National Healthcare Group

Adding years of healthy life

NHG ROAM

Research Online Administration & Management

General Guidebook for Researchers

Version 1

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1 ACCESSING THE PI USER ACCOUNT

- User Interface Functions
- Submitting New Studies
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  - Events
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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

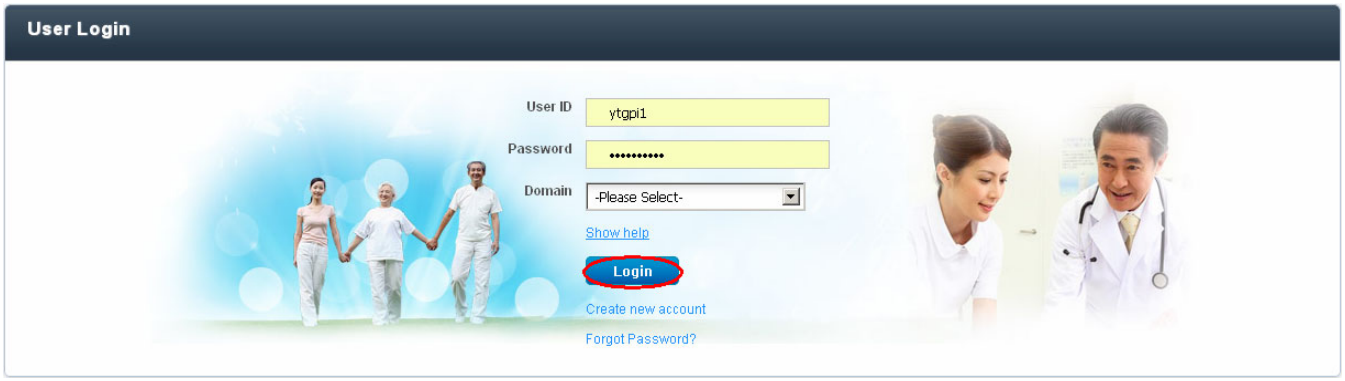


Figure 1 - Login Page

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.

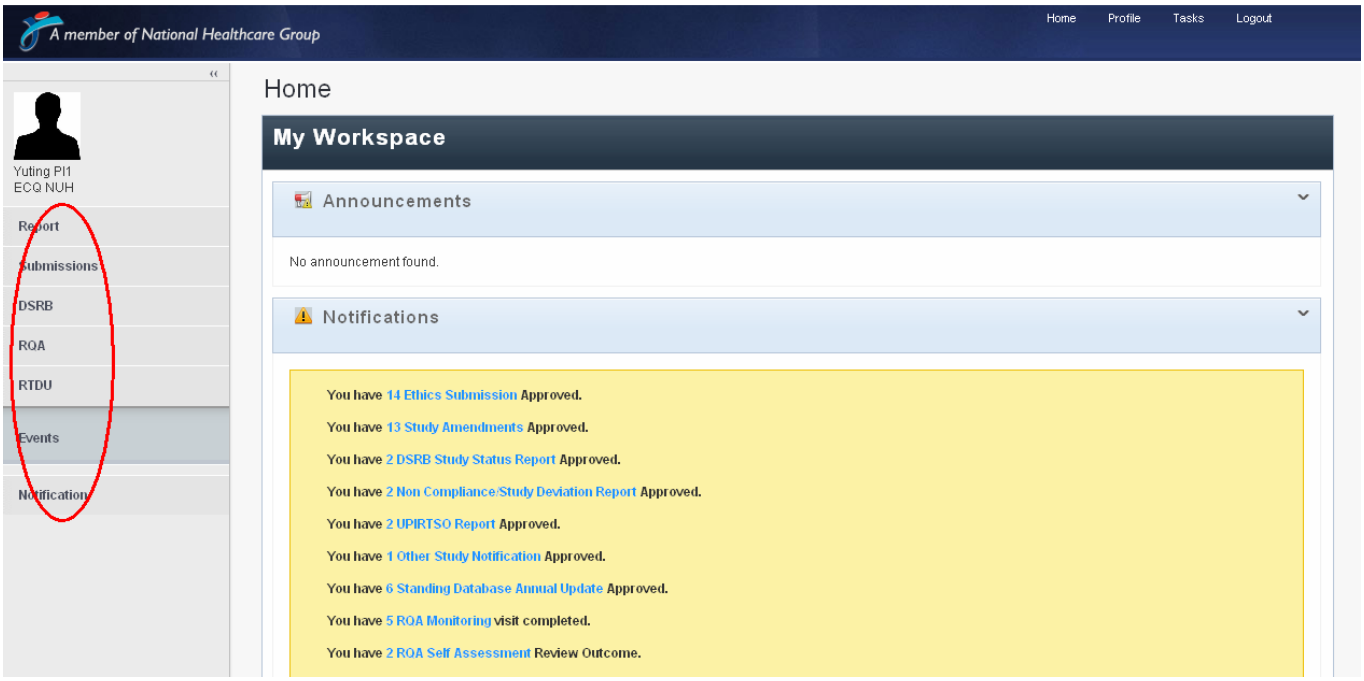
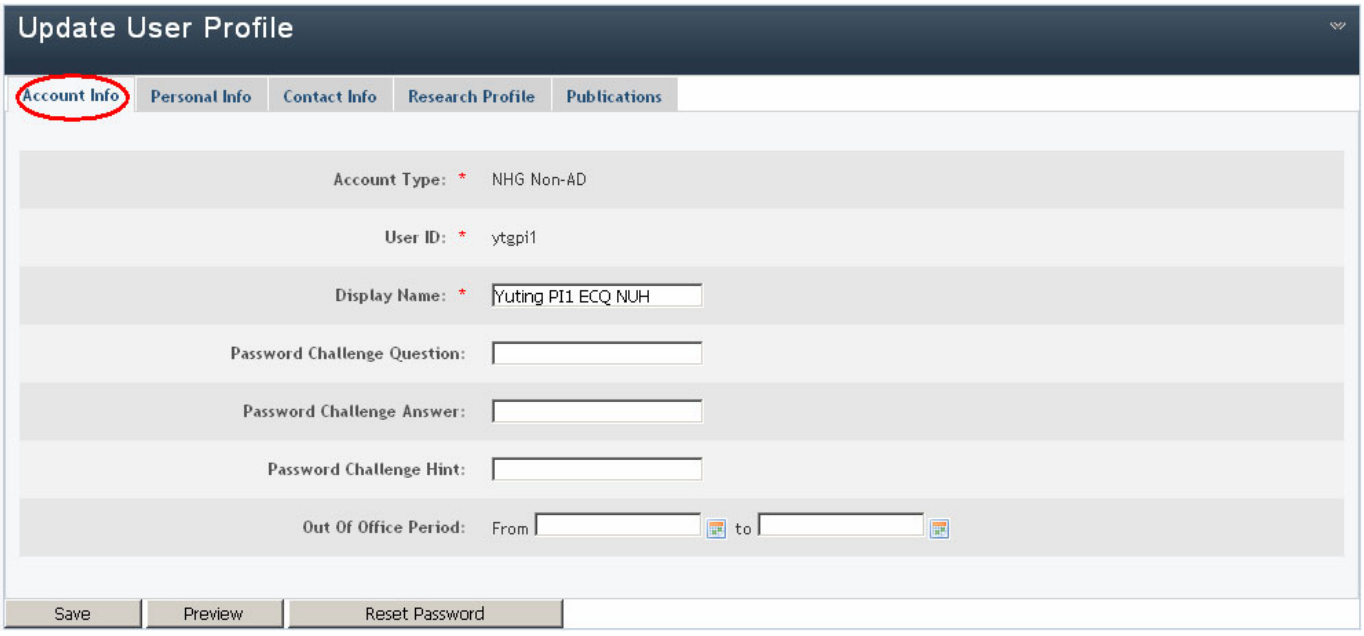
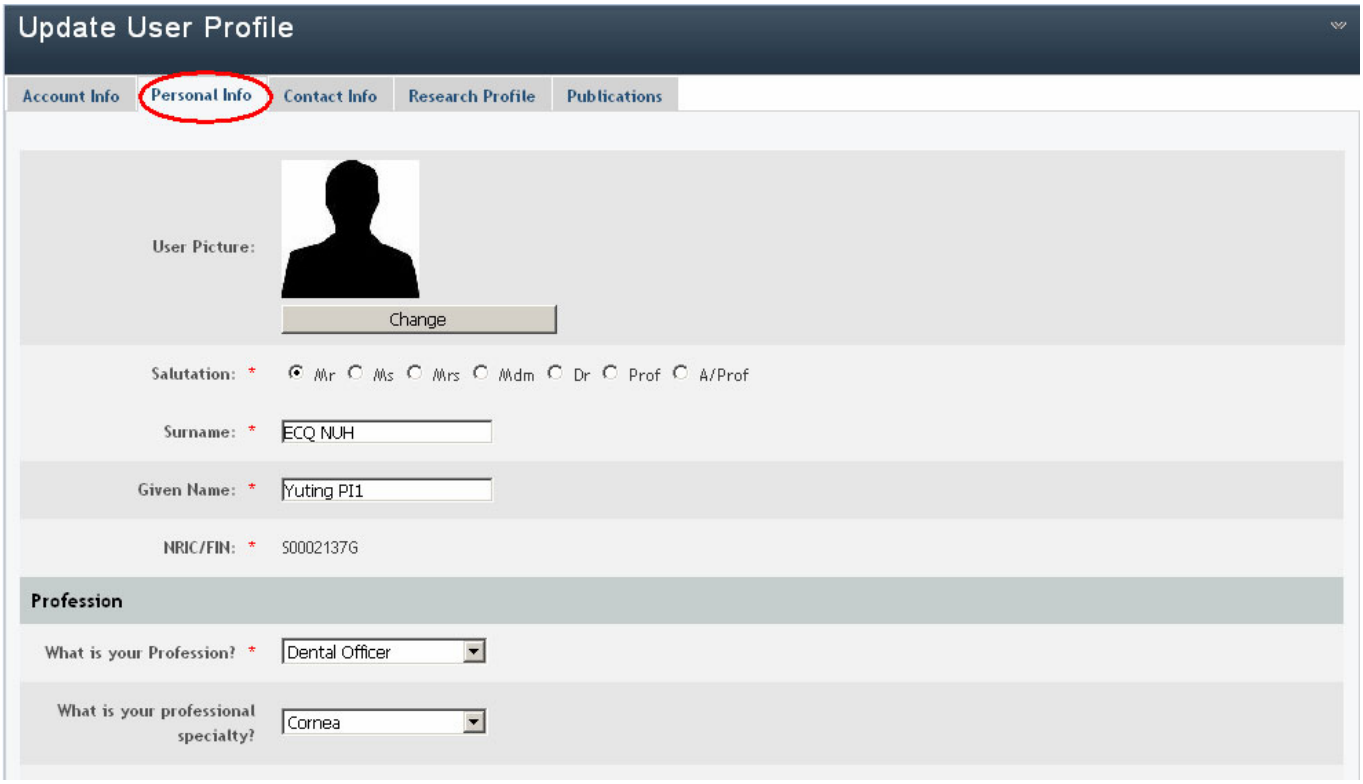


