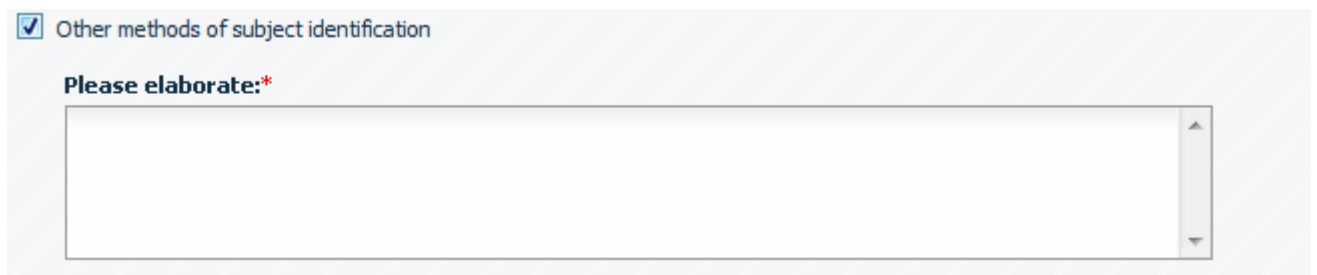


Medical Records

c. Please elaborate how the names and NRIC of subjects be obtained.*

Figure 37 - Section H Question H1 Part I

12. For Section H Question H1 Part I;
13. If 'Medical Records' is checked;
14. User will require elaborating more in the textbox provided.



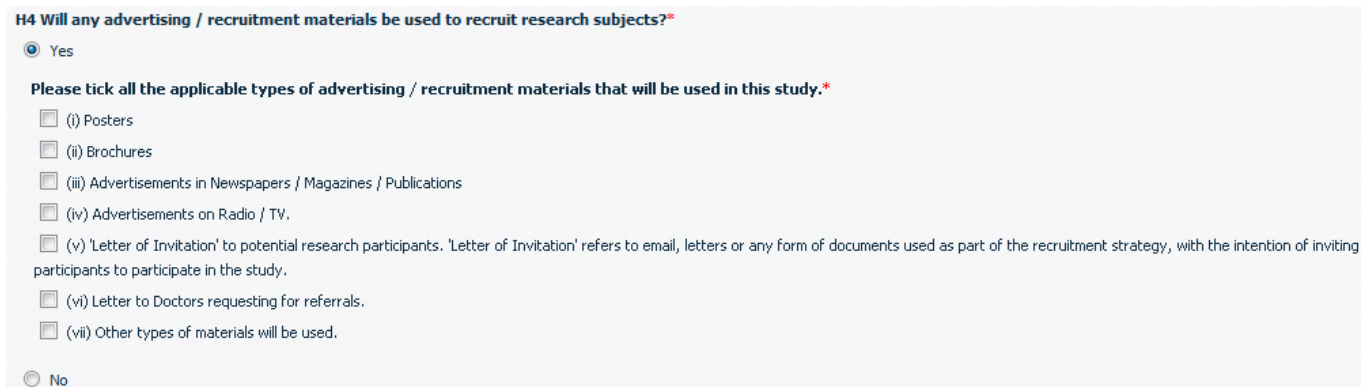
Other methods of subject identification

Please elaborate:*

Figure 38 - Section H Question H1

15. For Section H Question H1;
16. If selection is 'Other methods of subject identification'.

17. User will require elaborating more in the textbox provided.



H4 Will any advertising / recruitment materials be used to recruit research subjects?*

Yes

Please tick all the applicable types of advertising / recruitment materials that will be used in this study.*

- (i) Posters
- (ii) Brochures
- (iii) Advertisements in Newspapers / Magazines / Publications
- (iv) Advertisements on Radio / TV.
- (v) 'Letter of Invitation' to potential research participants. 'Letter of Invitation' refers to email, letters or any form of documents used as part of the recruitment strategy, with the intention of inviting participants to participate in the study.
- (vi) Letter to Doctors requesting for referrals.
- (vii) Other types of materials will be used.

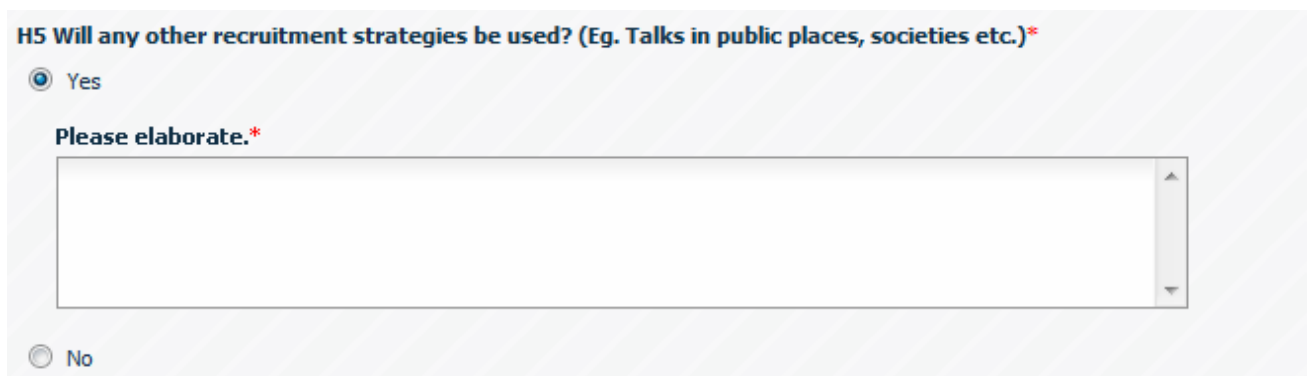
No

Figure 39 - Section H Question H4

18. For Section H Question H4;

19. If selection is 'Yes';

20. User will require to checking on the list of applicable materials used for the study.



H5 Will any other recruitment strategies be used? (Eg. Talks in public places, societies etc.)*

Yes

Please elaborate.*

No

Figure 40 - Section H Question H5

21. For Section H Question H5;

22. If selection is 'Yes';

23. User will require elaborating more in the textbox provided.

I2 Is this study part of an international study?*

Yes

Please state the total number of worldwide research subjects targeted for enrollment into this study. If exact numbers are not available, please give an approximate number:

No

Figure 41 - Section I Question I2

2.2.7 For Section I Question I2;

1. If selection is 'Yes';
2. User will require stating the approximated number on the textbox provided.

K4 Are there any recruitment restrictions based on the gender of the research subjects?*

Yes

Please give reasons for the gender restriction.*

No

Figure 42 - Section K Question K4

2.2.8 For Section K Question K4;

1. If selection is 'Yes';
2. User will require elaborating more in the textbox provided.

K5 Are there any recruitment restrictions based on the race of the research subjects?*

Yes

Please give reasons for the race restriction.*

No

Figure 43 - Section K Question K5

3. For Section K Question K5;
4. If selection is 'Yes';
5. User will require elaborating more in the textbox provided.

K6 Do the potential research subjects have a dependent relationship with the study team (E.g. doctor-patient, employee-employer, head-subordinate, student-teacher, depart relationship)?*

Yes

Please describe the dependent relationship.*

No

Figure 44 - Section K Question K6

6. For Section K Question K6;
7. If selection is 'Yes';
8. User will require elaborating more in the textbox provided.

K7 Does the study involve any of the vulnerable research participants?*

Yes

Please select all the applicable categories.*

- Pregnant Women, Foetuses and Neonates
- Children (persons who are less than 21 years of age)
- Prisoners
- Cognitively Impaired persons
- Others (E.g. mentally disabled persons, or economically or educationally disadvantaged persons.)

No

Figure 45 - Section K Question K7

9. For Section K Question K7;
10. If selection is 'Yes';
11. User is required to select the applicable categories from the list of selections.

Others (E.g. mentally disabled persons, or economically or educationally disadvantaged persons.)

(i) Why does your research need to involve this group of vulnerable subjects?*

(ii) What are the additional safeguards that will be provided to protect the rights and welfare of this group of vulnerable subjects?*

Figure 46 - Section K Question K7 (Others)

12. For Section K Question K7;
13. If selection is 'Yes';
14. User is required elaborating and answering question I and II in the textboxes provided.

Section Q - Consent Process - Waiver of Consent

Q NO. Informed consent will not be obtained from Research Participants before enrollment into the study.

The DSRB may waive the requirement to obtain informed consent if the DSRB finds that the study meets the following criteria:

Q1 The study pose no more than minimal risk to the Subjects.

Please elaborate and justify why your study meets this criterion.*

Q2 Waiver of informed consent will not adversely affect the rights and welfare of the Research Participants.

Please elaborate and justify why your study meets this criterion.*

Q3 The study cannot be practically conducted without the waiver of informed consent.

Please elaborate and justify why your study meets this criterion.*

Figure 47 - Section Q

2.2.9 For Section Q;

1. Questions with the asterisk (*) sign is a must answer question, please do not leave it blank.
2. User is required to answer in the textboxes provided.

Q4 Whenever appropriate, will the research participants be provided with additional pertinent information after participation?*

Yes
 No

Please describe.*

Figure 48 - Section Q Question Q4

3. For Section Q Question Q4;
4. If selection is 'Yes';
5. User is required elaborating more in the textbox provided.

Q5 Do you have any additional comments supporting the waiver of informed consent?*

No
 Yes

Please describe.*

Figure 49 - Section Q Question Q5

6. For Section Q Question Q5;
7. If selection is 'Yes';
8. User is required elaborating more in the textbox provided.

R1 Coded / anonymous research data will be sent to the study sponsor, and therefore no research database will be created and stored in NHG?*

No

i. Describe where the research data will be stored. (ie: Network or stand-alone PC, and the physical location)*

ii. Who will have access to the research data, and how will access to the research data be controlled and monitored?*

iii. Are there any other measures in place to protect the confidentiality of the research data?*

iv. Are there any research data sharing agreements with individuals or entities outside the Institution, to release and share research data collected?*

No
 Yes

v. Describe what will happen to the research data when the study is completed.*

Yes

Figure 50 - Section R Question R1

2.2.10 For Section R Question R1;

1. If selection is 'No';
2. User is required to answer all the questions in the textboxes provided.
3. Questions with the asterisk (*) sign, is a must answer question.

iv. Are there any research data sharing agreements with individuals or entities outside the Institution, to release and share research data collected?*

No
 Yes

Please describe the agreement. Submit a copy of the agreement if available.*

Figure 51 - Section R Question R1 Part IV

4. For Section R Question R1 Selection 'No'; Question part IV;
5. If selection is 'Yes';
6. User is required elaborating more in the textbox provided and attach relevant file.

7. Click on the 'attach' button to attach a copy of the agreement.

R2 Will any part of the study procedures be recorded on audiotape, film/video, or other electronic medium?*

No

Yes

i. Please describe what will be recorded.*

ii. What is the medium (audio tape / video etc) used for recording?*

iii. Explain how the recorded information will be used in the study.*

iv. For how long and where will the recording medium be stored? Who will have access, and how will access be controlled and monitored?*

v. How will the recording medium be disposed?*

Figure 52 - Section R Question R2

8. For Section R Question R2;
9. If selection is 'Yes';
10. User is required to answer the following questions, in the textboxes provided.

S1 Will any biological materials (such as blood or tissue) be used as part of the study? This includes both prospectively collected and existing biological materials.*

No

Yes

i. Please state what biological materials are used and whether they are obtained prospectively or existing.*

ii. For prospective biological materials, please state how they are obtained. For existing biological materials, please state the source.*

iii. How frequently are the biological materials being collected? How much biological material is being collected each time?*

iv. What are the tests that will be performed on these biological materials?*

v. Will results from the tests be communicated to the research participant? Please elaborate.*

Figure 53 - Section S Question S1

2.2.11 Section S Question S1;

1. If selection is 'Yes';
2. User is required to answer all the questions in the textboxes provided.

vi. How are the biological materials identified? (Please tick all the applicable boxes.)*

No Identifiers

Biological materials are coded and the code is maintained at source

Identifiers present

Other methods

Please elaborate:*

Figure 54 - Section S Question S1 (Yes) Part VI (Other methods)

3. For Section S Question S1 'Yes'; Question part VI;
4. If selection is 'Other methods';
5. User is required to elaborate more in the textbox provided.

vii. Will any cell lines be created from the biological materials?*

Yes

No

a. How will the cell lines be identified?*

The cell lines are stripped of any identifiers and cannot be linked or traced back to its donor.

The cell lines are coded.

By other methods.

Figure 55 - Section S Question S1 (Yes) Part VII (Yes)

6. For Section S Question S1 'Yes'; Question VII;
7. If selection is 'Yes';
8. User is required to answer the question as shown.

a. How will the cell lines be identified?*

The cell lines are stripped of any identifiers and cannot be linked or traced back to its donor.

The cell lines are coded.

By other methods.

Who will maintain the codes linking the cell lines and its donor?*

Figure 56 - Section S Question S1 (Yes) Part VII (Yes) Qn. A

9. For Section S Question S1 'Yes'; part VII 'Yes' Question A;
10. If selection is 'The cell lines are coded';
11. User is required to elaborate more in the textbox provided.

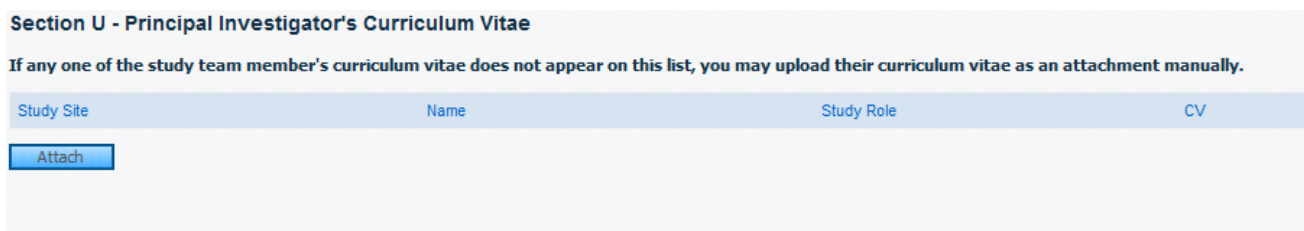


Figure 57 - Section U

2.2.12 For Section U;

- 1. User can choose to attach the study curriculum vitae by clicking on the 'attach' button;
- 2. A popup for user to select the files they want to upload will appear;

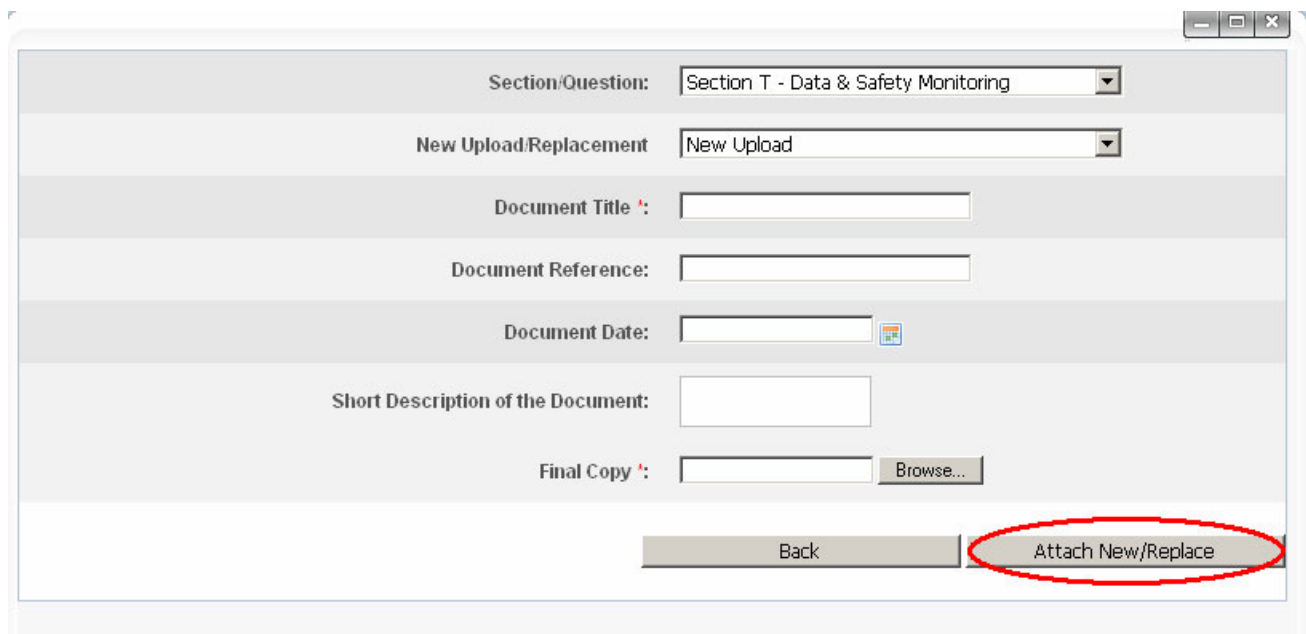


Figure 58 - Section U Attaching file

- 3. After attaching the file;
- 4. Click on the 'Upload' button to upload the file.

Section V

Section V - Declaration of Principal Investigator

Your DSRB Application is now complete and ready for submission.

Principal Investigator's Declaration

I will not initiate this study until I have received approval notification from the DSRB and all applicable regulatory authorities.

I will not initiate any change in the study protocol without prior written approval from the DSRB, except when it is necessary to reduce or eliminate Participants. Thereafter, I will submit the proposed amendment to the DSRB and all applicable regulatory authorities for approval.

I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that may occur in the course of this study.

I will maintain all relevant documents and recognise that the DSRB staff and applicable regulatory authorities may inspect these records.

I understand that failure to comply with all applicable regulations, institutional and DSRB policies and requirements may result in the suspension of my research.

I declare that there are no existing or potential conflicts of interest for any of the investigators participating in this study.

By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration

I have read and agree to the above declaration.