Figure 2 - User Homepage

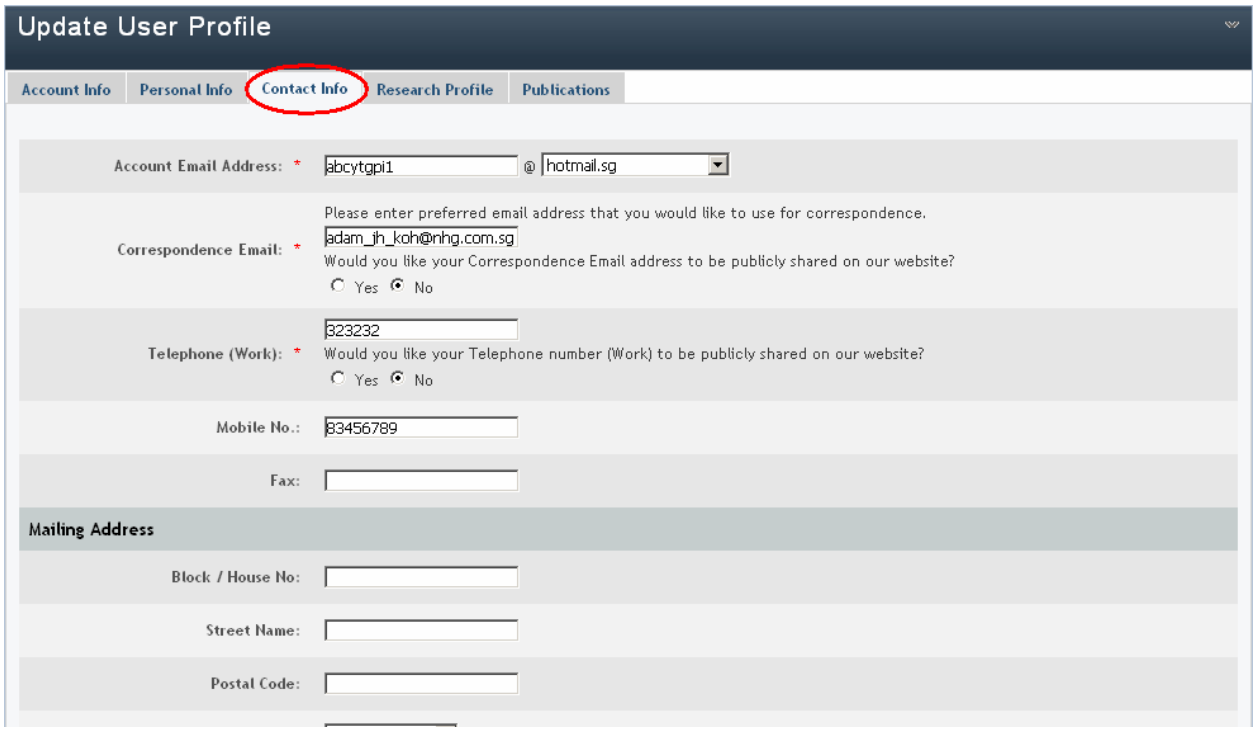
5.2 Editing and changing of user profile.



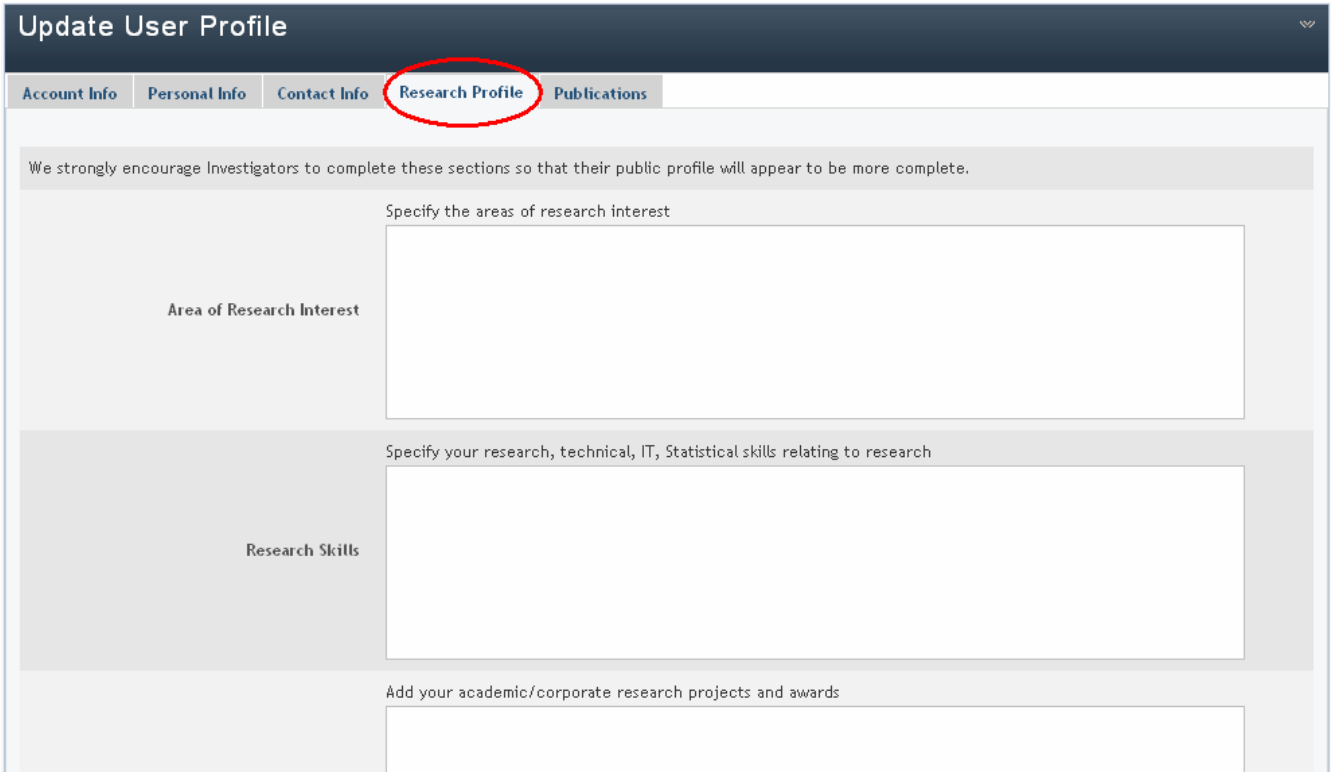
1. User could update their profile by clicking on the ‘Profile’ button
2. Edit the User Account Info.



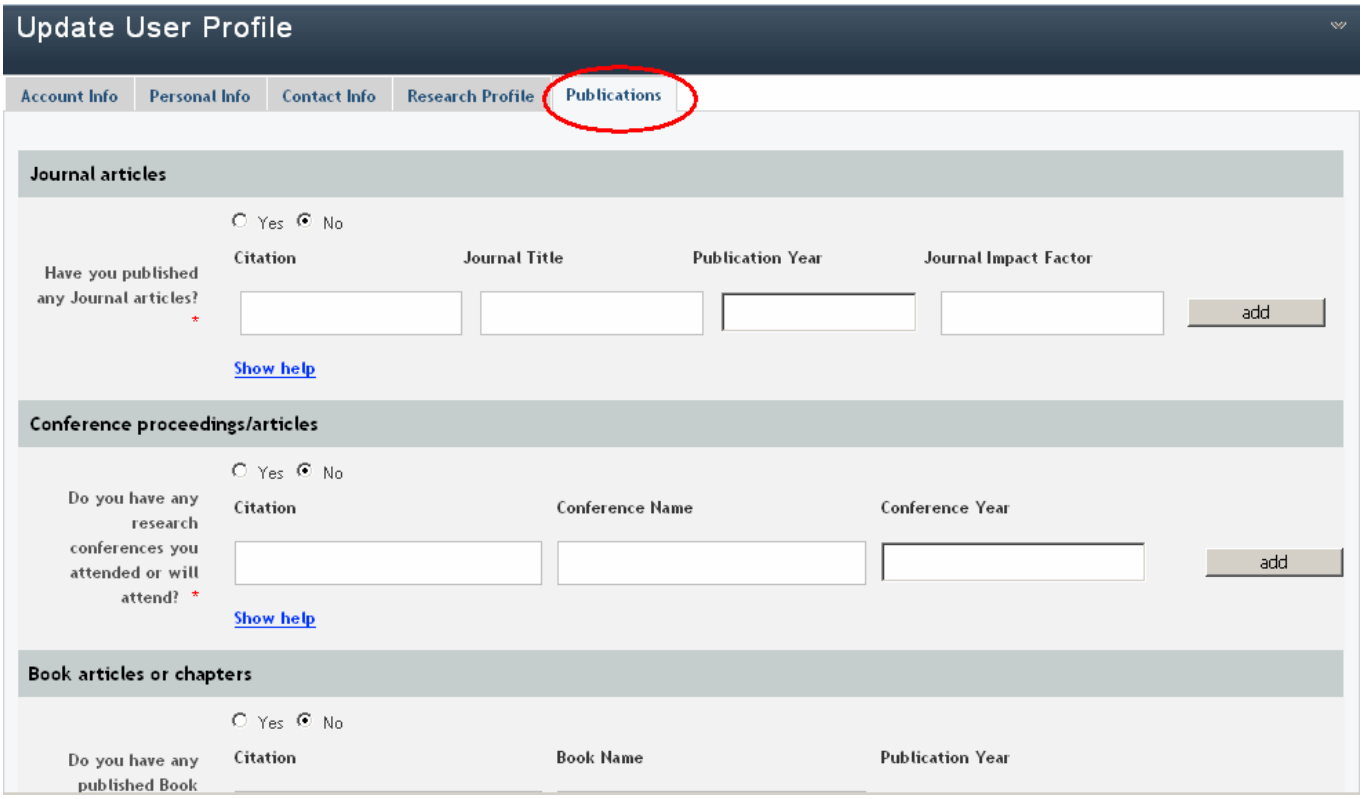
3. Edit the Personal Info.



4. Edit the Contact Info.



5. Edit the Research Profile.



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.

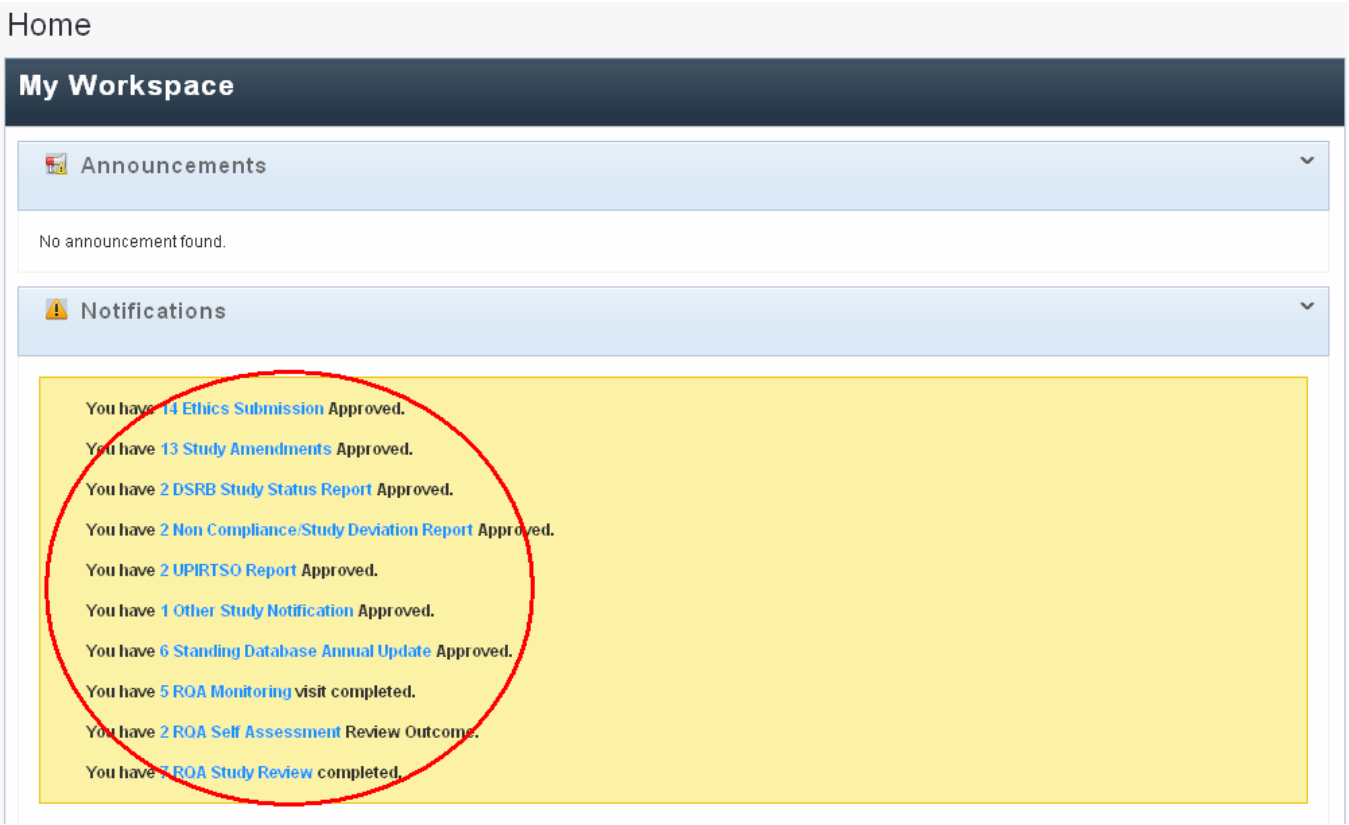


Figure 2 - PI User Homepage_Notification

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

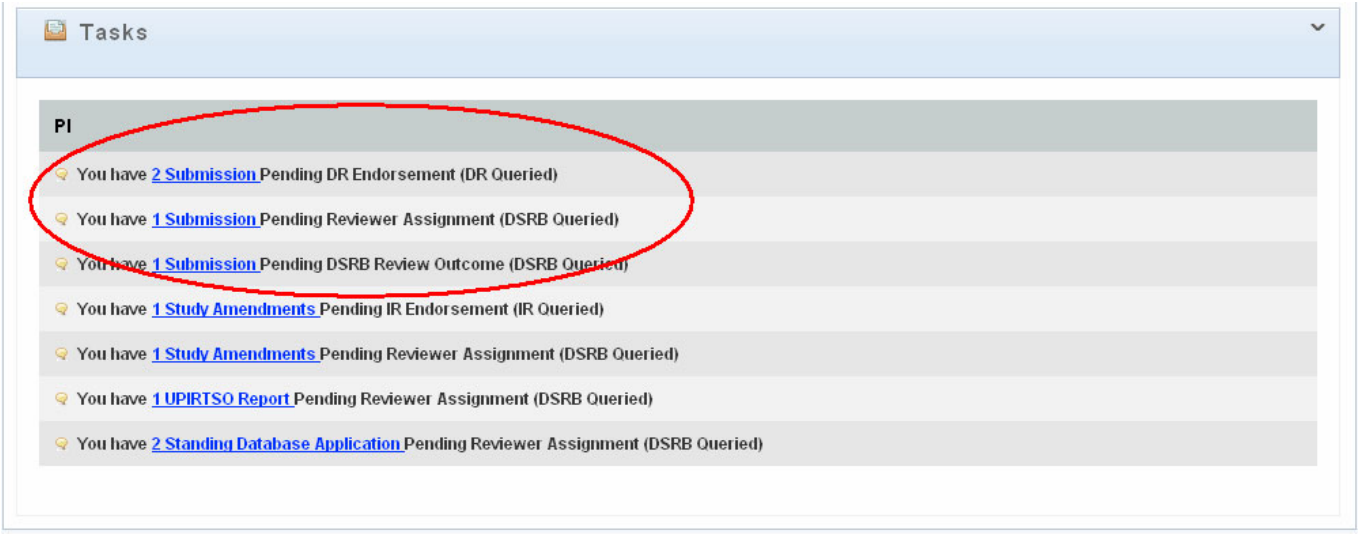


Figure 3 - PI User Homepage_Tasks

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.