Figure 59 - Section V

2.2.13 Section V;

1. Click on the checkbox to agree with the above declaration;
2. Then click on the 'Submit Application' button to submit form.
3. *Note: 'Submit Application' button will only appear when the agreement checkbox is checked.

Navigation bar with buttons: Previous, Next, Save Draft, Submit Application (circled in red), Printer Friendly, Close.

Figure 60 - Section V Submitting Form

3 ACTIONS AFTER SUBMISSION

3.1 After Submission

1. After a draft is submitted, it is no longer editable.
2. Clicking on the same icon now shows the current status.

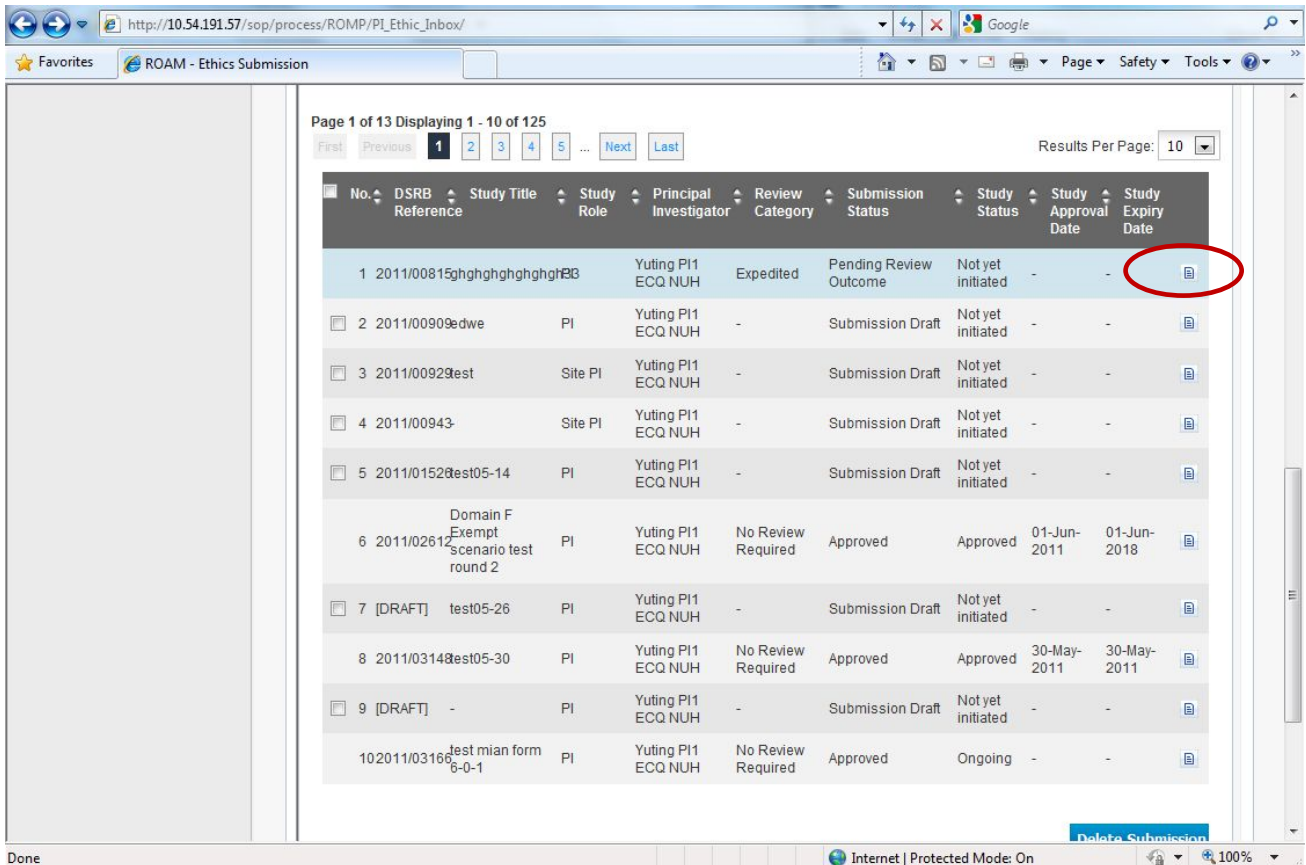


Figure 63 After a Draft becomes a Submitted Study

3. As shown, the parts of the review status screen consist of the following panels.

3.2 The Submission Status Diagram:

1. This is a simple graphical view of which stage the submitted study is in.

3.3 The Details Panel:

1. These panels provide a summary of the information pertaining to the submission. More details about each details follows.

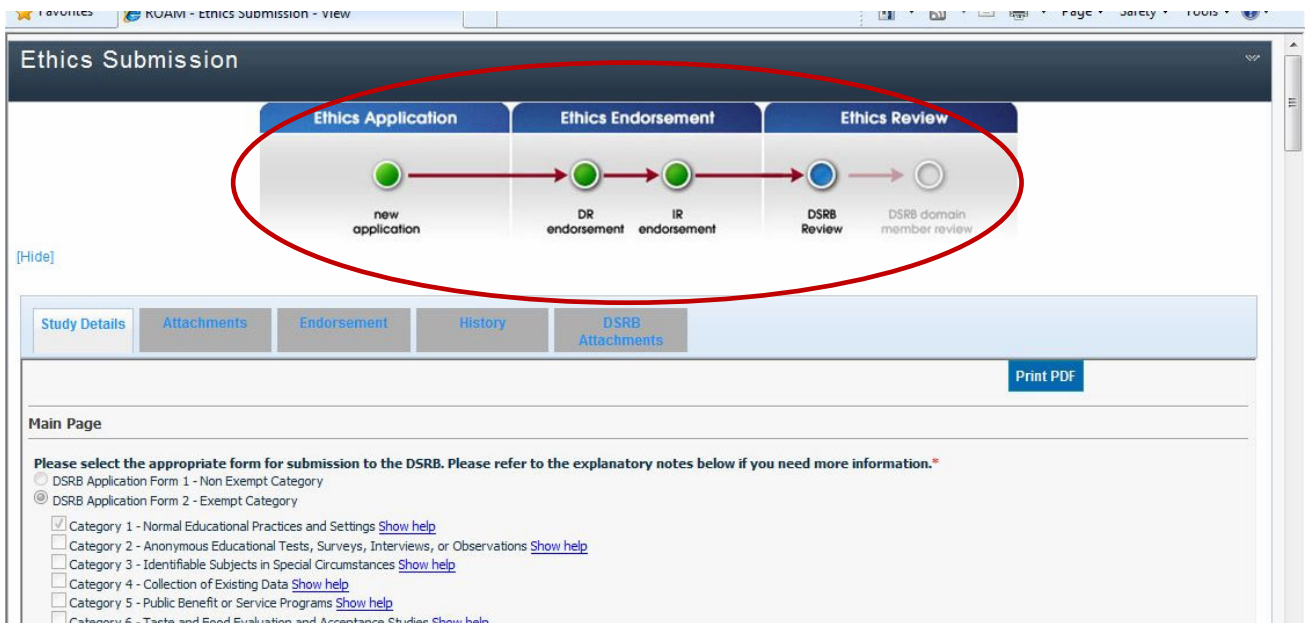


Figure 64 Submission Status Screen.

3.4 Study Details Panel

1. This panel shows the same information as the draft. It shows all the information that was submitted.
2. This submission can be saved as a PDF, by pressing the button Print PDF as indicated.

[Hide]

new application → DR endorsement → IR endorsement → DSRB Review → DSRB domain member review

Study Details Attachments Endorsement History DSRB Attachments

Print PDF

Main Page

Please select the appropriate form for submission to the DSRB. Please refer to the explanatory notes below if you need more information.*

DSRB Application Form 1 - Non Exempt Category

DSRB Application Form 2 - Exempt Category

- Category 1 - Normal Educational Practices and Settings [Show help](#)
- Category 2 - Anonymous Educational Tests, Surveys, Interviews, or Observations [Show help](#)
- Category 3 - Identifiable Subjects in Special Circumstances [Show help](#)
- Category 4 - Collection of Existing Data [Show help](#)
- Category 5 - Public Benefit or Service Programs [Show help](#)
- Category 6 - Taste and Food Evaluation and Acceptance Studies [Show help](#)

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be able to qualify for the Exempt category.

Please click on the **DSRB Application Form 2 - Exempt Category** option above to view the categories.

Don't know which to choose? [Click here](#)

Section A - Study Title & Study Administrator

Figure 65 Study Details and Print PDF

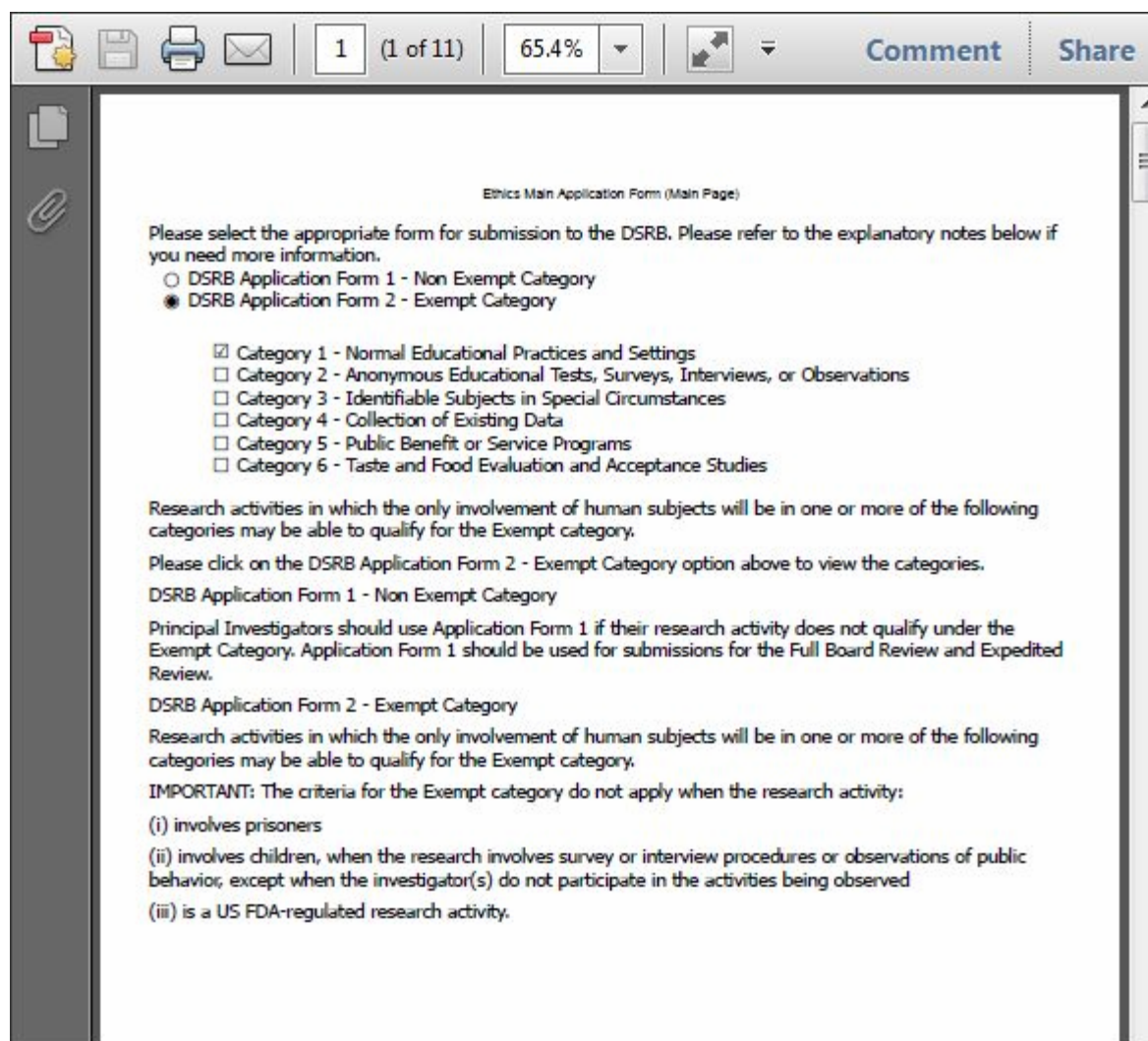


Figure 66 PDF Sample

3.5 Attachments Panel

1. This panel shows all the attachments that accompanied this submission.
2. The top portion is a Search utility in case the study contains a lot of documents.
3. The lower portion is a list of the documents.
4. The list can be sorted according to preference by clicking the arrows beside each column, and each page can show more or less documents by setting the Results Per Page option.

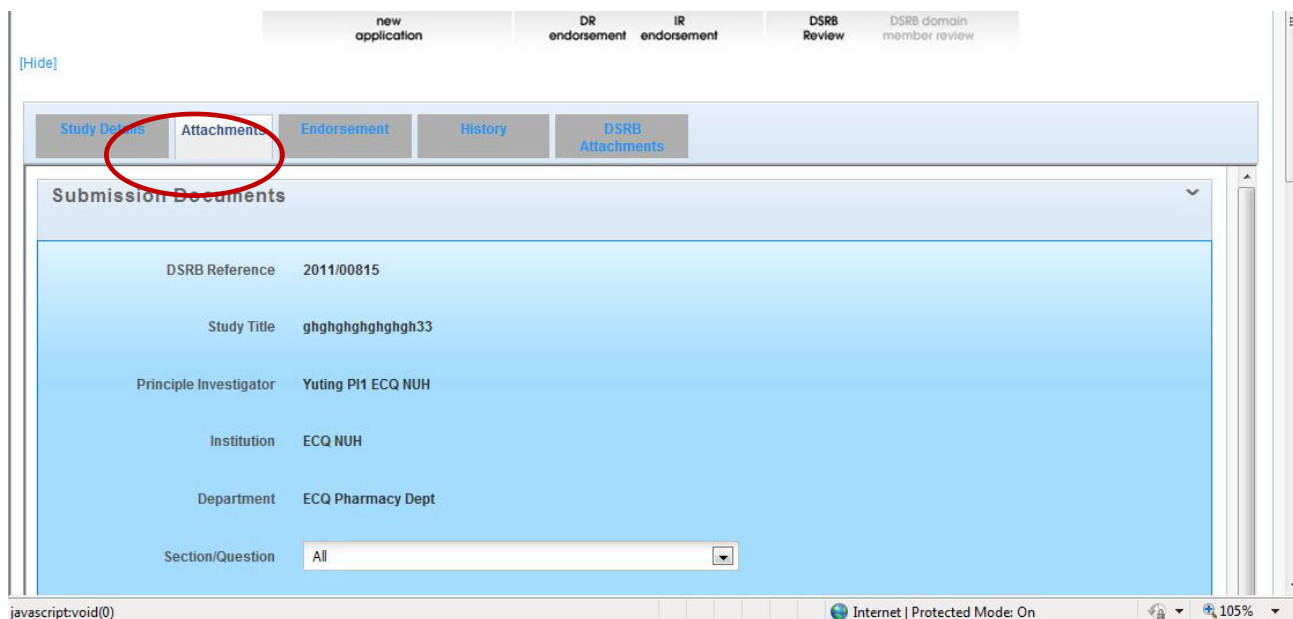


Figure 67 Attachments Panel

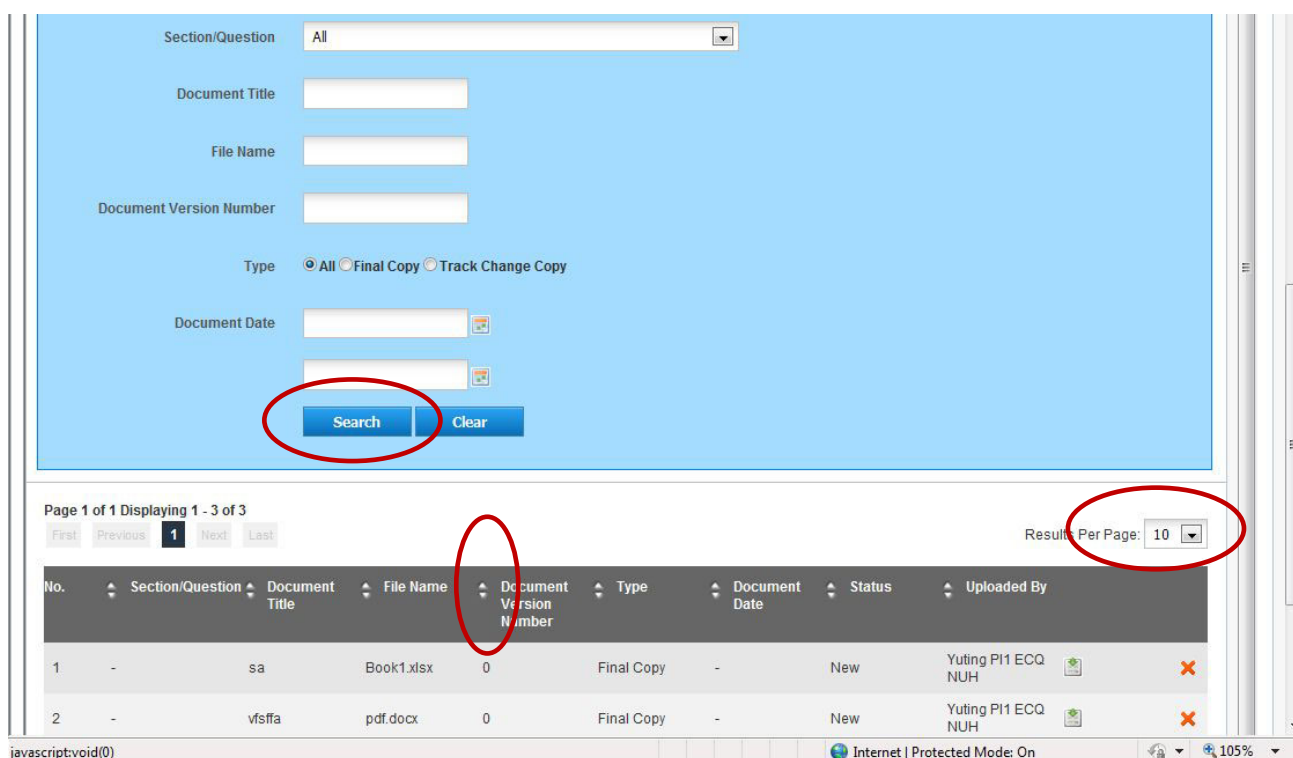


Figure 68 Search, Sort and Paginate functions.