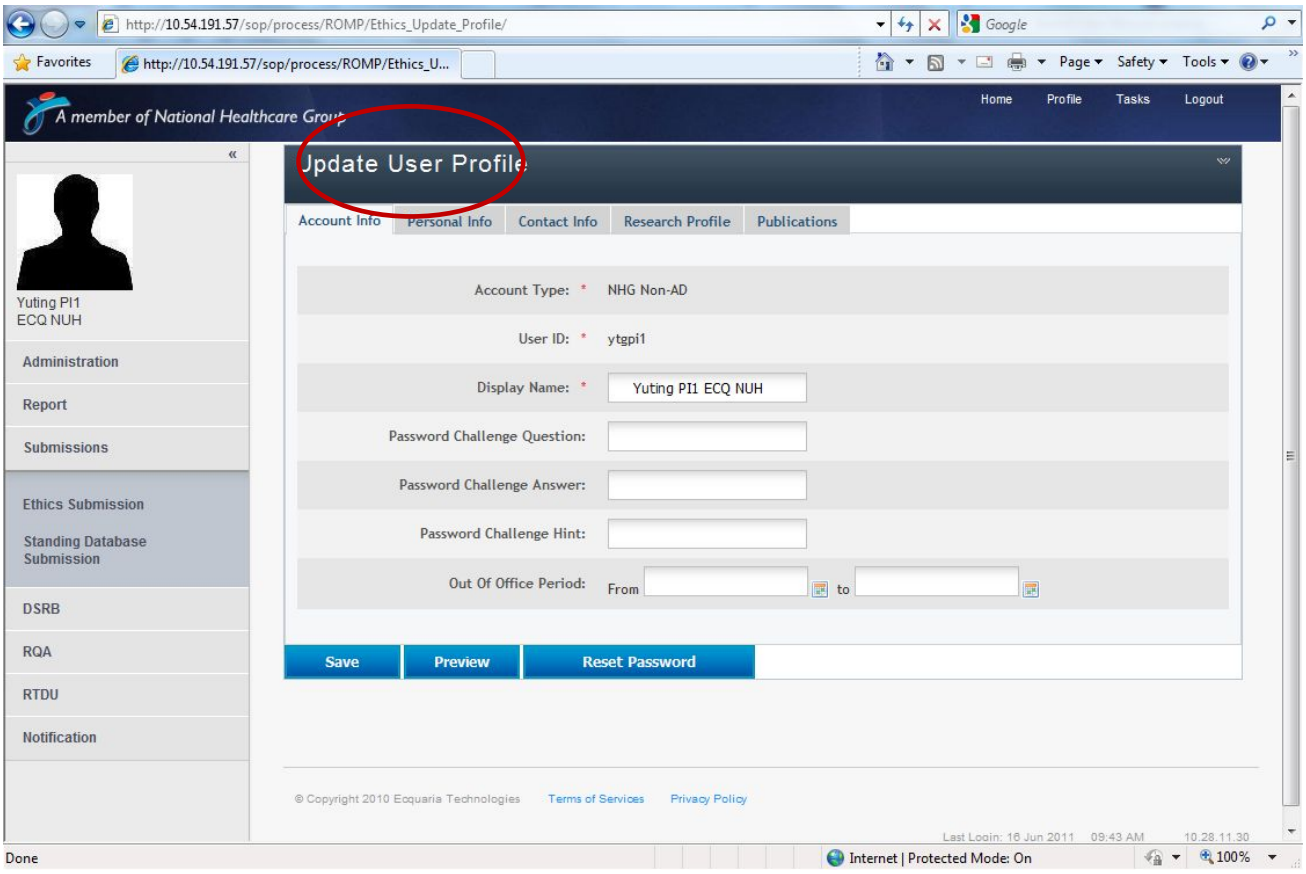


Figure 3 User Profile: Account Info

1.2.2 Personal Information

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

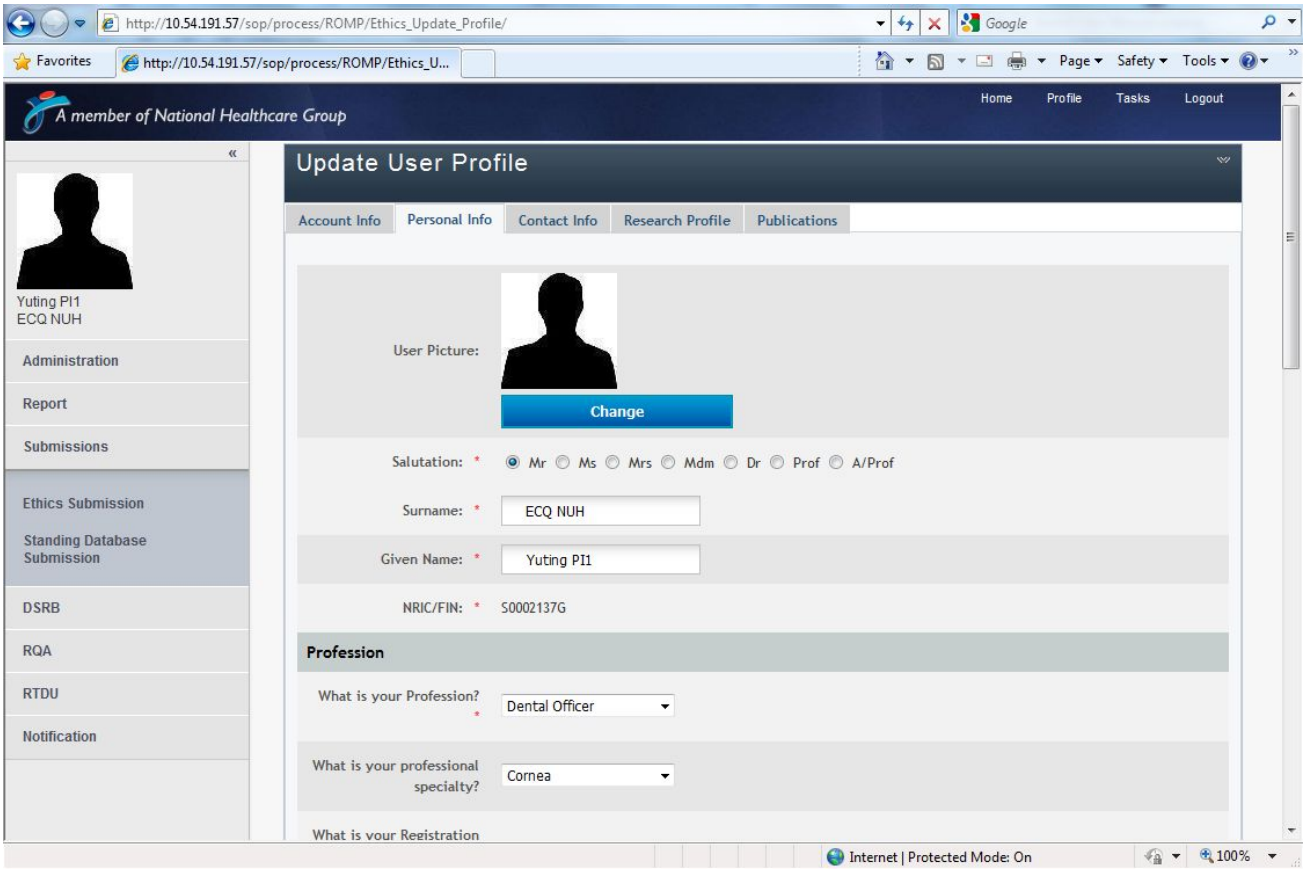


Figure 4 User Profile : Personal Info I

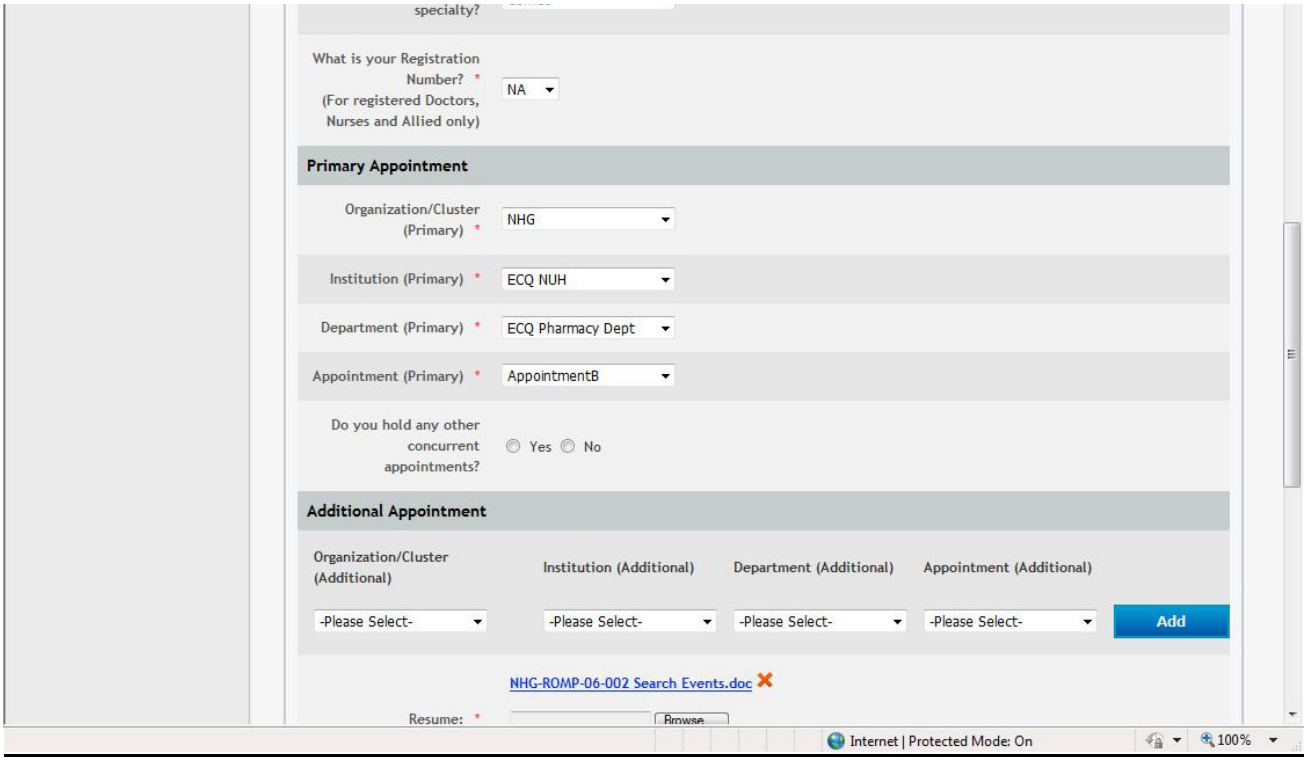


Figure 5 User Profile : Personal Info II

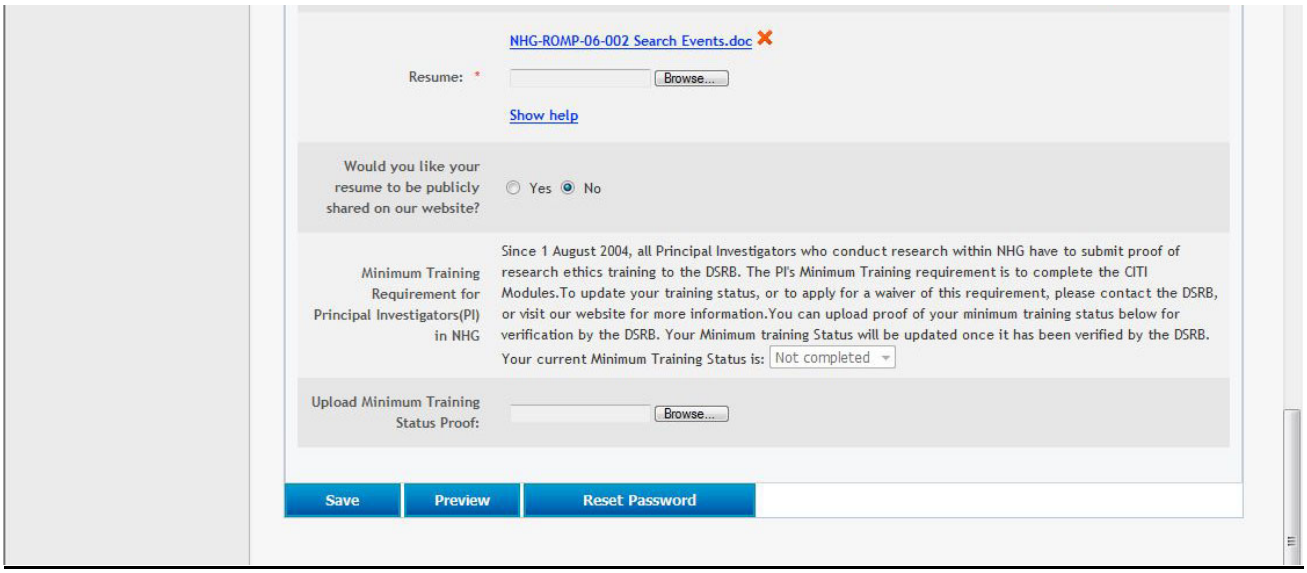


Figure 6 User Profile : Personal Info III

1.2.3 Contact Information

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

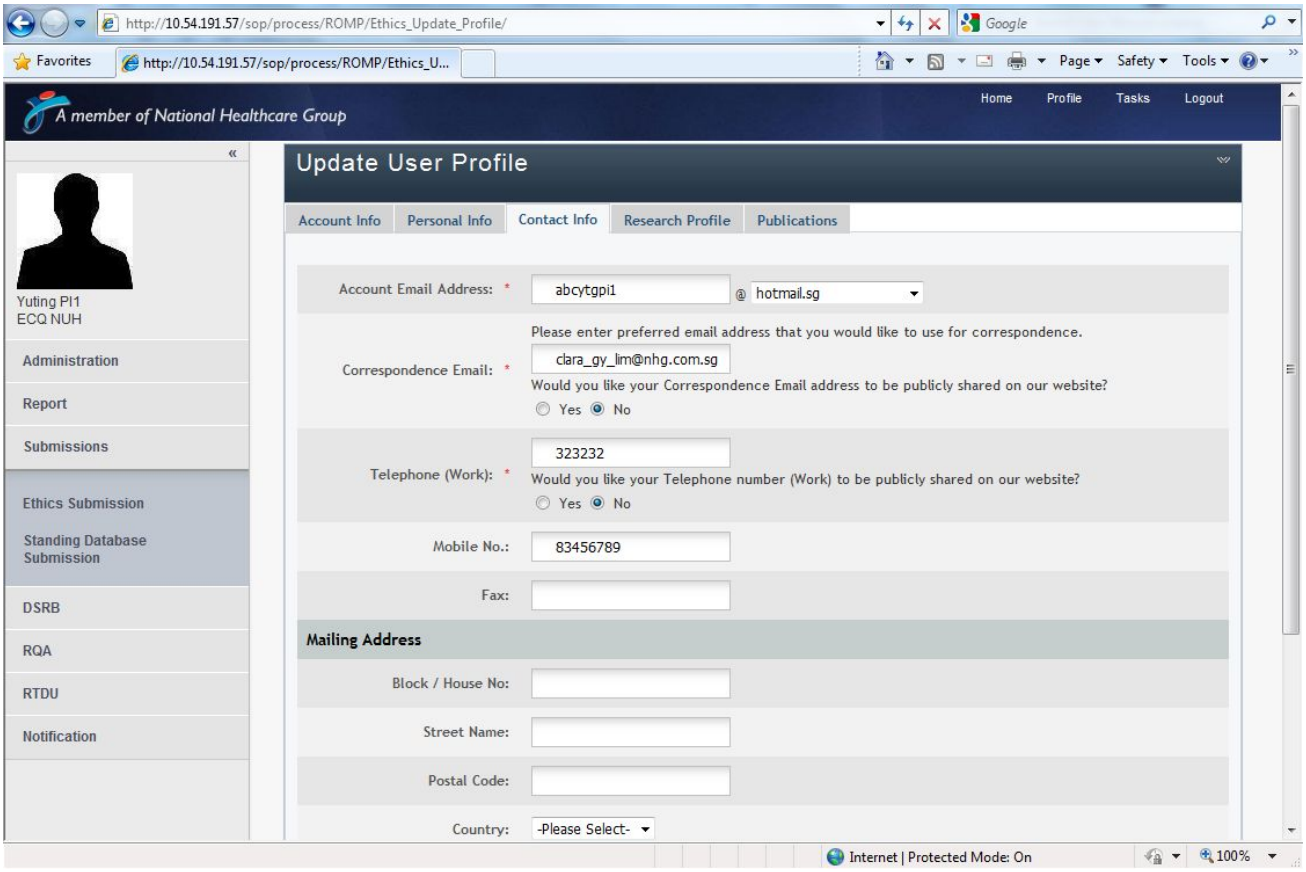


Figure 7 User Profile: Contact Info

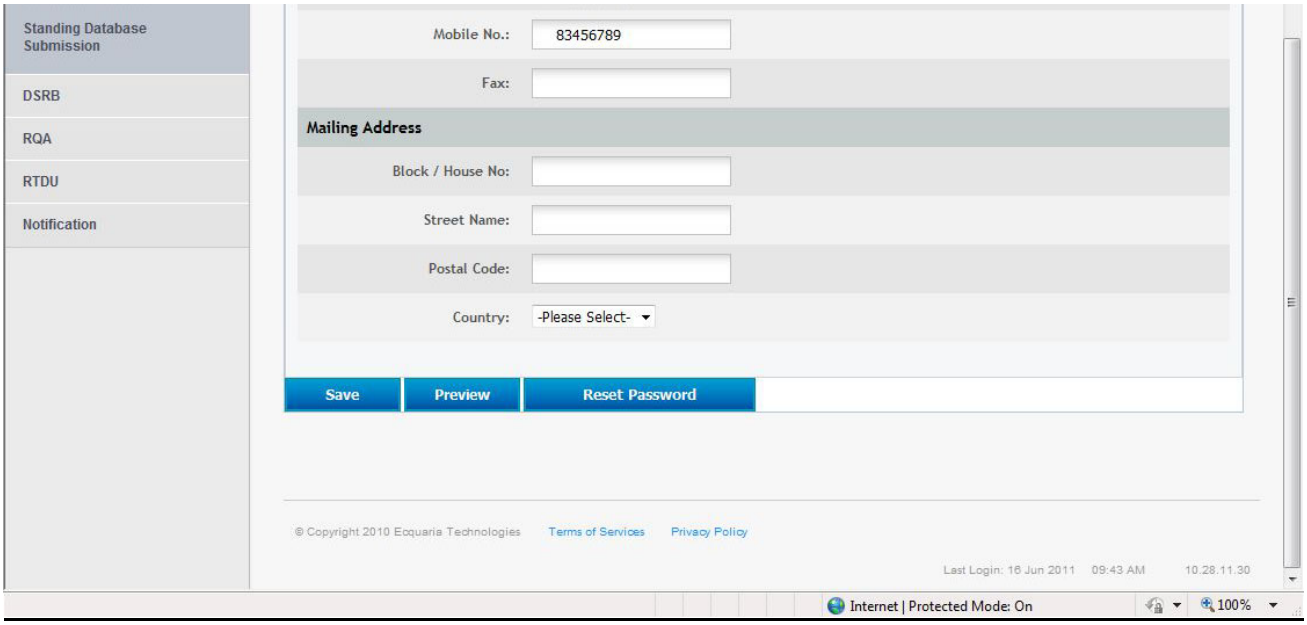


Figure 8 User Profile: Contact Info II

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.

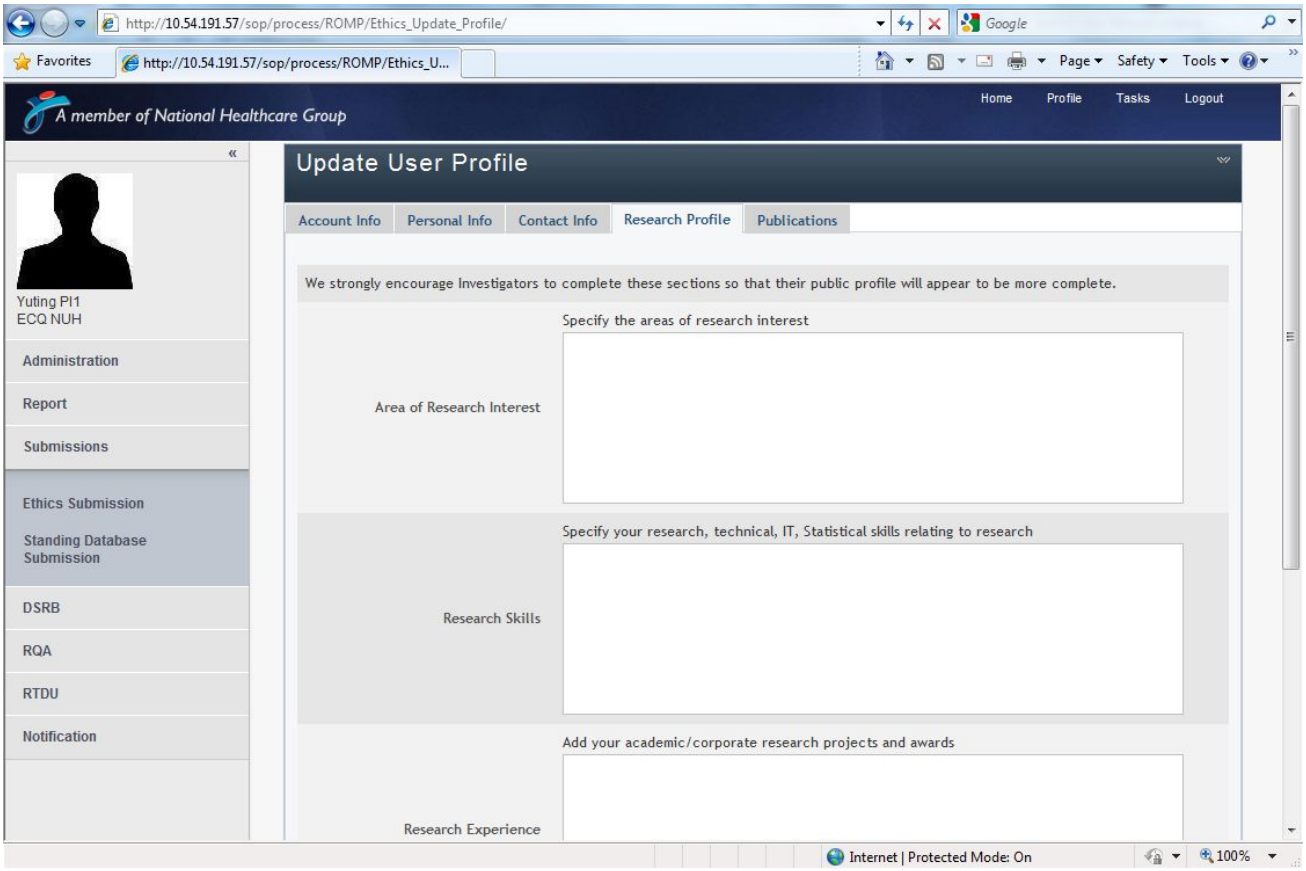


Figure 9 User Profile: Research Profile

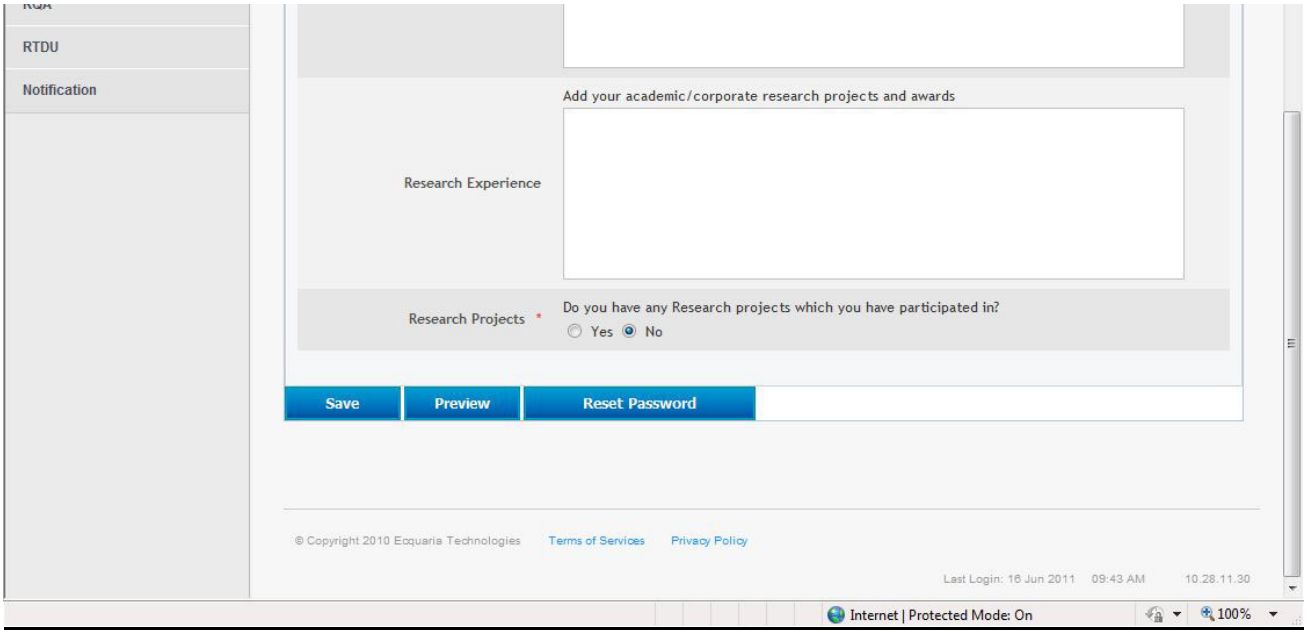


Figure 10 User Profile: Research Profile

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.