3.6 Endorsements Panel

1. This panel will show the DR and IR endorsements, if the submission has received them, otherwise they will be empty.

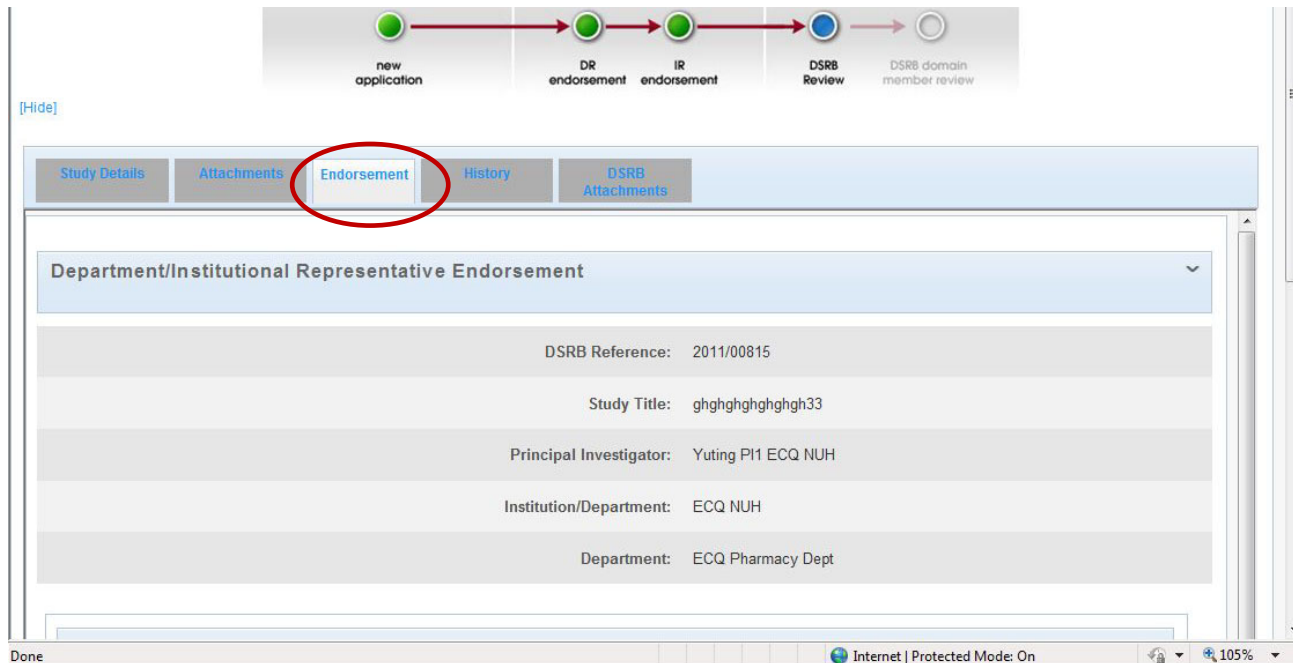


Figure 69 Endorsements

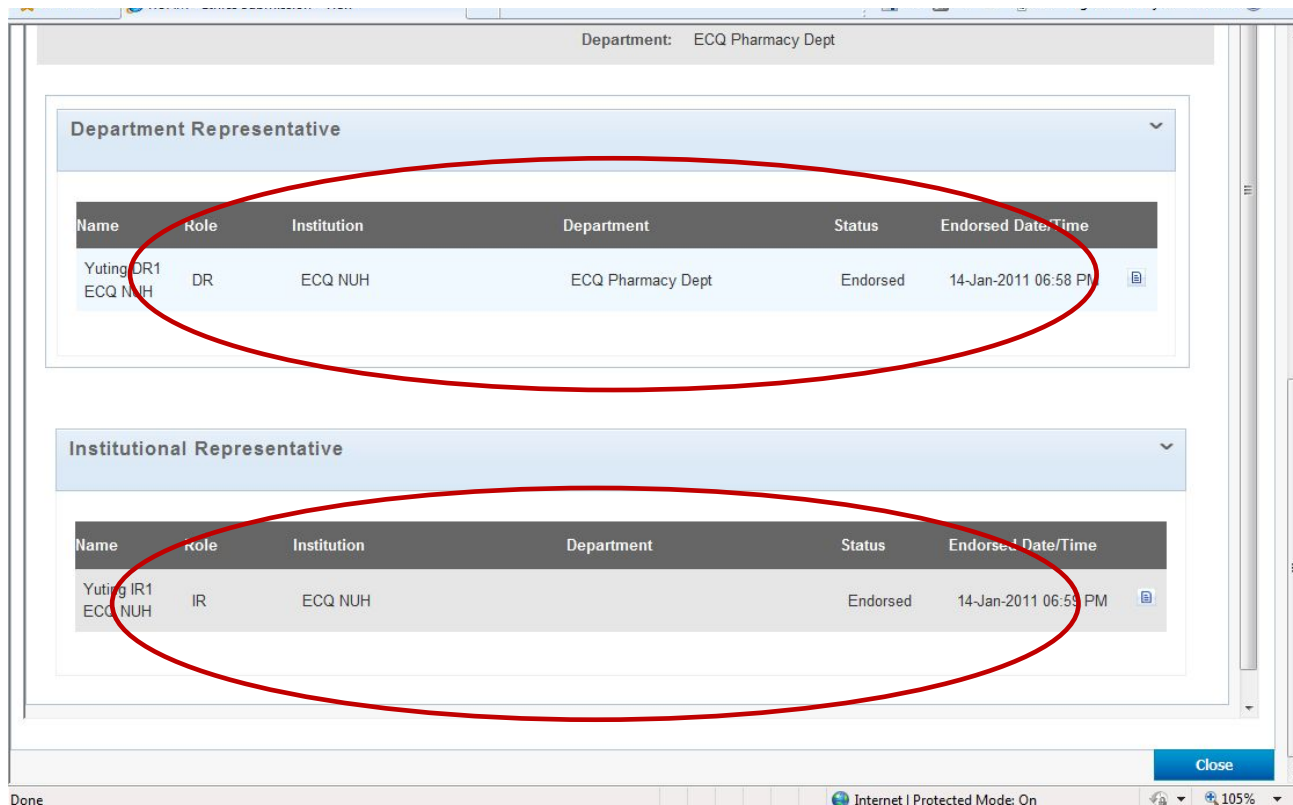


Figure 70 Endorsements II

3.7 History Panel

1. This panel shows all the various action states that have been done on the submission. The Submission History actions include notifications to other parties, and changes made.
2. This panel can be scrolled in its own part of the screen, as the list of actions increase.
3. The Message History allows simple comments to be posted and is visible between all parties involved in the study.

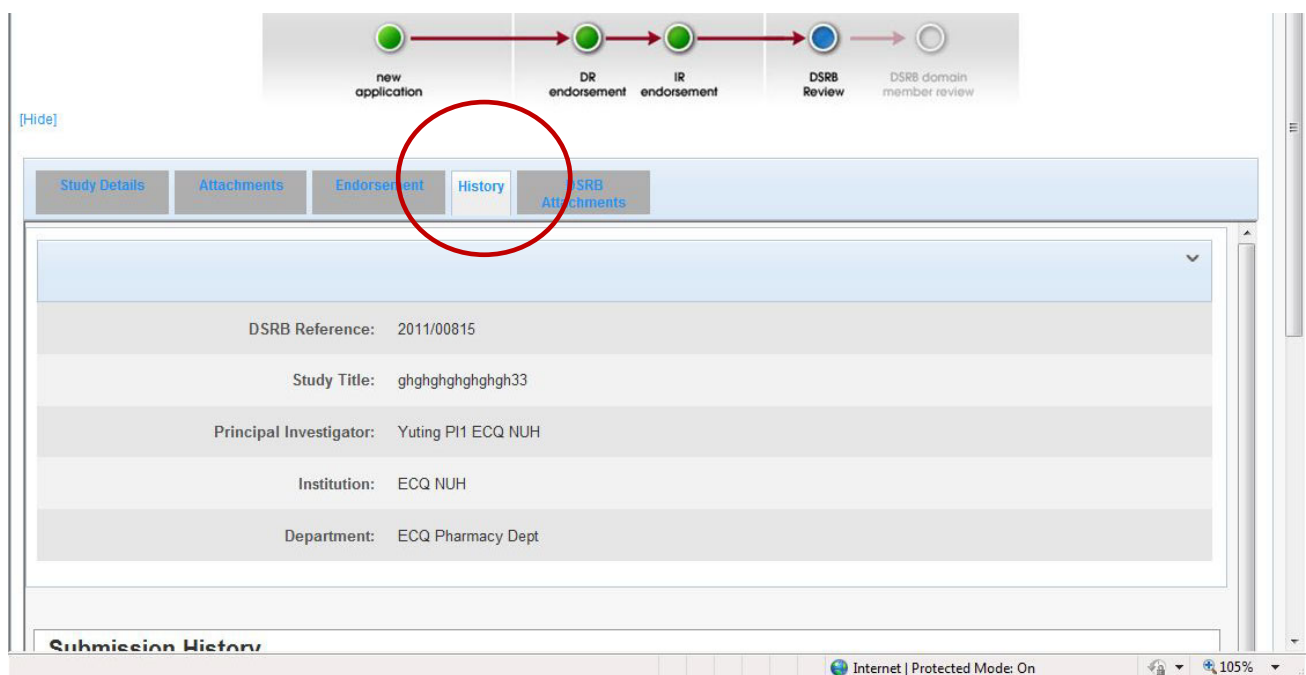


Figure 71 History

The screenshot shows a web browser window with the URL http://10.54.191.57/sop/process/ROMP/Ethics_View_Submission?submissionId=11282. The page title is "ROAM - Ethics Submission - View".

Principal Investigator: Yuting PI1 ECQ NUH
Institution: ECQ NUH
Department: ECQ Pharmacy Dept

Submission History

No.	Date/Time	Name	Study Role	Comments
2	2011-Mar-13 11:00 AM	Yuting DSRB Coord ECQ TTSH	DSRBStaff	Reviewer outcome
3	2011-Mar-14 07:02 PM	Yuting DSRB Coord ECQ TTSH	DSRBStaff	Notify reviewers
4	2011-Mar-14 07:02 PM	Yuting DSRB Coord ECQ	DSRBStaff	Update review category

Message History

Page 1 of 1 Displaying 0 - 0 of 0

First Previous **1** Next Last Results Per Page: 10

No.	Date/Time	Name	Study Role	Comments
No record found				

Close

Internet | Protected Mode: On 105%

Figure 72 History II

3.8 DSRB Attachments Panel

1. this panel is for DSRB reviewers to send documents to the PI during the query process.

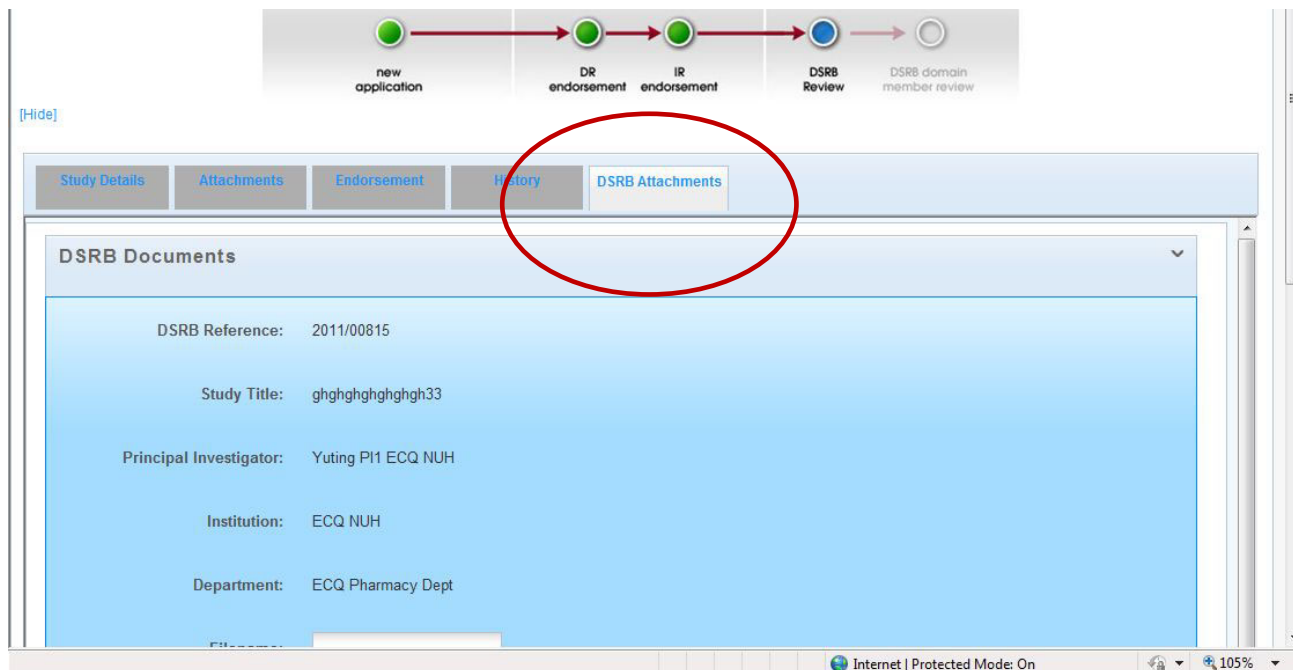


Figure 73 DSRB Attachments

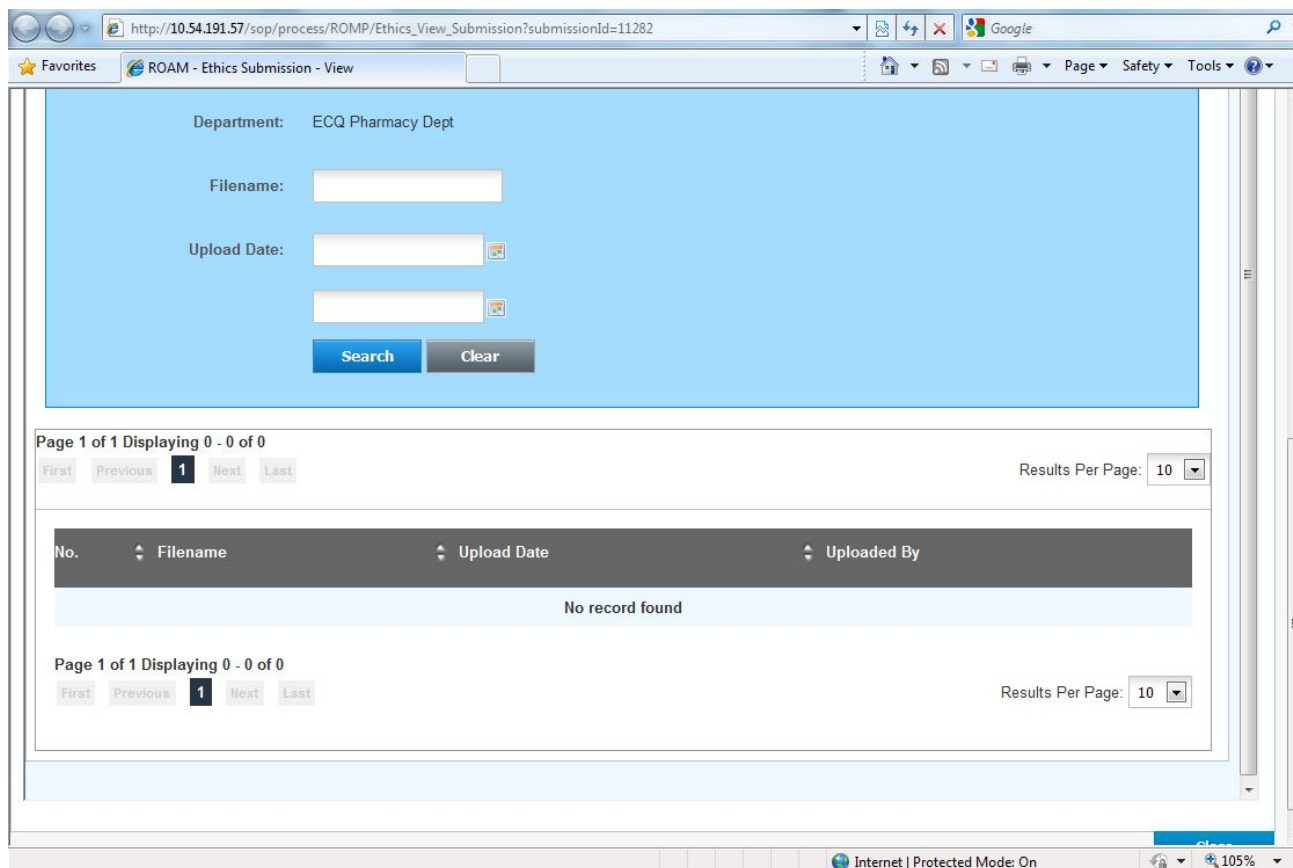


Figure 74 DSRB Attachments II

4 AMENDMENTS

The Amendments section allows the PI to submit changes or addendums to a study after the initial study has been submitted.