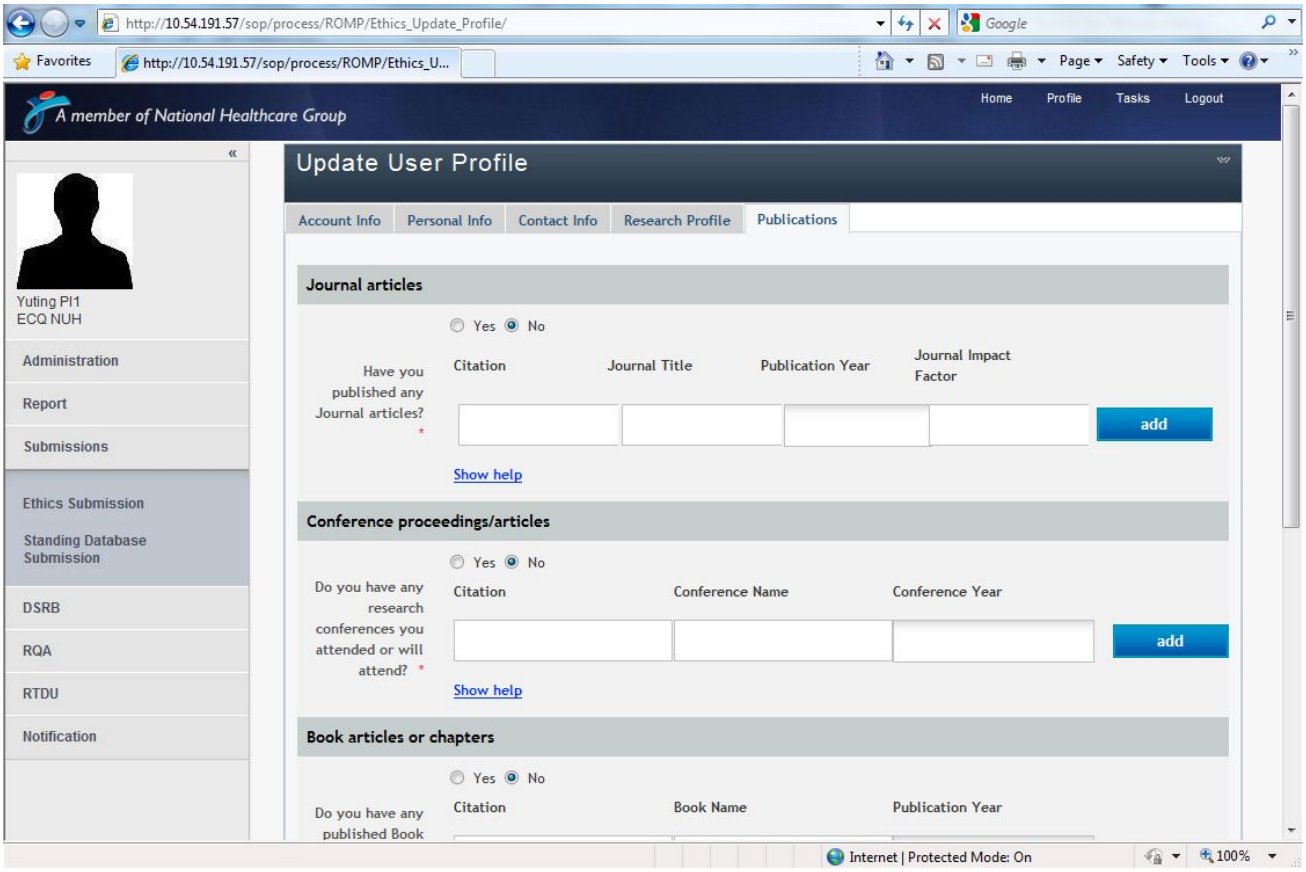


Figure 11 User Profile: Publications

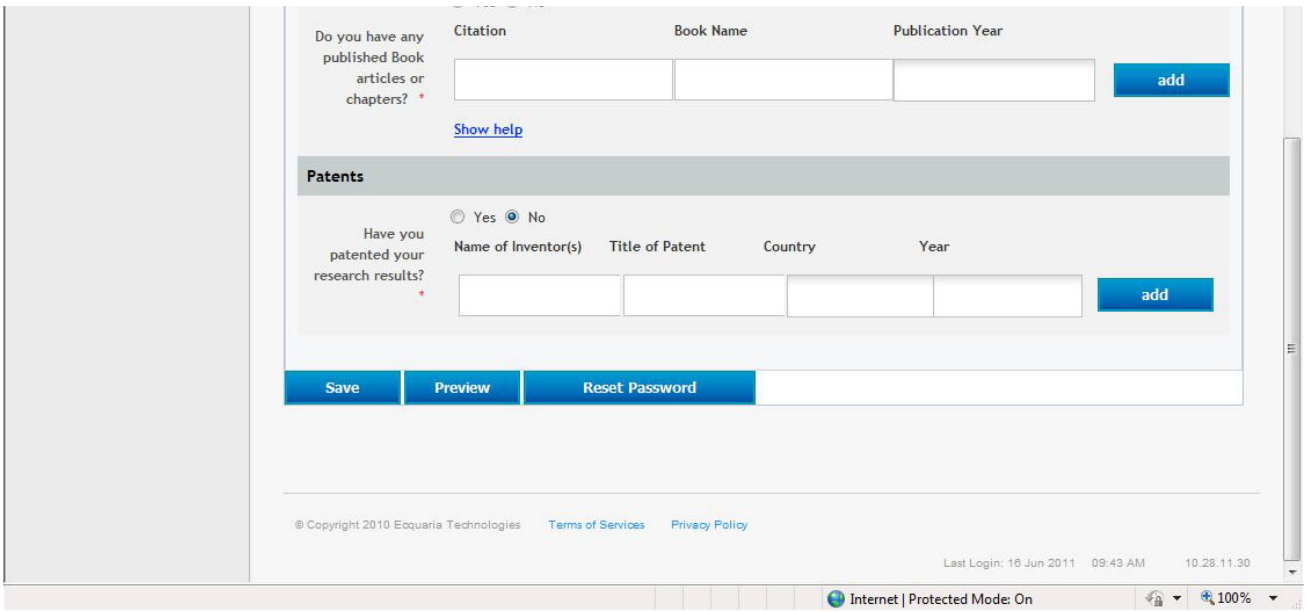


Figure 12 User Profile: Publications

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.

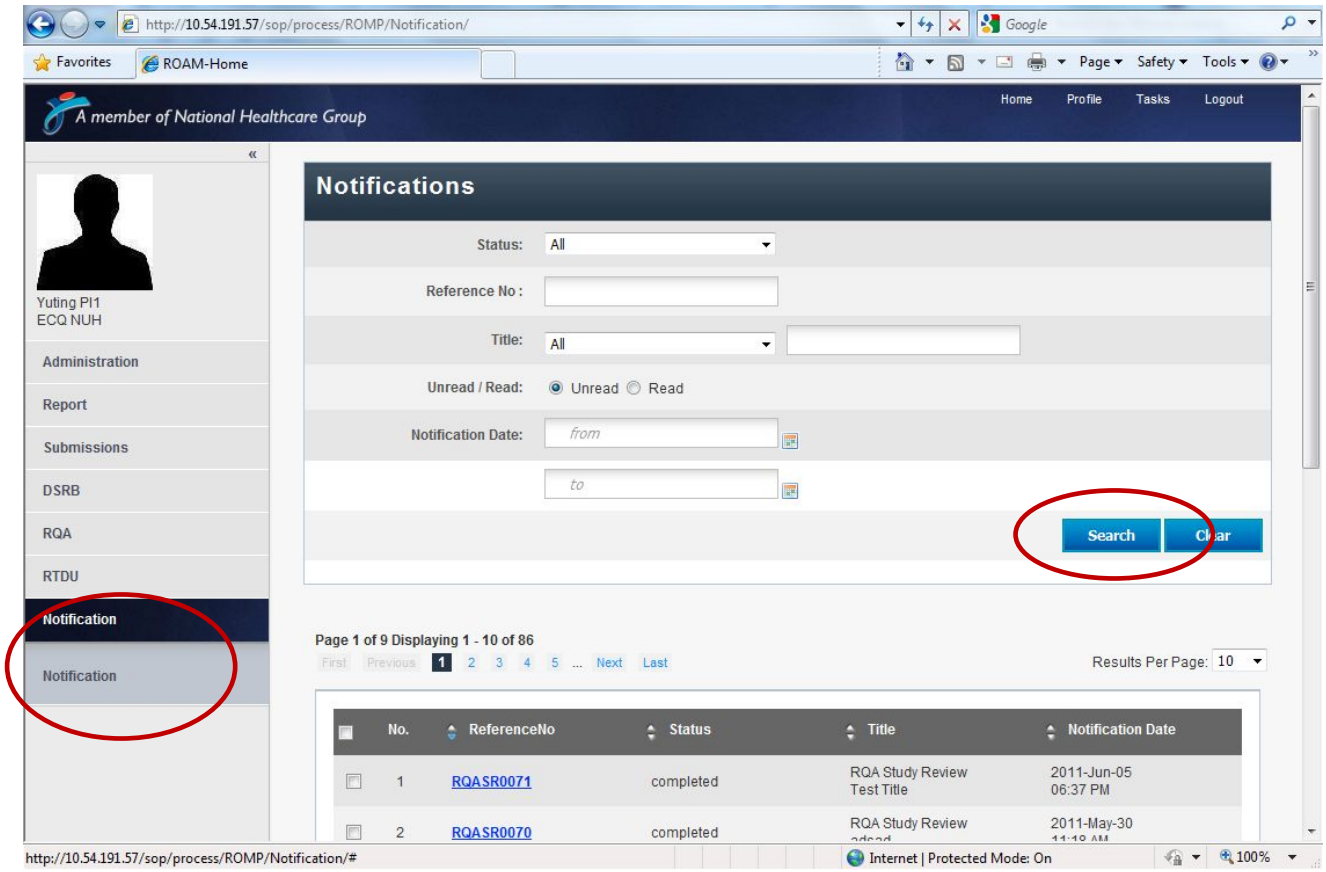


Figure 13 Notifications screen : Search

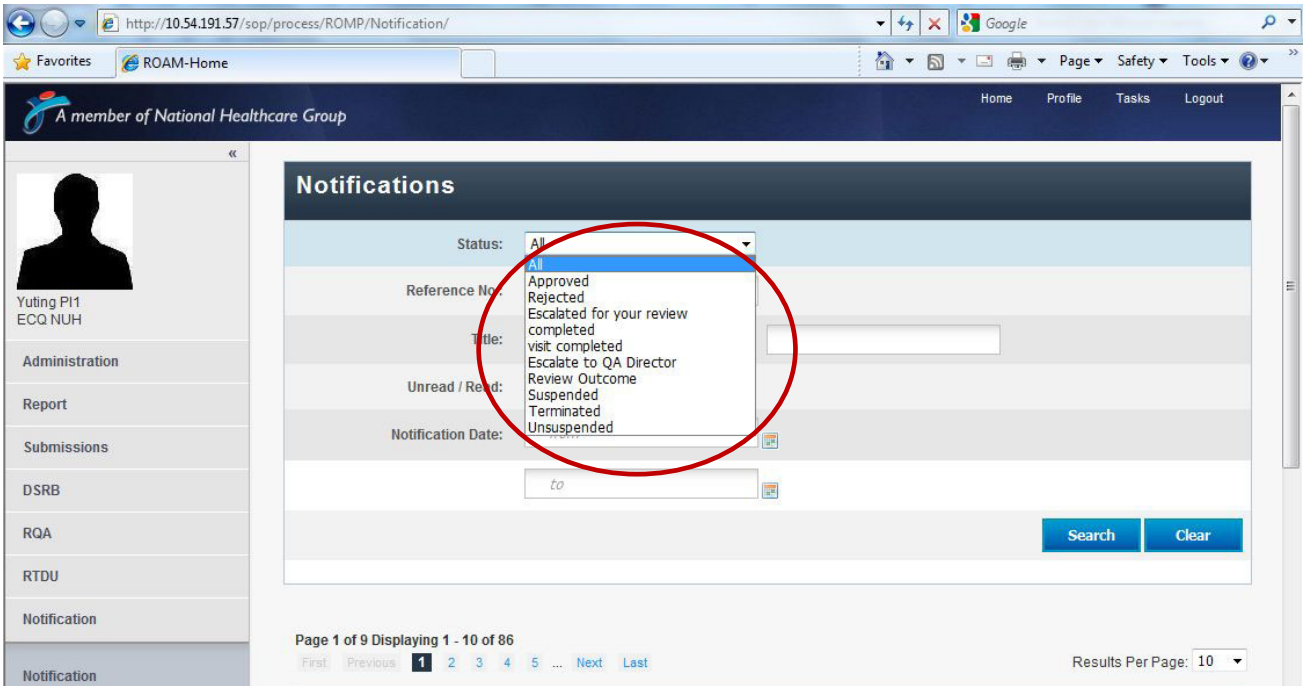


Figure 14 Notifications screen : Search II

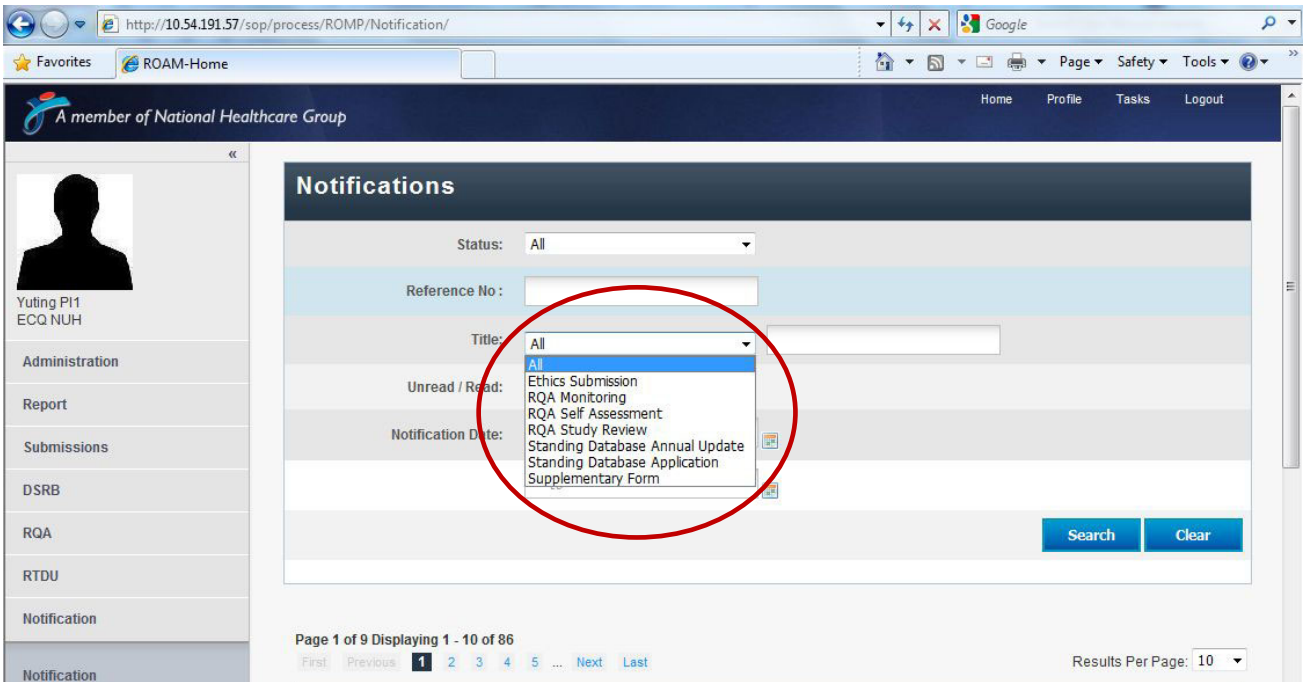


Figure 15 Notifications screen : Search III

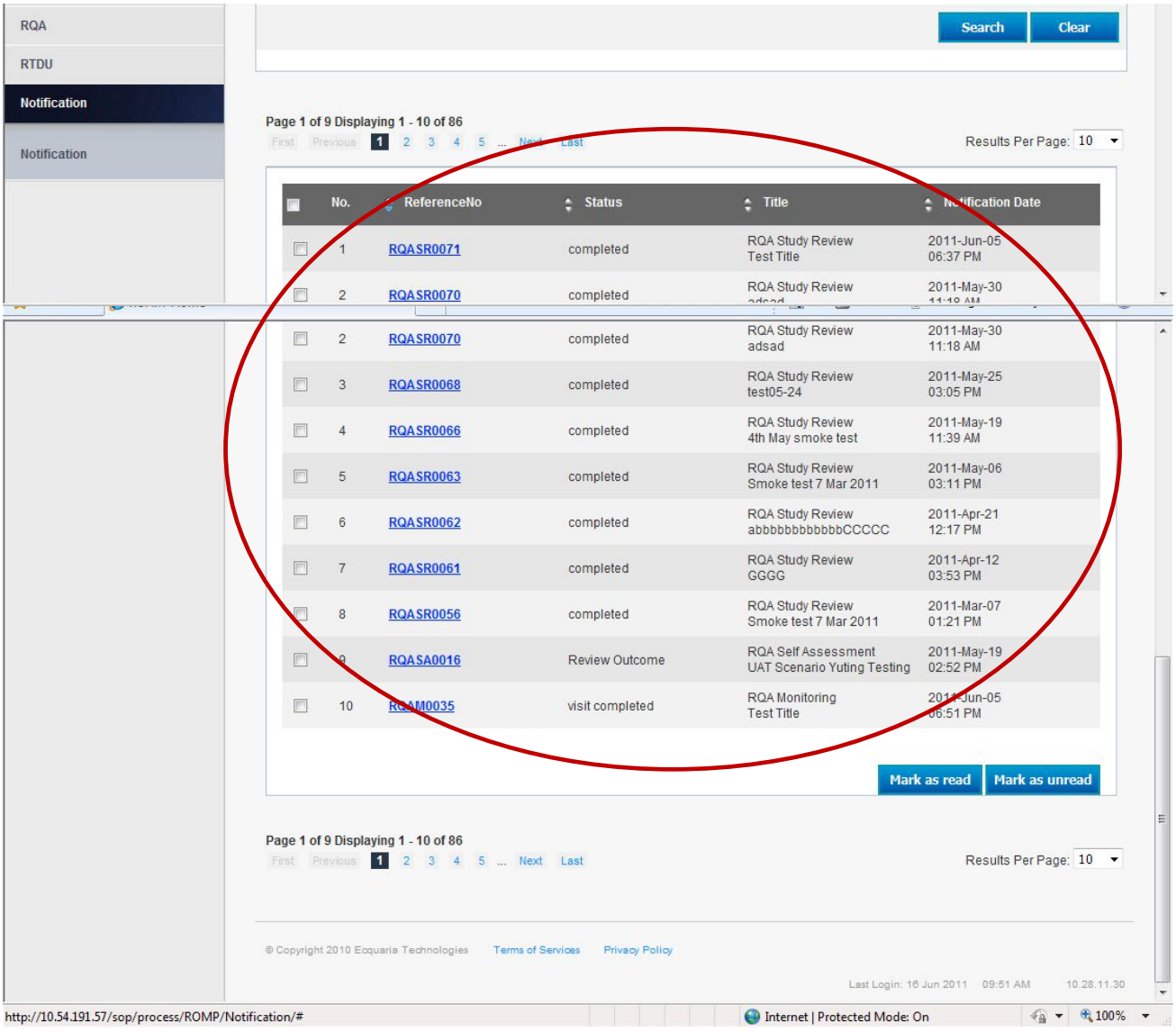


Figure 16 Notifications screen : Listing

2 SUBMITTING NEW STUDIES

2.1 Ethics Submission

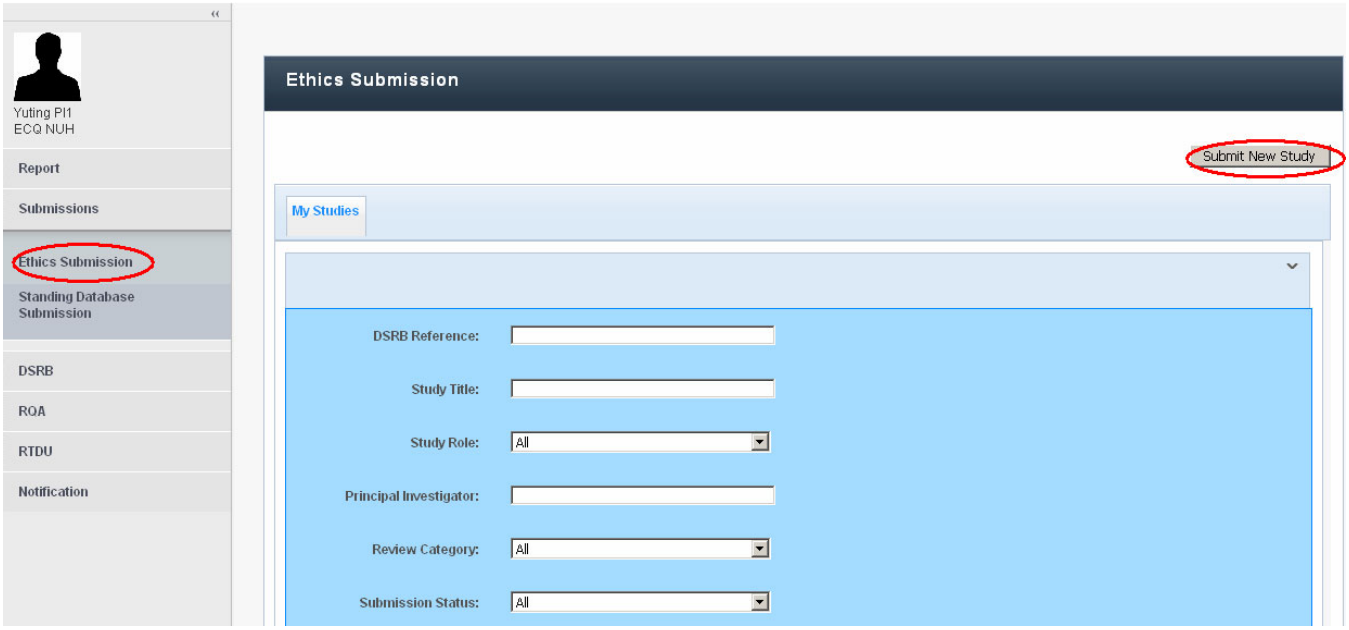


Figure 17

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

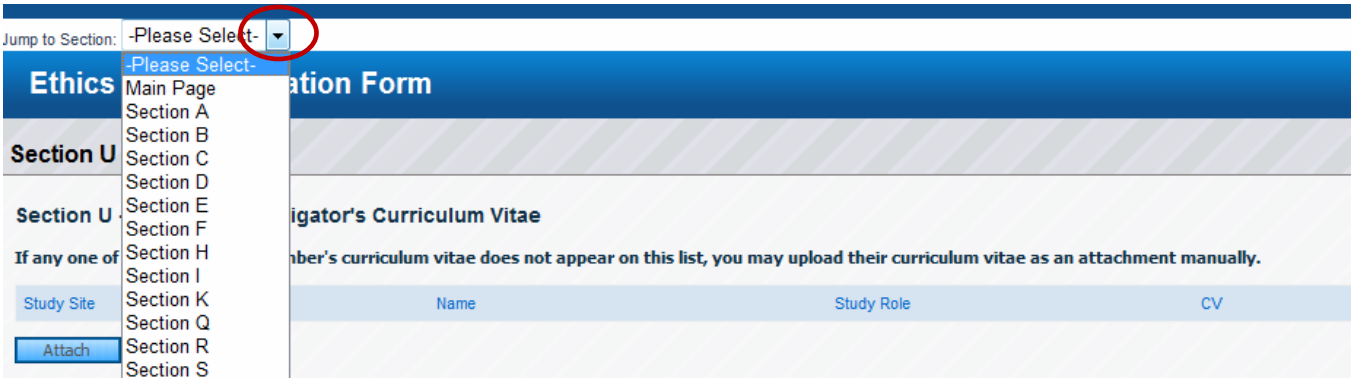
Figure 18