4.1 Amendment Panels

4.1.1 Study Summary

1. This panel is a summary view of the submission and its details.

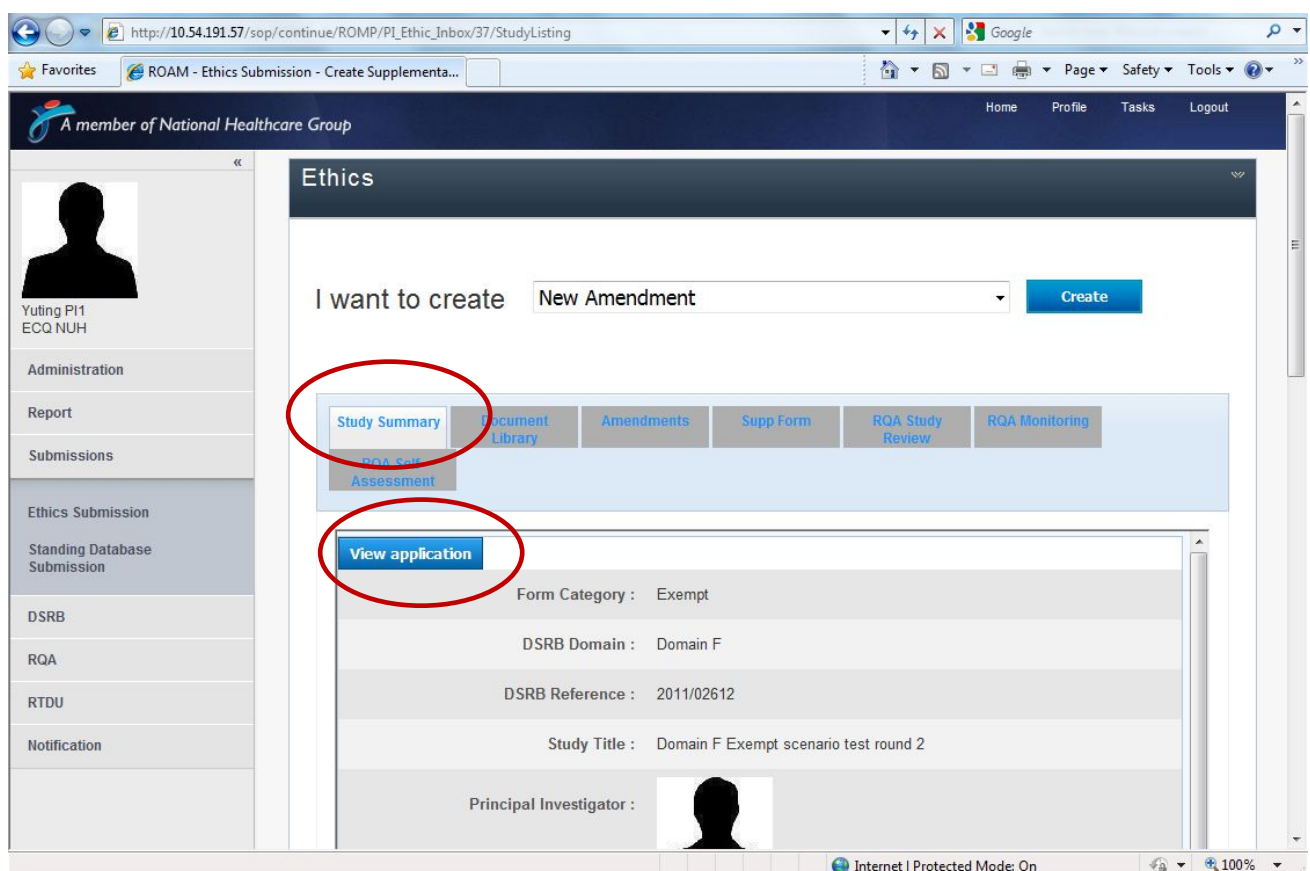


Figure 75 Study Summary

2. Clicking on View Application will launch the screen showing the full form that was submitted.



Figure 76 Study Summary II

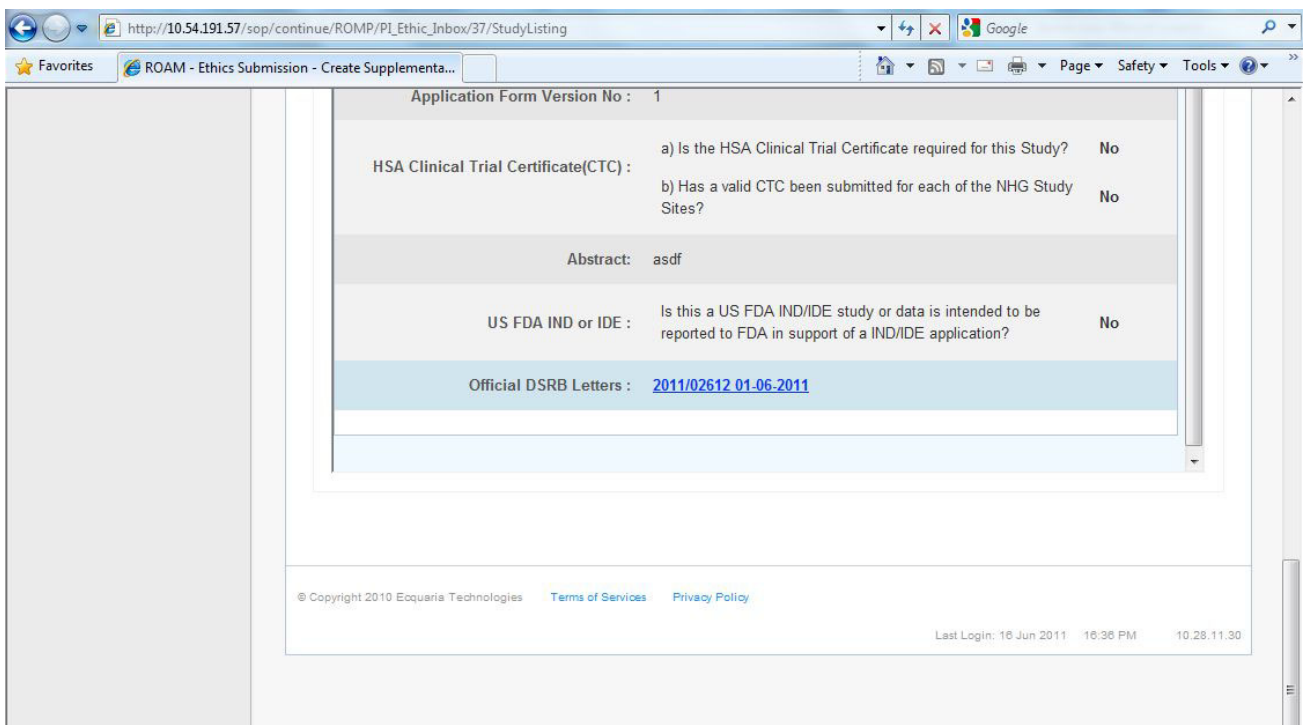


Figure 77 Study Summary III

4.1.2 Document Library

1. This panel shows the documents that have been submitted for the study so far.

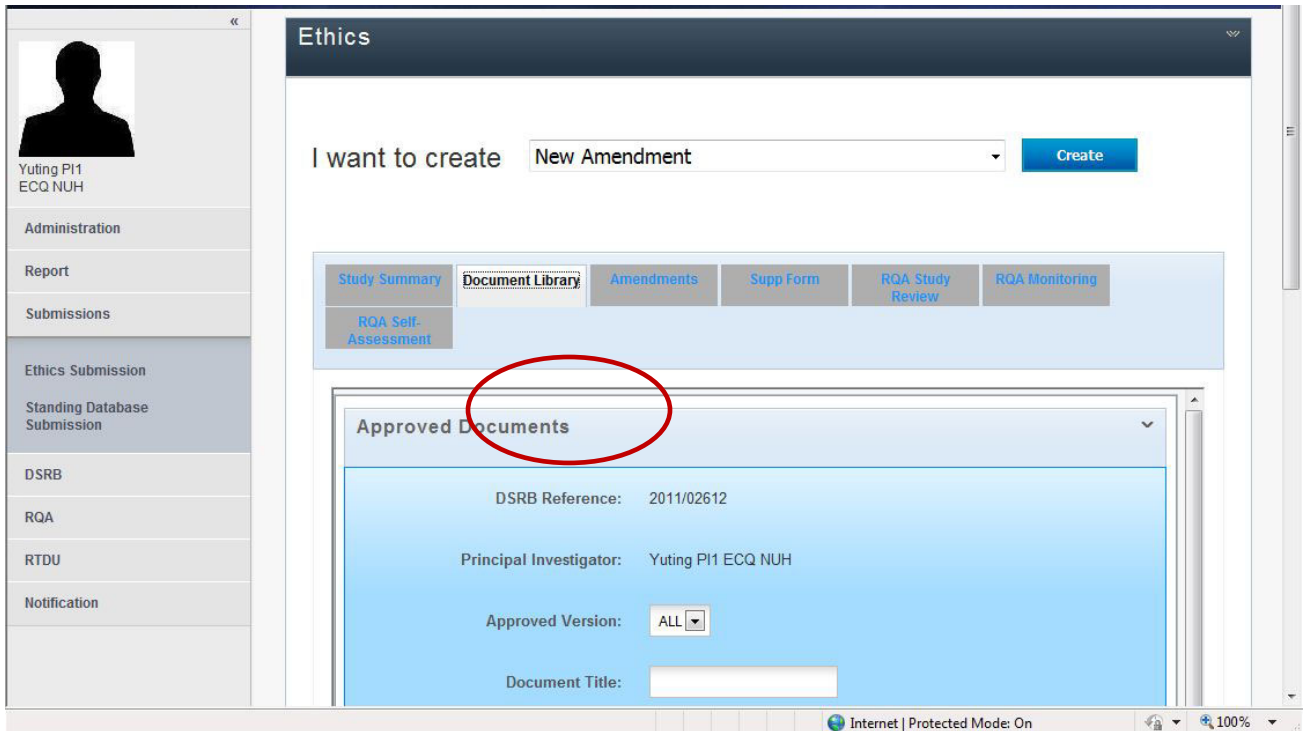


Figure 78 Document Library

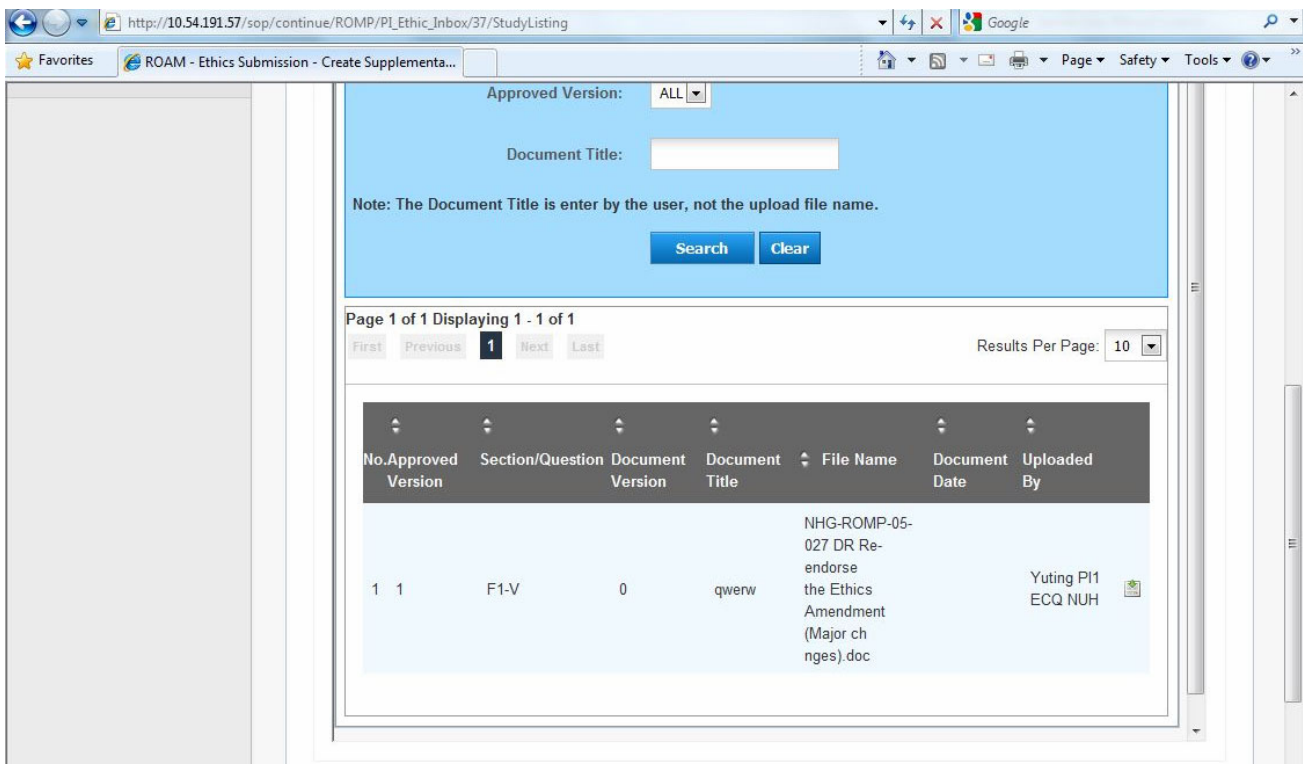


Figure 79 Document Library II

4.1.3 Amendments

1. This panel shows the amendments that have been submitted for the study so far

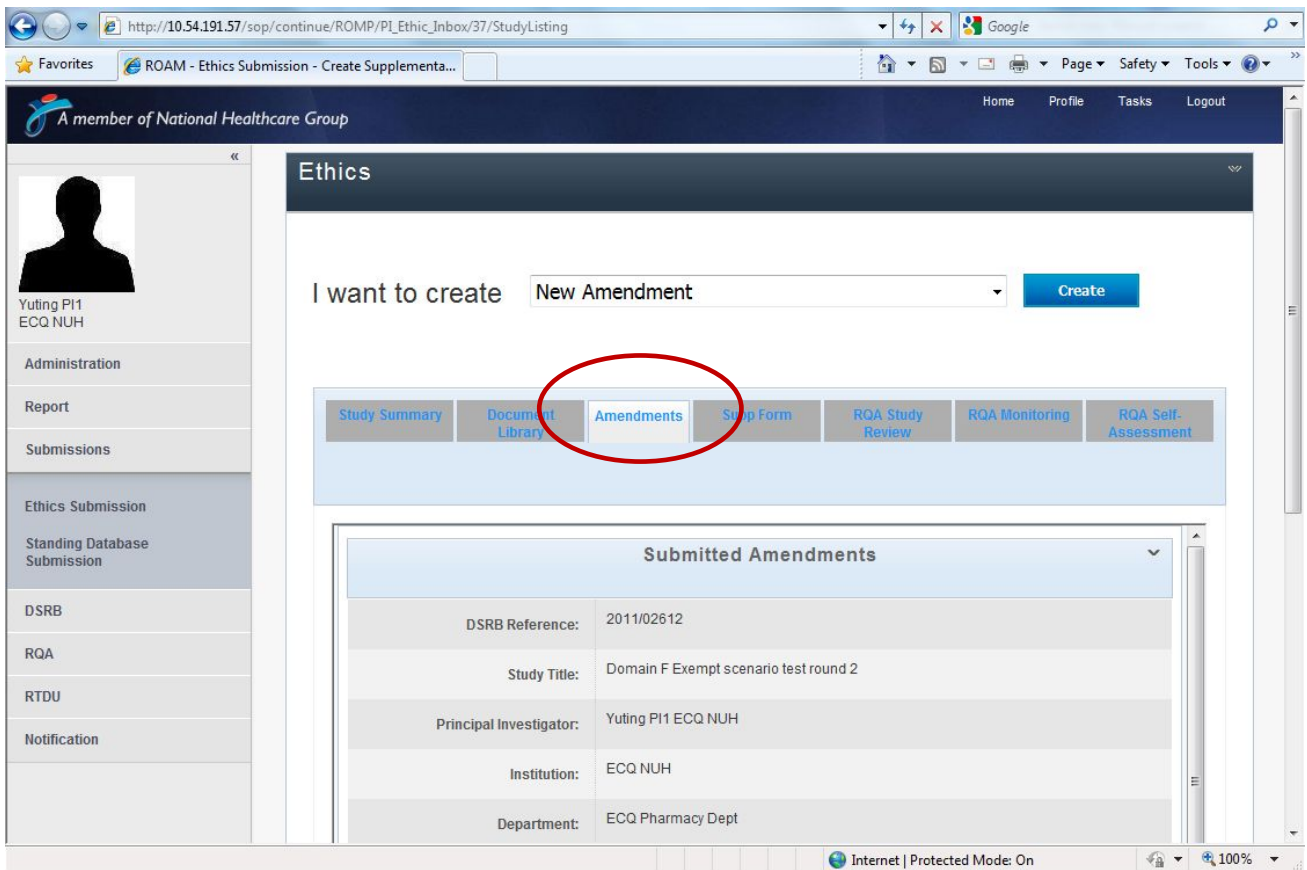


Figure 80 Amendments

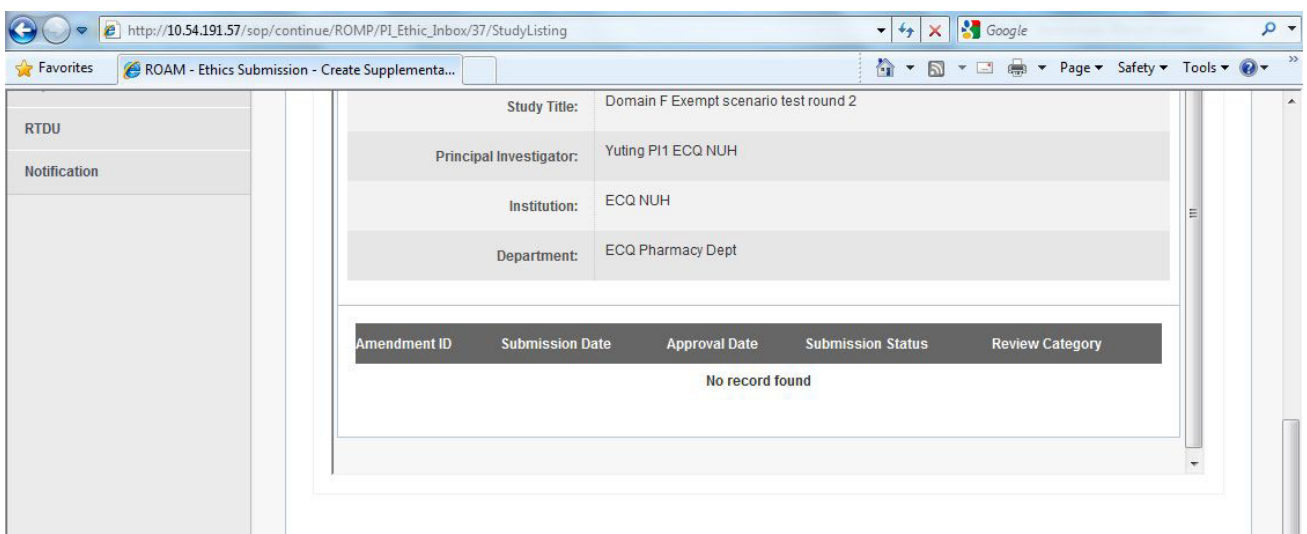


Figure 81 Amendments II

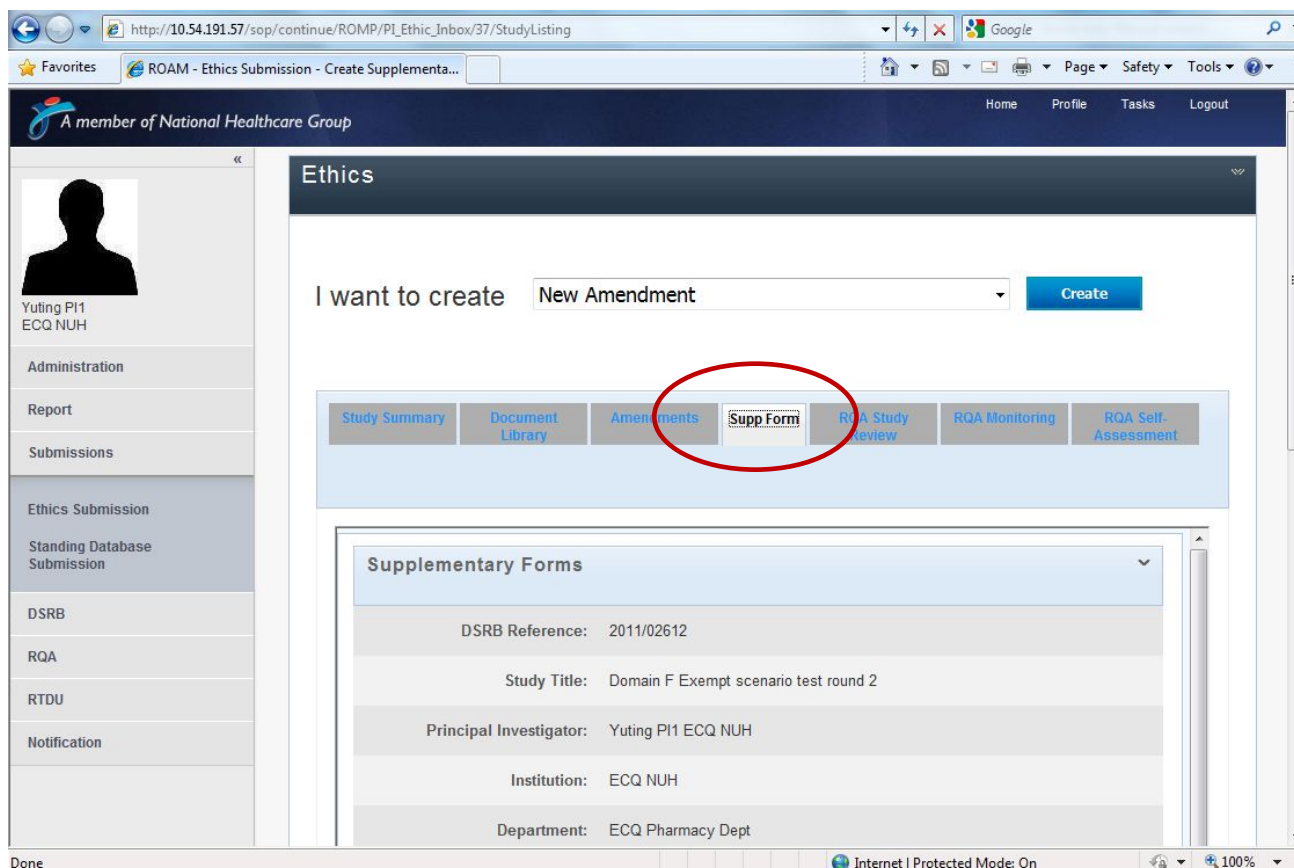


Figure 82 Supplementary Forms

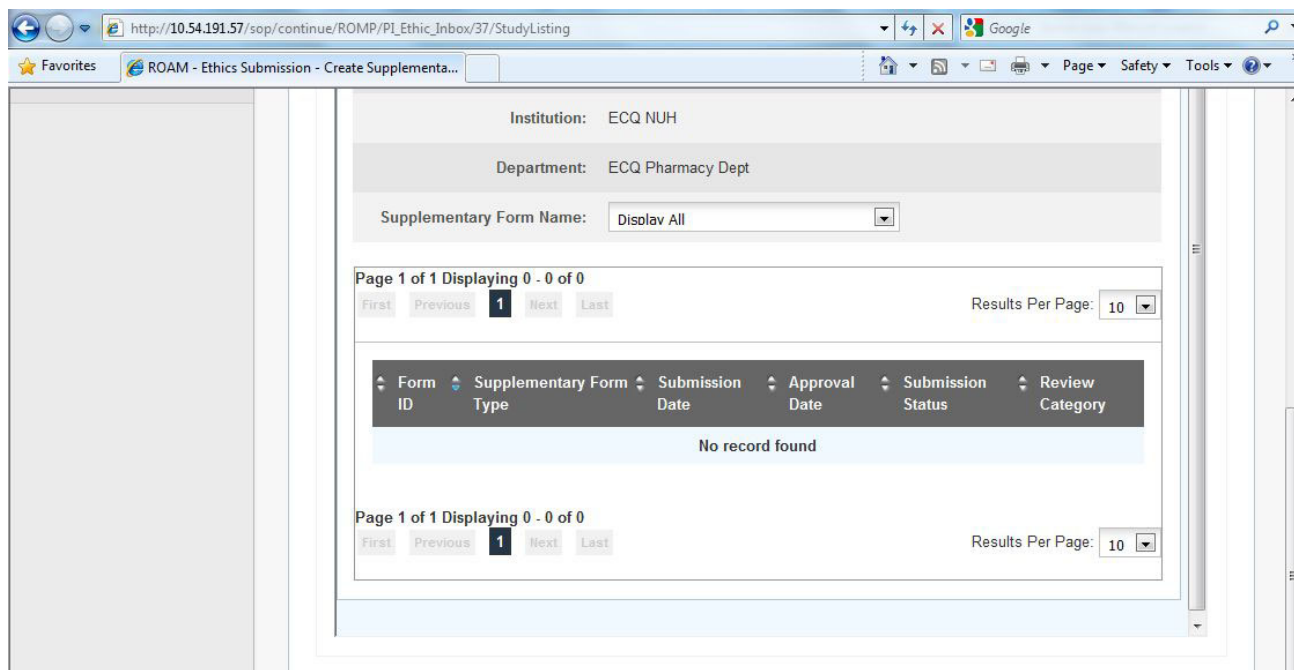


Figure 83 Supplementary Forms II

4.2 Creating a New Amendment

1. To create a new amendment, select the type and click the Create button. This will launch the New form in a new browser window.
2. For supporting documents, clicking on Attach will allow you to upload related documents pertaining to the report.
3. For managing and also uploading supporting documents, the Attachments will allow you to manage related documents pertaining to the report.
4. The History panel shows what actions and status changes have happened to this study, and also holds the same Message history exchanges.
5. For DSRB attachments please use the DSRB Attachments tab.
6. Finally, the “I agree” declaration check box must be ticked to allow the submission to proceed.

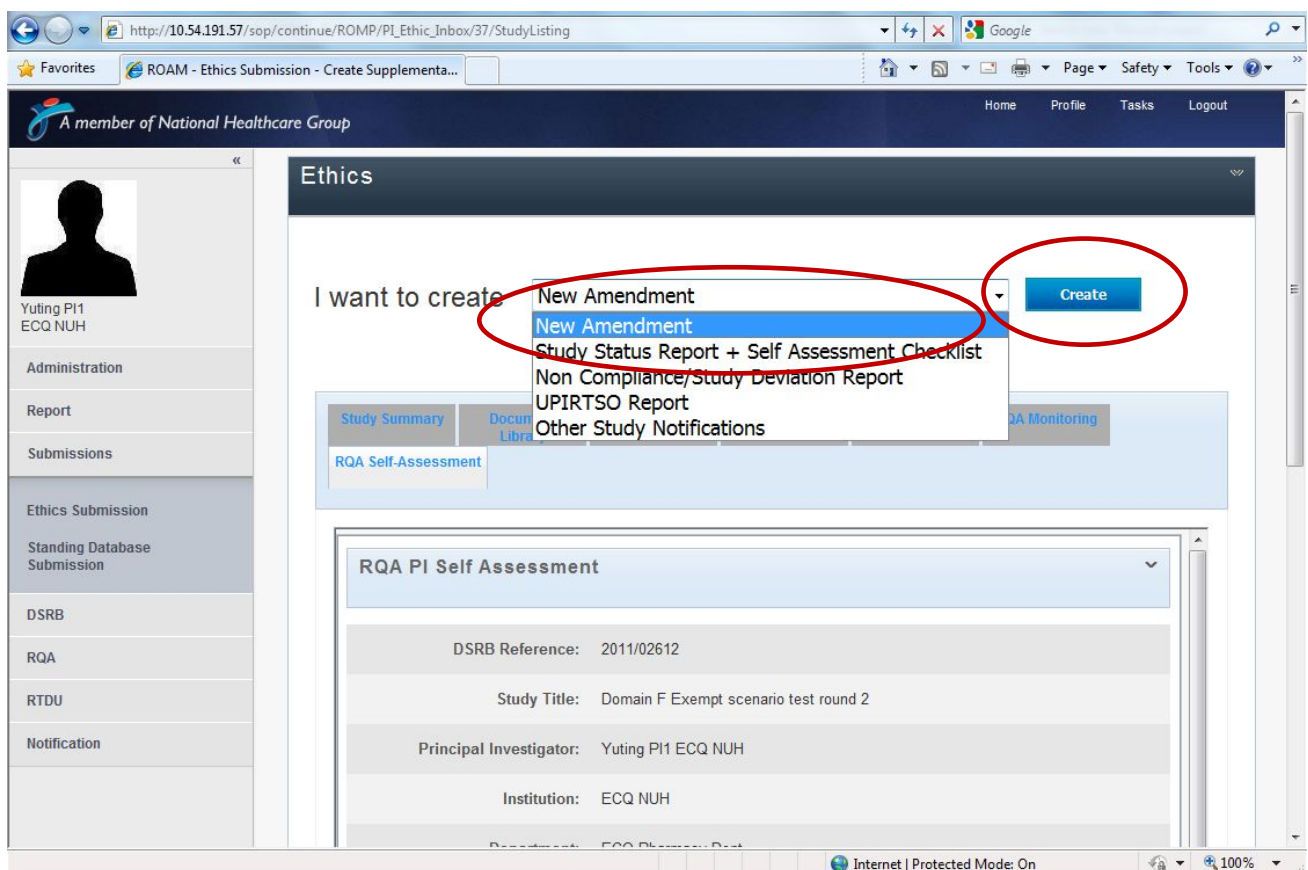


Figure 84 New Amendment drop down list

http://10.54.191.57/sop/newform/Application_Form_For_Domain_F?popup=true&isDomainF=Yes&submissionId=35535&submissionType=02

Cover Note Study Details Attachments History DSRB Attachments

Study Amendment Cover Note

Type of changes*
 Major Minor Admin

Rationale for changes:*

Will the enrolled study participants be informed of these changes?*

No Yes

Will the enrolled study participants be re-consented?*

No Yes

If you have a separate document that summarises all the amendments being submitted for review, please attach it here.
Please note that this document must contain the following information for each amendment:

- Location and name of document being amended
- Original Text
- Amended Text
- Rationale for amendment

Attach

Do the proposed amendments:*

- Significantly change the original objectives, innovation and scientific methodology (e.g. re-design of study methodology, change in investigational product used, etc) and/or the alignment of the study to the institutions' research objectives, image and standards of the research study?
- Require additional resources (e.g. expertise, manpower, time, budget) for the study to be properly conducted?
- Significantly increase the overall risk or negatively alter the risk benefit ratio to the subjects of the study?

No Yes

Next Save Re-Submit Application

Done Internet | Protected Mode: On 105%

Figure 85 Study Amendment Cover Note

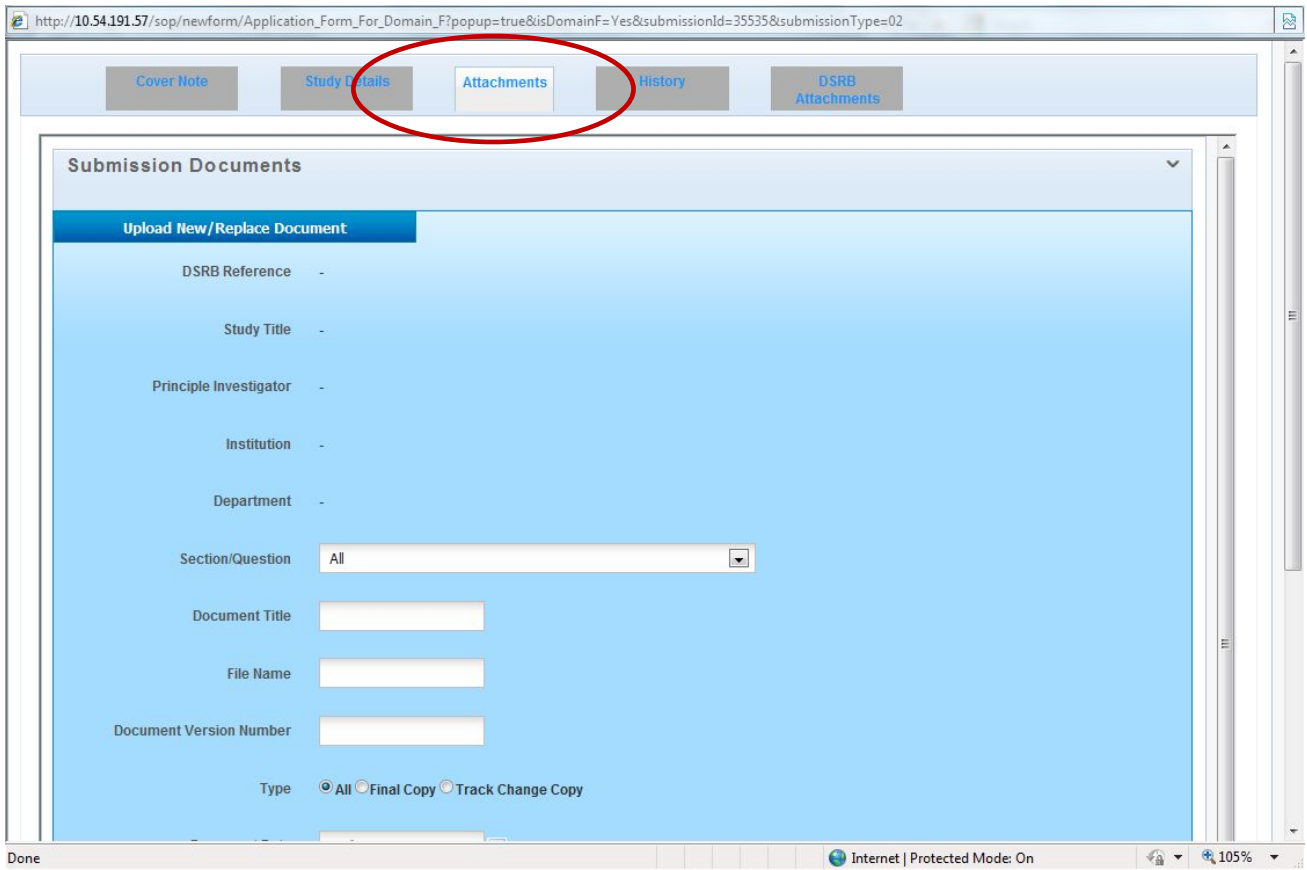


Figure 86 Study Amendment Attachments

http://10.54.191.57/sop/newform/Application_Form_For_Domain_F?popup=true&isDomainF=Yes&submissionId=35535&submissionType=02

Institution -

Department -

Section/Question All

Document Title

File Name

Document Version Number

Type All Final Copy Track Change Copy

Document Date from to

Search Clear

Page 1 of 1 Displaying 0 - 0 of 0

First Previous 1 Next Last

Results Per Page: 10

No record found

Done Internet | Protected Mode: On 105%

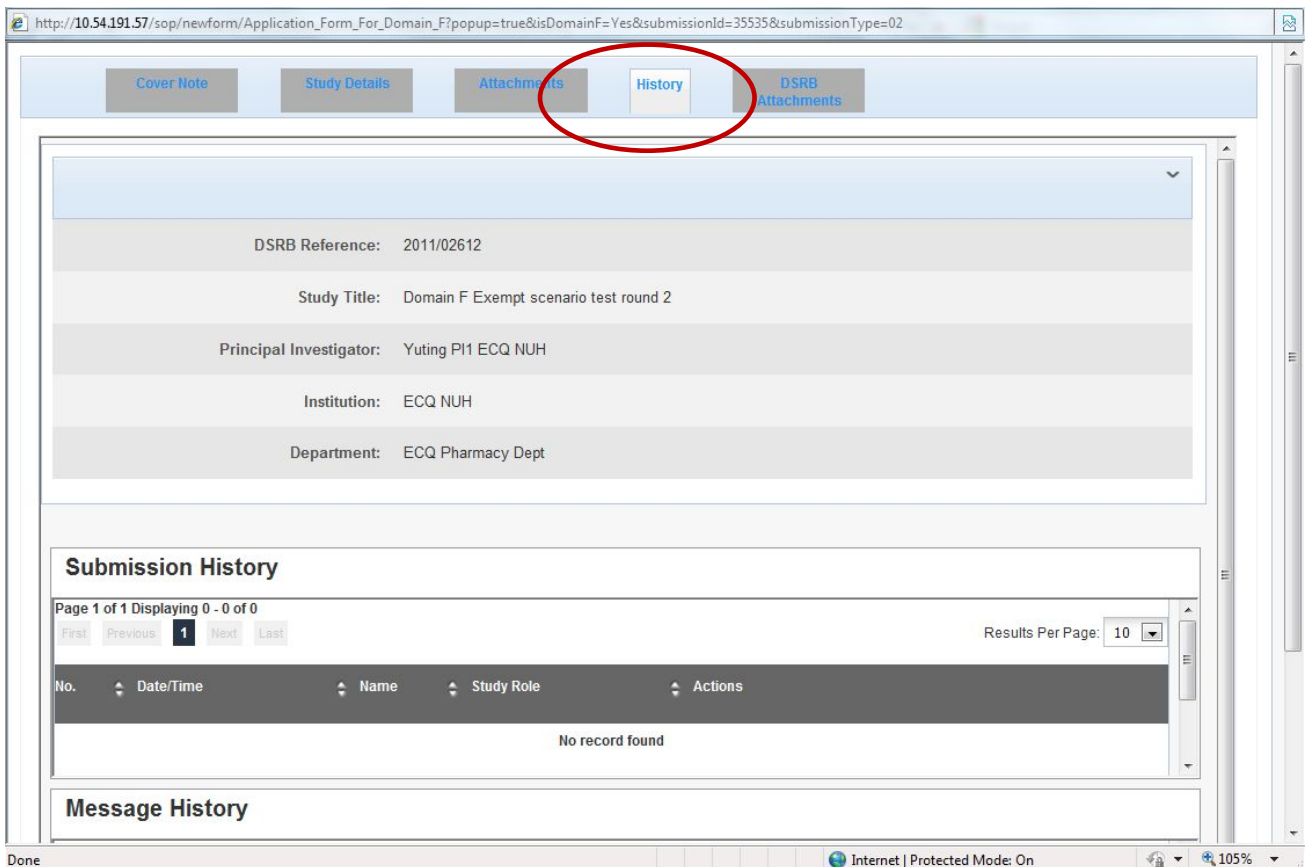


Figure 87 Study Amendment History

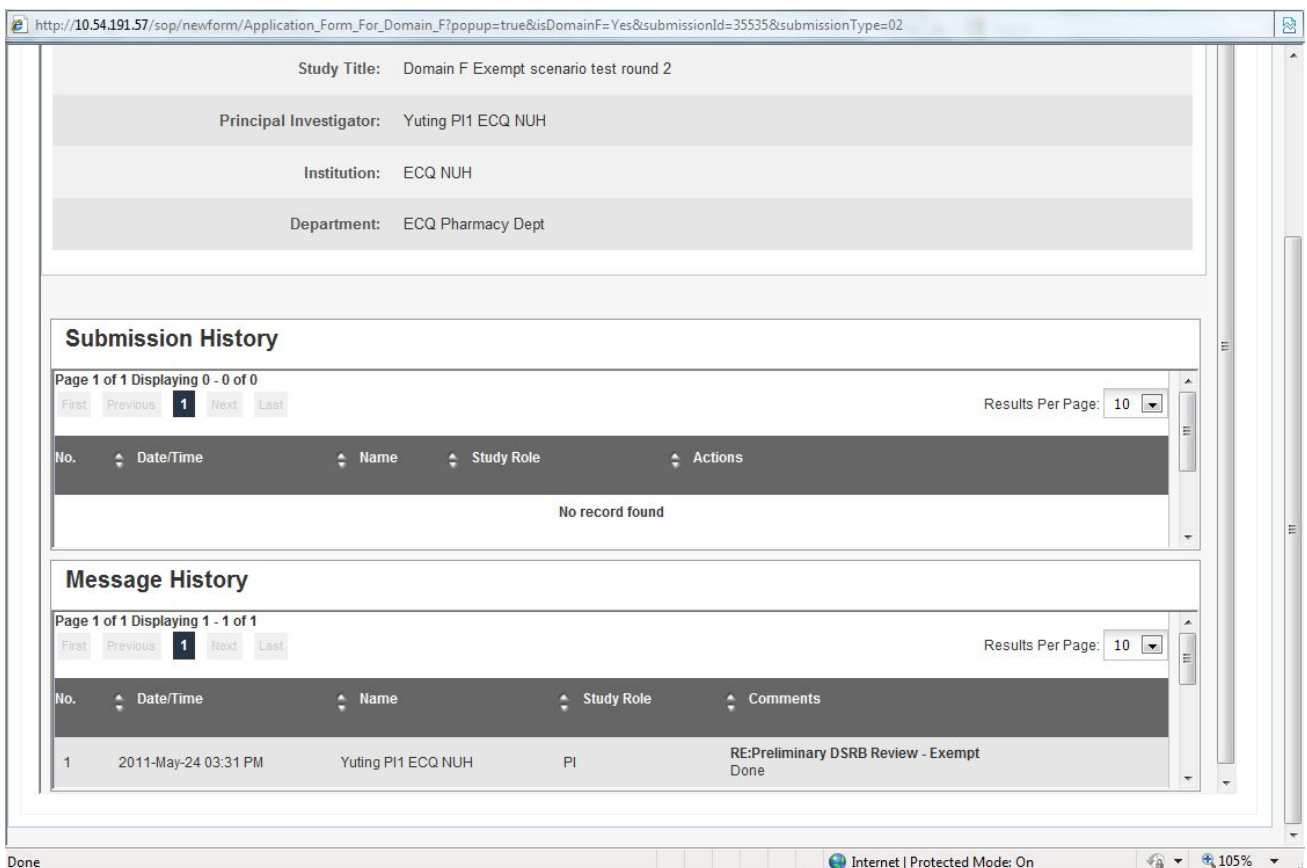


Figure 88 Study Amendment History II

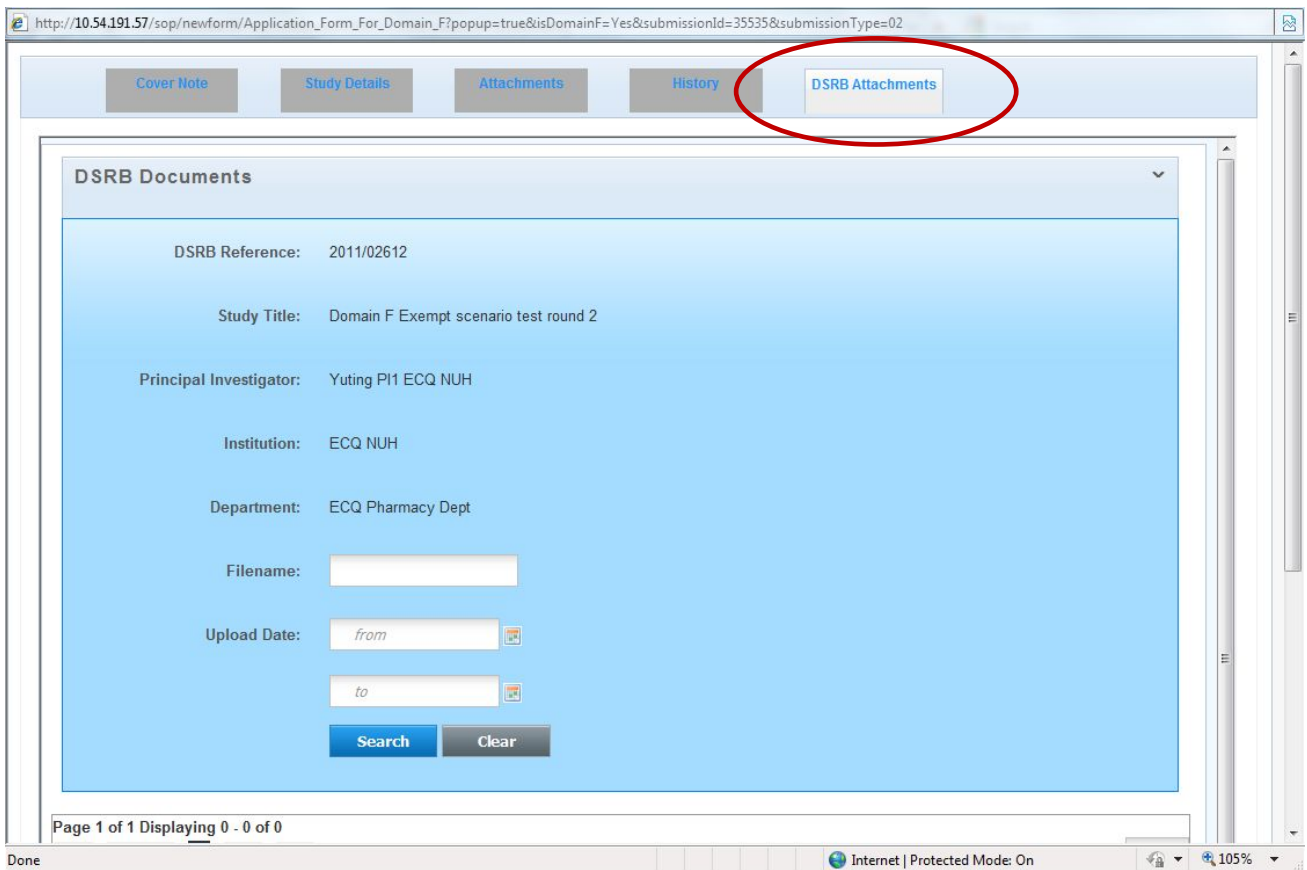


Figure 89 Study Amendment DSRB Attachments

Creating a Study Status Report

2. For filing updates on Study Status, the Study Status Report Form is used.
3. For supporting documents, clicking on Attach will allow you to upload related documents pertaining to the report.
4. For managing and also uploading supporting documents, the Attachments will allow you to manage related documents pertaining to the report.
5. Finally, the “I agree” declaration check box must be ticked to allow the submission to proceed.

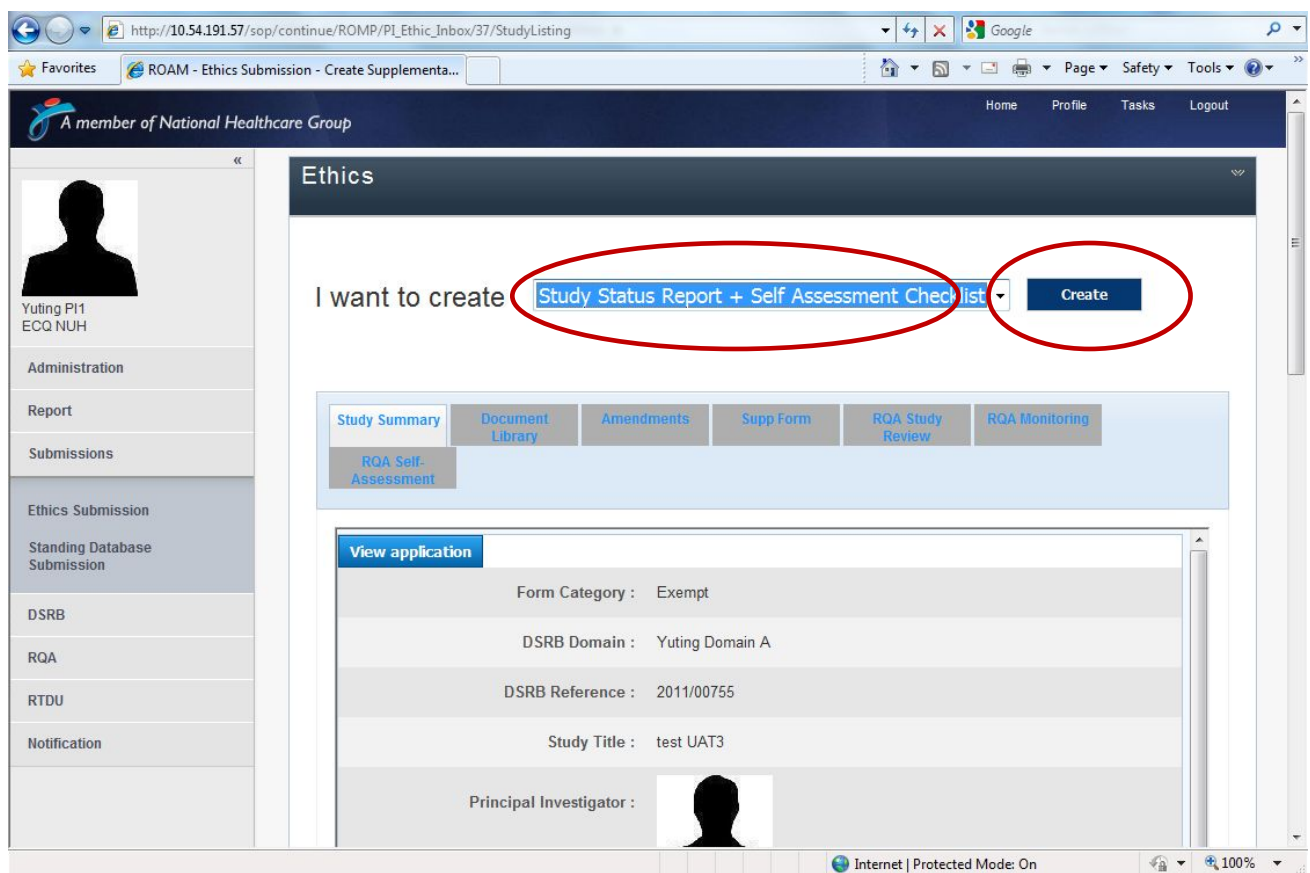


Figure 90 Creating a new Study Status Report

Figure 91 Study Status Report Form

Figure 92 Study Status Report Form II

Section D: Report On Research To Date

1. Did you encounter any problems relating to ethical issues?*

No

Yes- If "Yes", what were the problems and what did you do about them?

2. Did you comply with the approved consent procedures and documentation?*

Yes

No-If "No", please explain the reasons for the deviation.

3. Please state the document version number and/or version date of the consent document being currently used at the study site(s) if applicable.*

4. What measures are being taken to protect confidentiality of research data?*

(Eg: Where are the paper/electronic records stored? Are they access-controlled? Has there been any breach of the confidentiality of the research data?)

5. Are there any new proposed amendments to the current study?*

No

Yes-If "Yes", please submit the amended documents separately with the DSRB Study Amendment Form.

6. Are there any unanticipated events involving risks to subjects or others (including serious adverse events) at your trial sites, which have yet to be reported to the DSRB?*

No

Yes-If "Yes", please submit the reports using the Unanticipated Problems Involving Risks To Subjects or Others (UPIRTSO) Report Form before you submit this Study Status Report Form and quote UPIRTSO purposes.

7. Are there any DSMB reports, evaluation reports of study-wide adverse events, interim findings, recent literature, or any other information that may affect the risk/benefit ratio of this study?*

No

Yes-If "Yes", please submit the reports with this Study Status Report

8. Considering the information listed above, has anything occurred since the last DSRB review which may have altered the risk/benefit relationship?*

No

Yes-If "Yes", please provide a current assessment of the risk/benefit relationship of the research based on results, internal and external adverse events and other factors. Also, in your opinion, should any change be made based on these results?

Figure 93 Study Status Report Form III

Completion:

11. Have you published your research findings?*

No

Yes-If "Yes", please provide details (e.g. report, dissertation, thesis, journal article, book, etc). Include details such as where published (e.g. name of journal, book chapter, etc):

12. Have there been any complaints about the research?*

No

Yes-If "Yes", please provide details of the complaints.

13. For completed/terminated studies, will the leftover samples or data be destroyed at the completion of the study, or will they be stored for future use?*

Not Applicable

Yes, the samples or data will be destroyed.

No, the samples or data will NOT be destroyed

Attach any applicable document(s).

Document Title	Document Reference	Document Name	Document Date
Attach			

Declaration of Principal Investigator

I confirm that the information submitted in the above study status report is true and accurate at the date of submission of the report. By checking the "I agree" box, you confirm that you have read, understood and accept the Declaration of the Principal Investigator.

I agree

Next **Save Draft** **Cancel**

Figure 94 Study Status Report Form IV

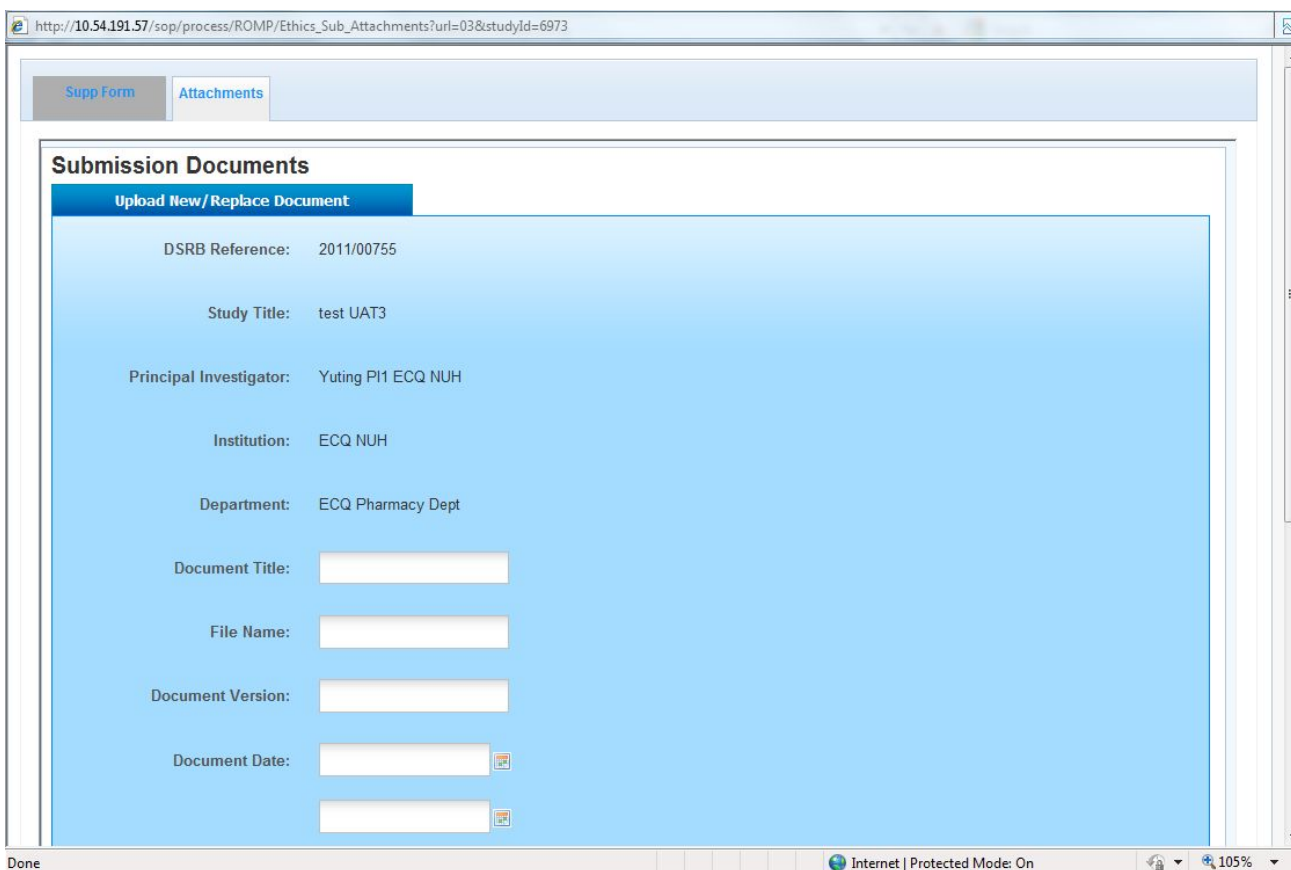


Figure 95 Study Status Attachments

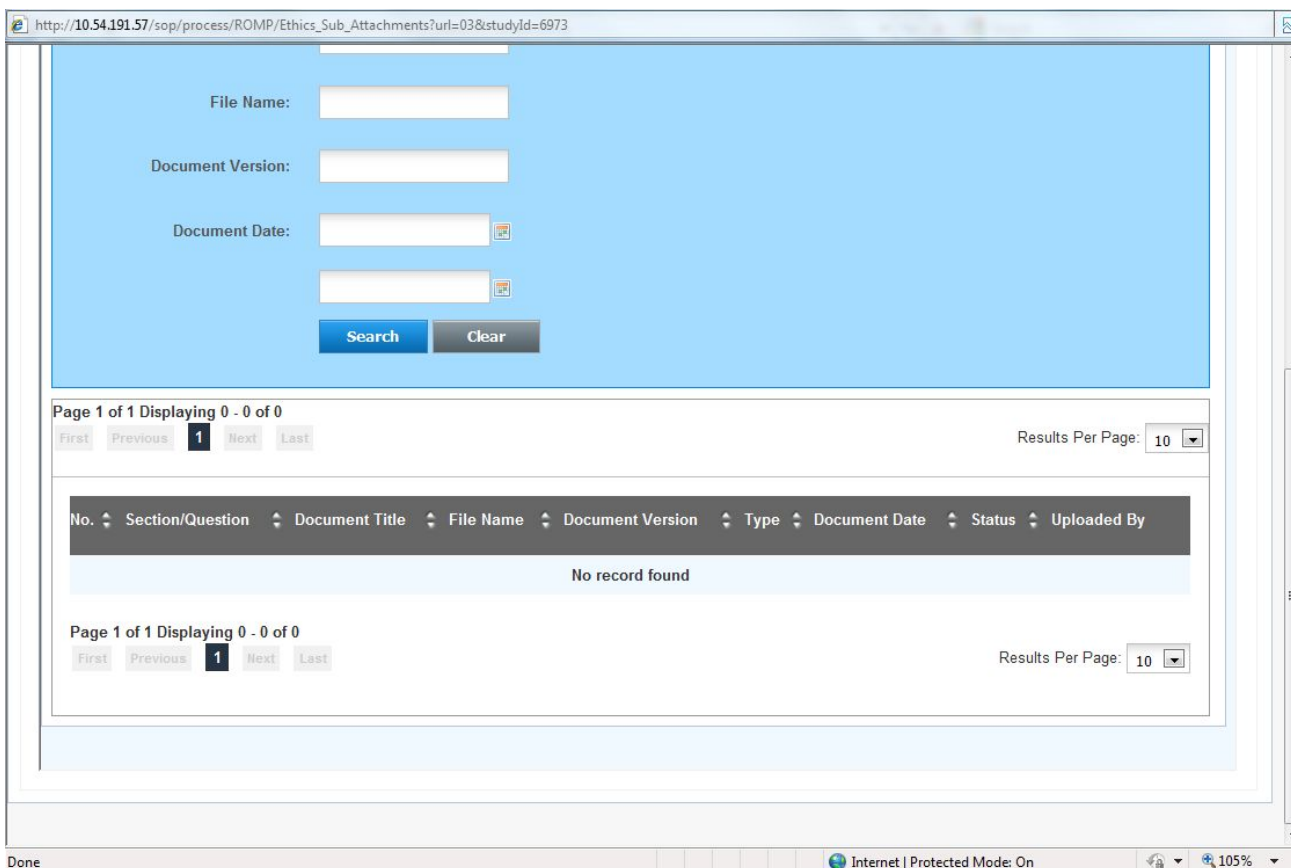


Figure 96 Study Status Attachments II

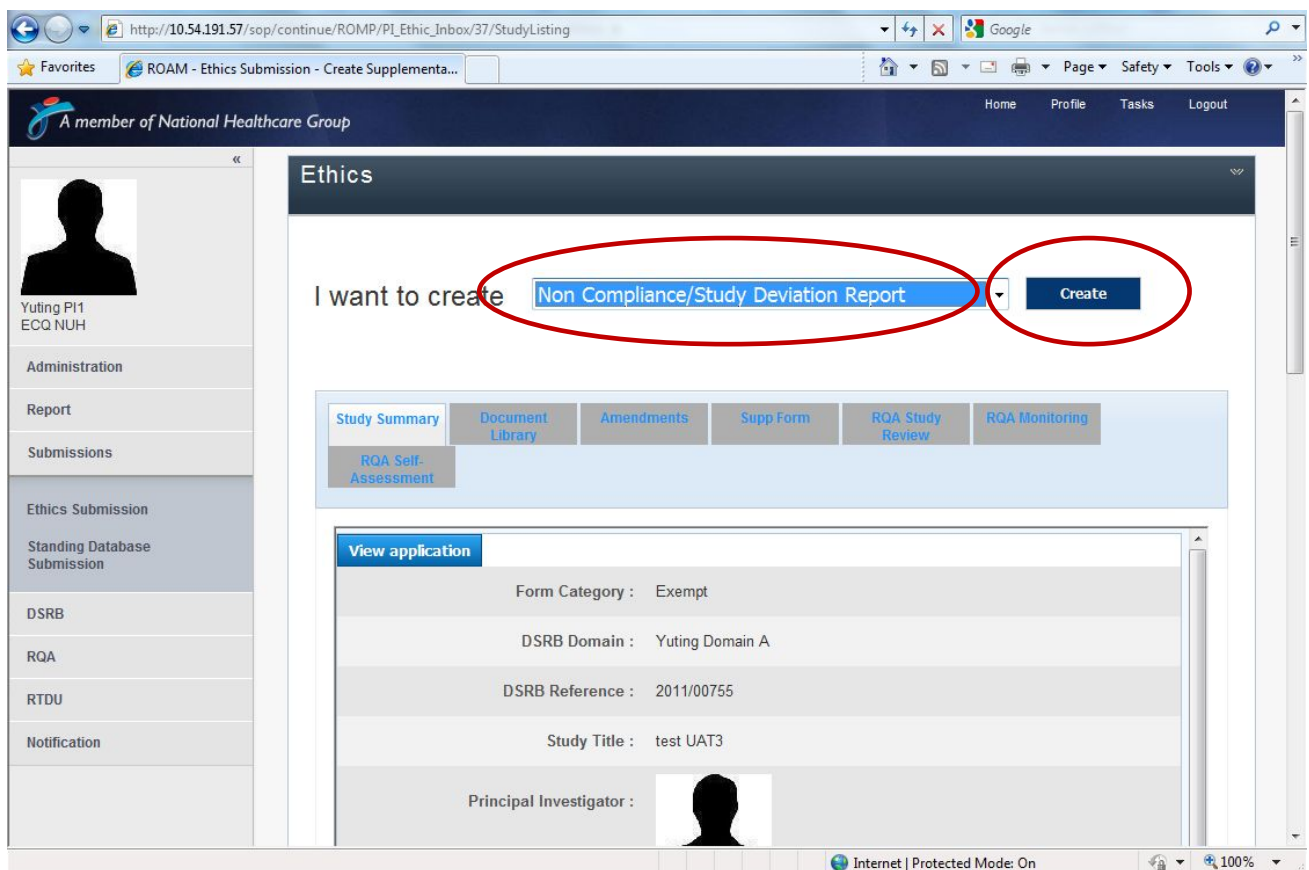


Figure 97 Creating a Non-compliance/ Study Deviation Report (NCR)

4.3 Creating a Non-Compliance Report (NCR)

6. In filing this Report, the NCR Form is used.
7. Each individual non-compliance report requires one submission.
8. For supporting documents, clicking on Attach will allow you to upload related documents pertaining to the report.
9. Finally, the “I agree” declaration check box must be ticked to allow the submission to proceed.

http://10.54.191.57/sop/process/ROMP/Ethics_Sub_Attachments?url=04&studyId=6973

Supp Form Attachments

NCR Form

Non Compliance/Study Deviation Report

*Denotes compulsory fields

Form Status: Submission Draft
 Form ID: 2011/00755-NCR0001
 DSRB Reference Number: 2011/00755
 Study Title: test UAT3
 Principal Investigator: Yuting PI1 ECQ NUH
 Institution: ECQ NUH
 Department: ECQ Pharmacy Dept

1. Date of Non-Compliance/Study Deviation *

2. Please describe in detail the nature of the Non-Compliance/Study Deviation including the date of occurrence.*

3. Explain why or how the Non-Compliance/Study Deviation occurred. Describe the outcome of the Non-Compliance/Study Deviation.*

4. In your judgement, did the Non-Compliance/Study Deviation affect the rights or welfare of the Research Participant and/or others?*

Done Internet | Protected Mode: On 105%

Figure 98 Non-compliance Report Form

http://10.54.191.57/sop/process/ROMP/Ethics_Sub_Attachments?url=04&studyId=6973

6. Describe any follow up action taken to prevent this Non-Compliance/Study Deviation from occurring in the future.*

7. Do you have any other comments on the Non-Compliance/Study Deviation?*

8. Has this Non-Compliance/Study Deviation been reported to the sponsor?
 Not applicable as there is no study sponsor.
 No If "No", please provide rationale for not reporting:
 Yes If "Yes", please describe what the sponsors response is:

9. Has this Non-Compliance/Study Deviation been reported to any other relevant authorities?
 Not applicable as this research is not under the governance of any other relevant authorities.
 No
 Yes

10. Attach any applicable document(s).

Document Title	Document Reference	Document Name	Document Date
<input type="button" value="Attach"/>			

Principal Investigator's Declaration
 I confirm that the information submitted in the above Non Compliance/Study Deviation Report is true and accurate at the date of submission of the report.
 By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration.

I agree

Done Internet | Protected Mode: On 105%

Figure 99 NCR Form II

Figure 100 NCR Attachments II

4.4 Creating an UPIRTSO Report

10. In filing an UPIRTSO Report, a maximum of 20 incidents that can be reported in the same form.
11. Each individual incident requires clicking on Add New Event to add a new row of details.
12. For supporting documents, clicking on Attach will allow you to upload related documents pertaining to the report.
13. Finally, the “I agree” declaration check box must be ticked to allow the submission to proceed.

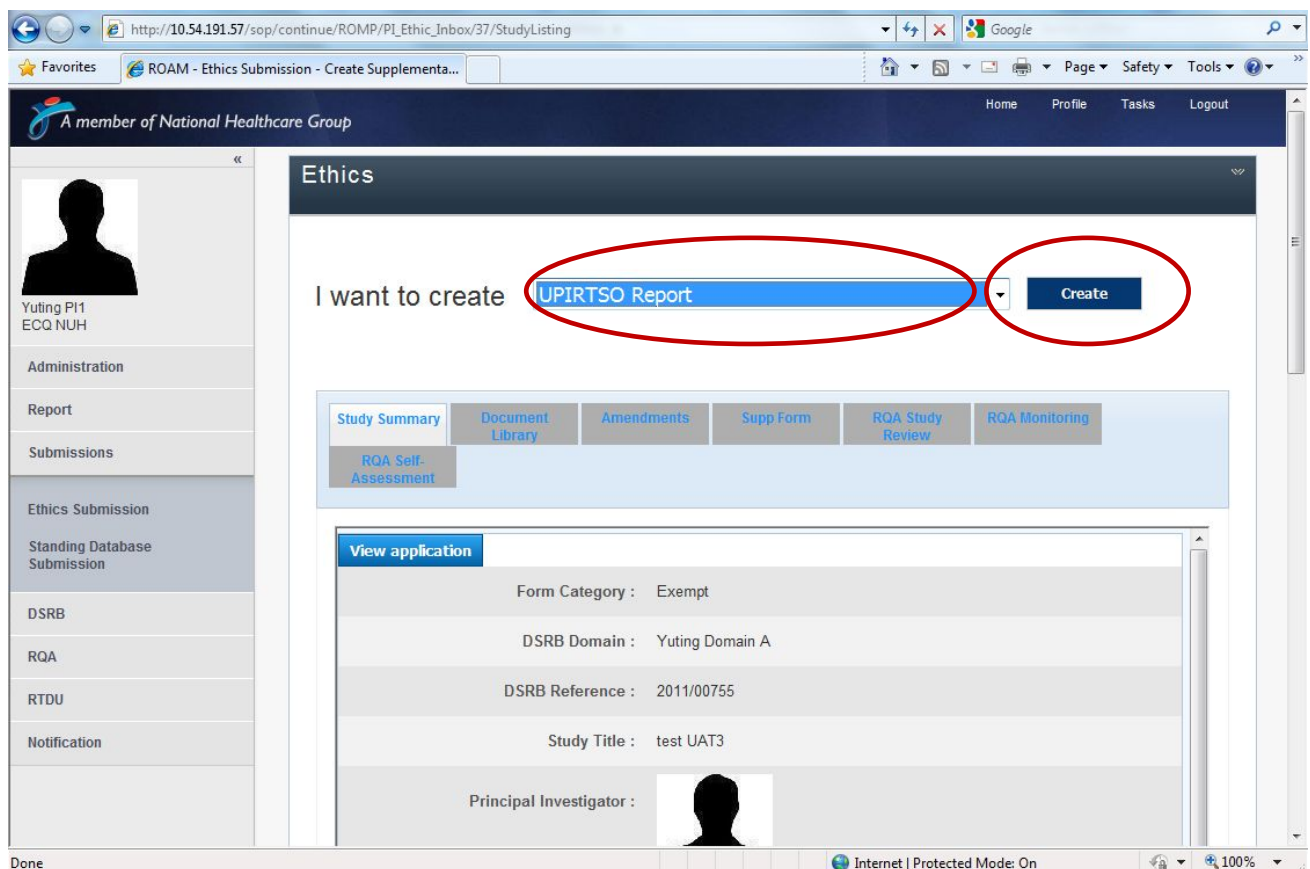


Figure 101 Creating an UPIRTSO Report

http://10.54.191.57/sop/process/ROMP/Ethics_Sub_Attachments?url=05&studyId=6973

Supp Form Attachments

UPT Form

UPIRTSO Reporting Form (Single/Multiple Event/s)

*Denotes compulsory fields

Form Status: Submission Draft
 Form ID: 2011/00755-UPT0001
 DSRB Reference Number: 2011/00755
 Study Title: test UAT3
 Principal Investigator: Yuting PI1 ECQ NUH
 Institution: ECQ NUH
 Department: ECQ Pharmacy Dept

Events (Maximum 20)

No.	Event Onset Date	Study Site	Death at Study Site Under The Oversight of NHG DSRB	Event Keywords	Study's risk-benefit ratio has changed
Add New Event					

Attach any applicable document(s).

Document Title	Document Reference	Document Name	Document Date
Attach			

Principal Investigator's Declaration
 I confirm that the information submitted in the above UPIRTSO report is true and accurate at the date of submission of the report.
 By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration.

I agree

Figure 102 UPIRTSO Form

http://10.54.191.57/sop/process/ROMP/Ethics_Sub_Attachments?url=05&studyId=6973

UPIRTSO Reporting Form (Single/Multiple Event/s)

*Denotes compulsory fields

Form Status: Submission Draft
 Form ID: 2011/00755-UPT0001
 DSRB Reference Number: 2011/00755
 Study Title: test UAT3
 Principal Investigator: Yuting PI1 ECQ NUH
 Institution: ECQ NUH
 Department: ECQ Pharmacy Dept

Events (Maximum 20)

No.	Event Onset Date	Study Site	Death at Study Site Under The Oversight of NHG DSRB	Event Keywords	Study's risk-benefit ratio has changed
Add New Event					

Attach any applicable document(s).

Document Title	Document Reference	Document Name	Document Date
Attach			

Principal Investigator's Declaration
 I confirm that the information submitted in the above UPIRTSO report is true and accurate at the date of submission of the report.
 By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration.

I agree

[Submit](#) [Save Draft](#) [Cancel](#)

Figure 103 UPIRTSO Form II

4.5 Creating Other Study Notifications

1. For filing other notifications that are not specifically classified, the Other Study Notifications form is used. Each individual notification requires one submission.
2. To upload and manage supporting documents, clicking on Attachments will allow you to use the standard upload screen.
3. Finally, the “I agree” declaration check box must be ticked to allow the submission to proceed.

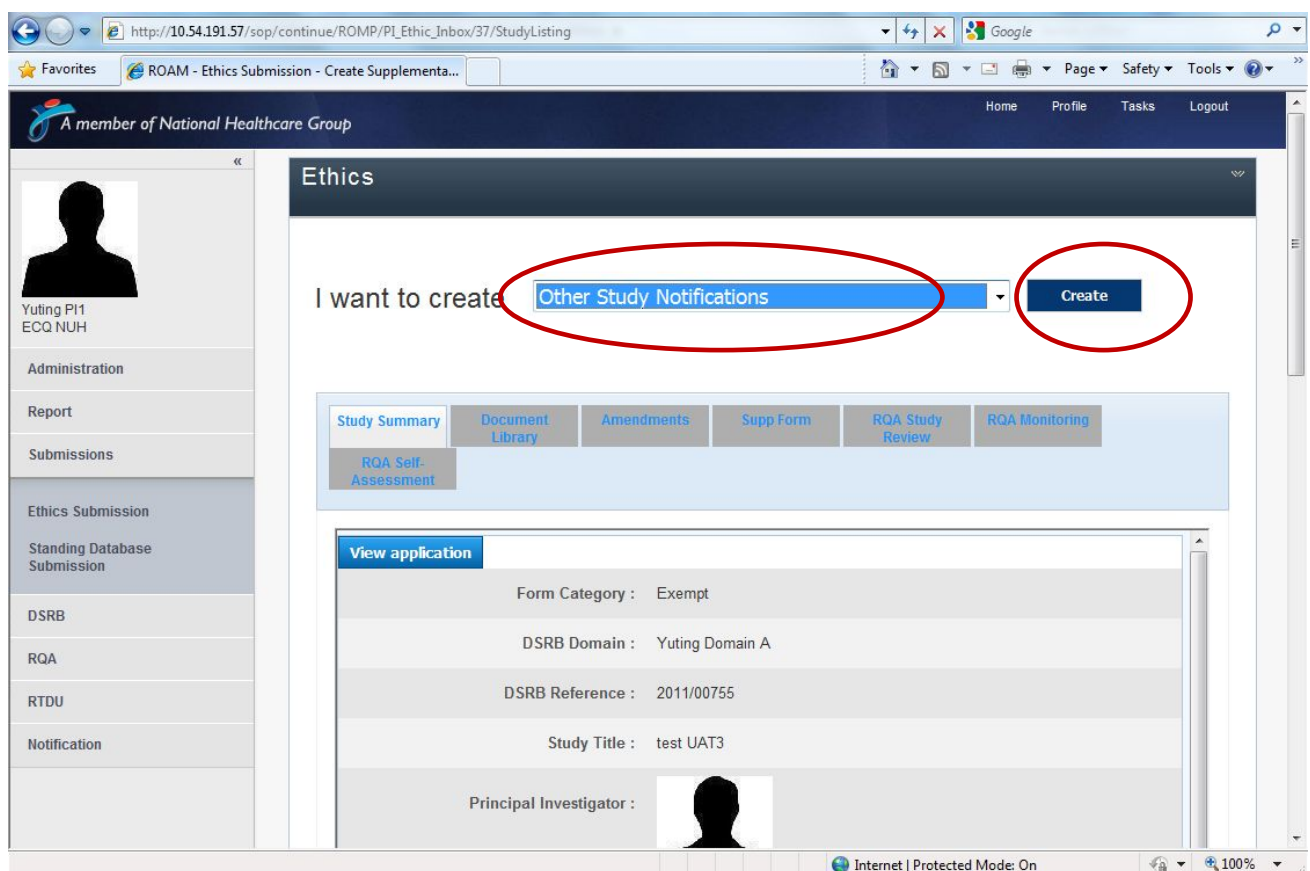


Figure 104 Creating Other Study Notifications

Figure 105 Other Study Notifications Form

Figure 106 Other Study Notifications Form II

5 EVENTS

1. Events are training sessions that PIs can sign up for. The sessions are managed by the Training Unit.

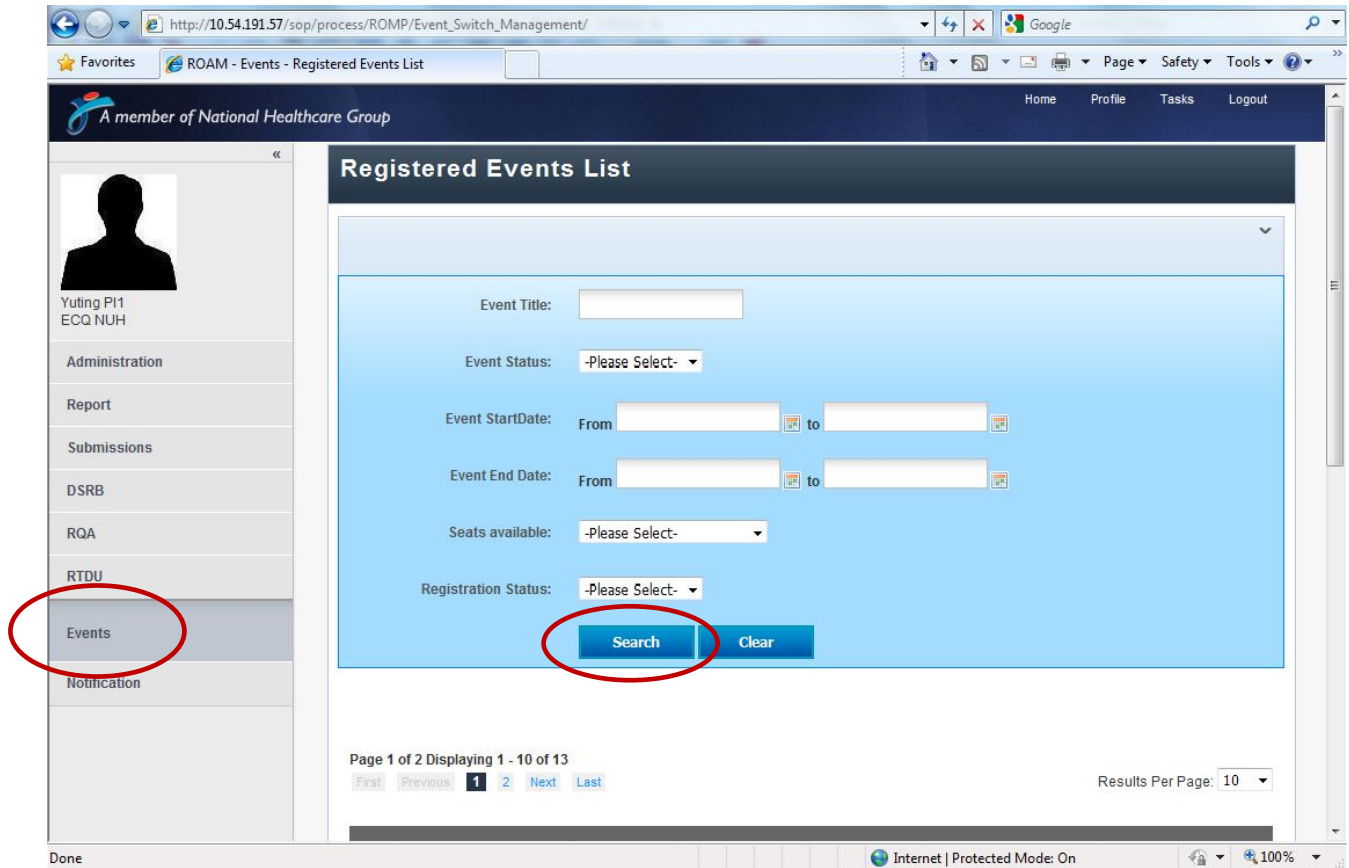


Figure 107 Events main screen

2. The screen consists of the standard Search screen, followed by a list of all the events that are available and their statuses.
3. To view an event for information and registration, click on the icon on the rightmost of the event row.
4. Within the Event form itself, you can Register or Withdraw from a previously registered event.

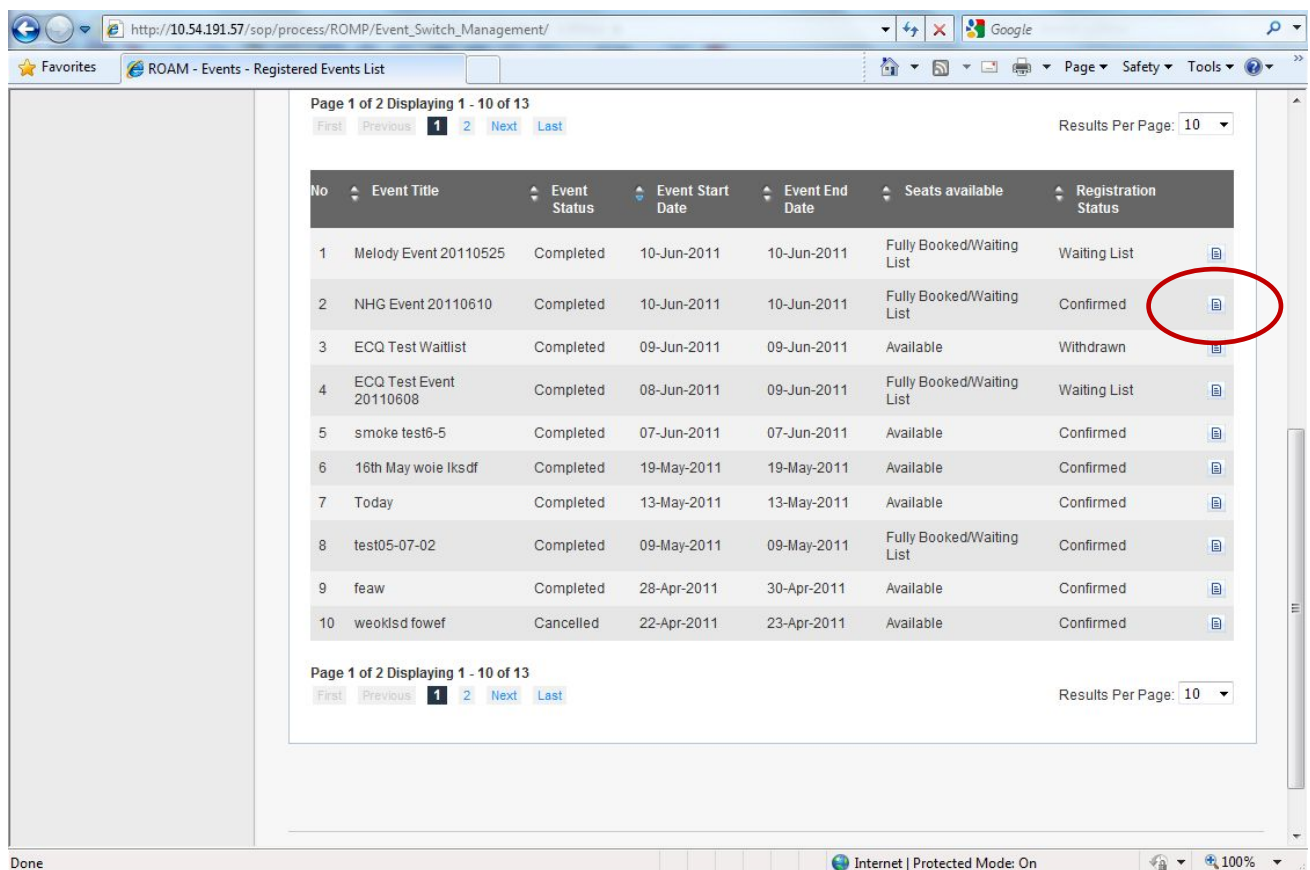


Figure 108 Events main screen II

The screenshot shows a web browser window with the URL http://10.54.191.57/sop/continue/ROMP/Events_User_Manage_Event/38/userEventList. The page header includes the National Healthcare Group logo and navigation links for Home, Profile, Tasks, and Logout. A sidebar on the left shows a user profile for 'Yuting PI1 ECQ NUH' and a menu with options like Administration, Report, Submissions, DSRB, RQA, RTDU, Events, and Notification. The main content area is titled 'Events' and 'Events Detail'. It displays the following information:

- Event: * Melody Event 20110525
- Event Date(s)/Time: * 10-Jun-2011 09:00-13:00
- Venue: * NUH Institute 01
- PublishDate: * From 05-Jun-2011 to 10-Jun-2011
- Closing Date for Registration: * 09-Jun-2011
- Registration Fee: *

Type of Participants	Fee
Category 1	\$100
Category 2	\$200
Category 3	\$300
- Seats Available: * Fully Booked/Waiting List
- Who should attend: * Principal Investigators, Researchers, Research Administrators
- Certification Nature: * Certificate of Attendance
- Certification Template: * Certificate of Attendance

Figure 109 Specific event Form

The screenshot shows the same web browser window as Figure 109, but displaying a different section of the event form. The information shown includes:


- Research Administrators
- Certification Nature: * Certificate of Attendance
- Certification Template: * Certificate of Attendance
- Certificate Downloadable By User: Yes
- Approval Type: Auto Accept
- Registration Required: Yes
- Synopsis: This event is for Melody's testing.
- Speakers' Info:
 - Speaker 1:  Britney is a event organiser.
 - Britney is a event organiser.
 - Britney is a event organiser.
 - Britney is a event organiser.

Figure 110 Event form II

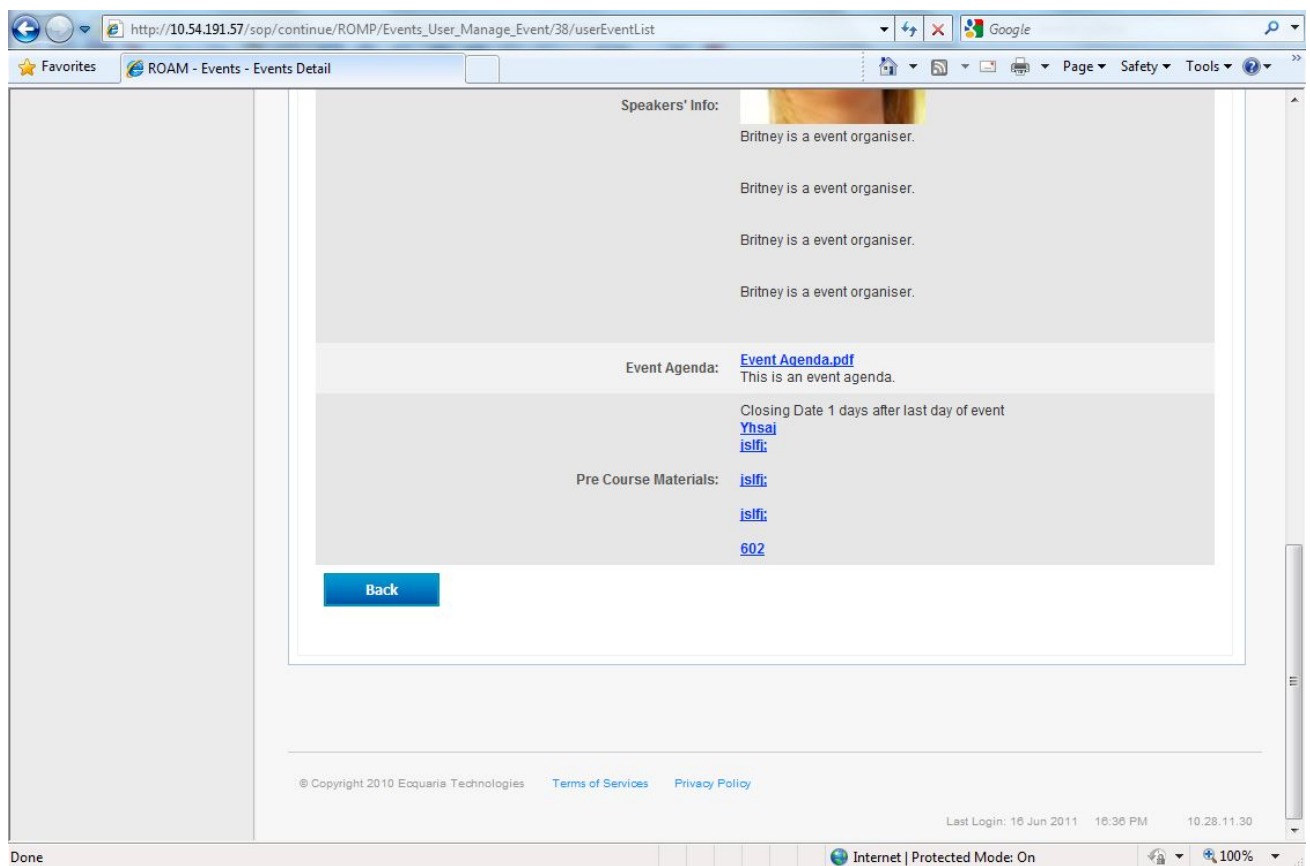


Figure 111 Event form III

End of Document