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.

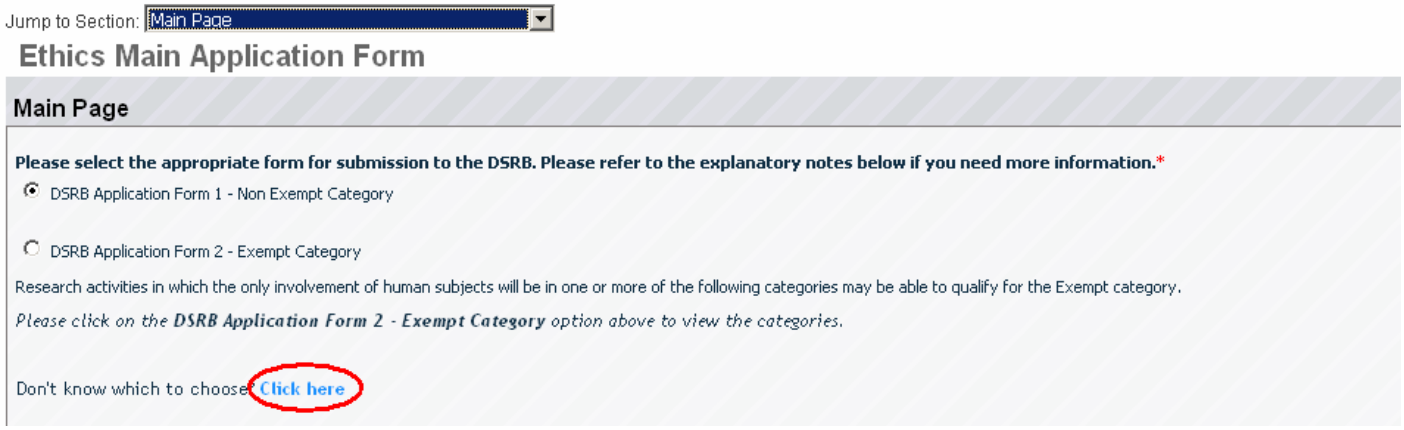


Figure 19 – Display Form's Main Page

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

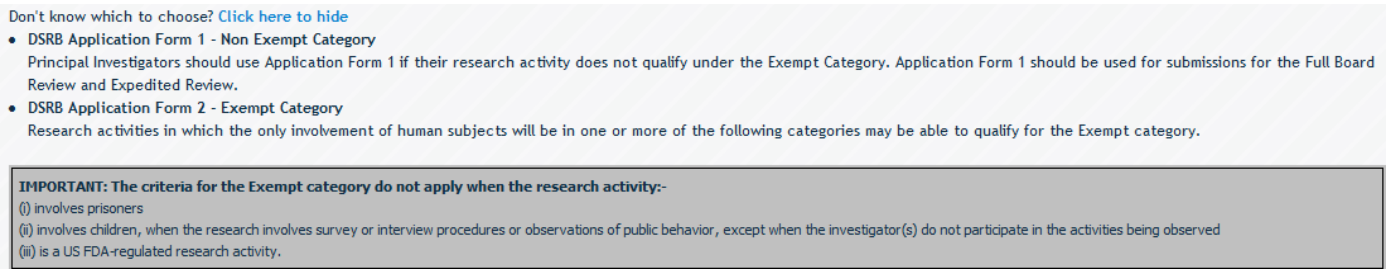


Figure 20

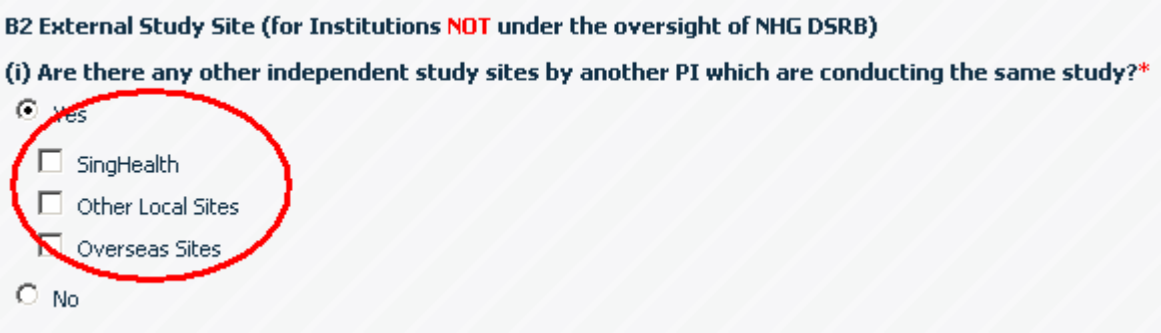
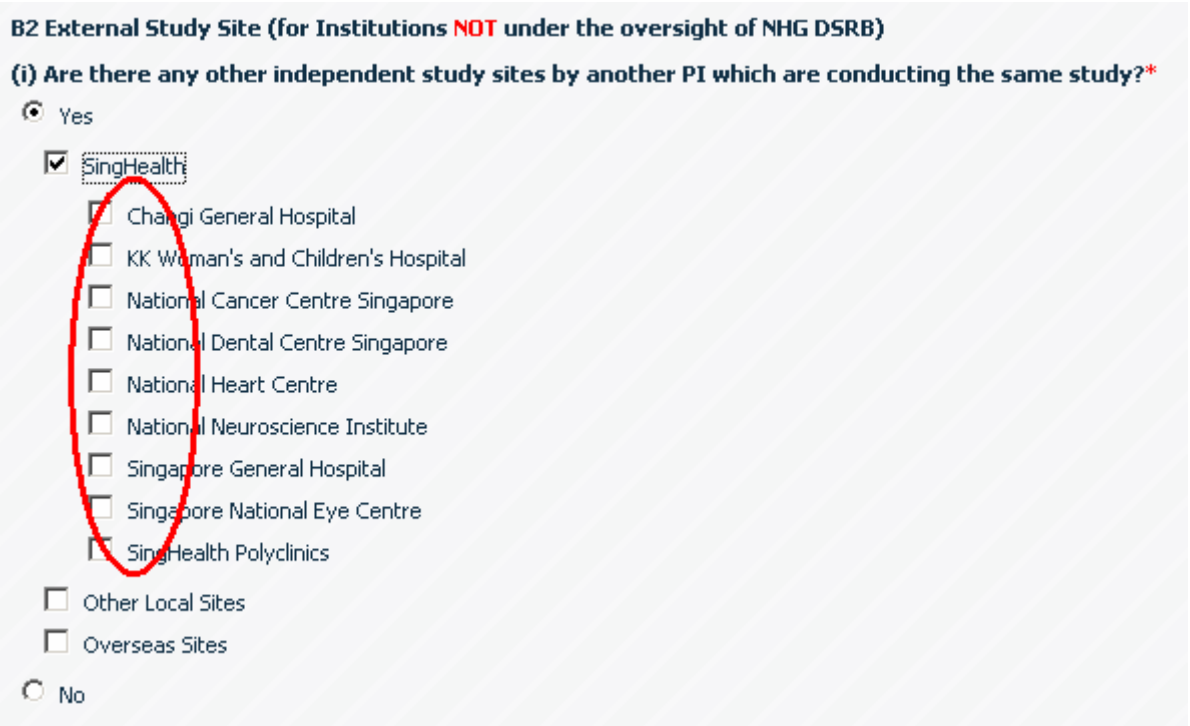


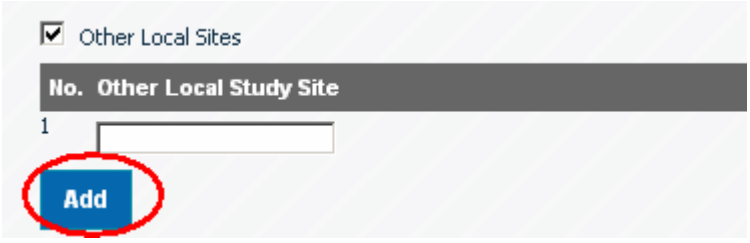
Figure 21 – Section B Question B2

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.



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



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

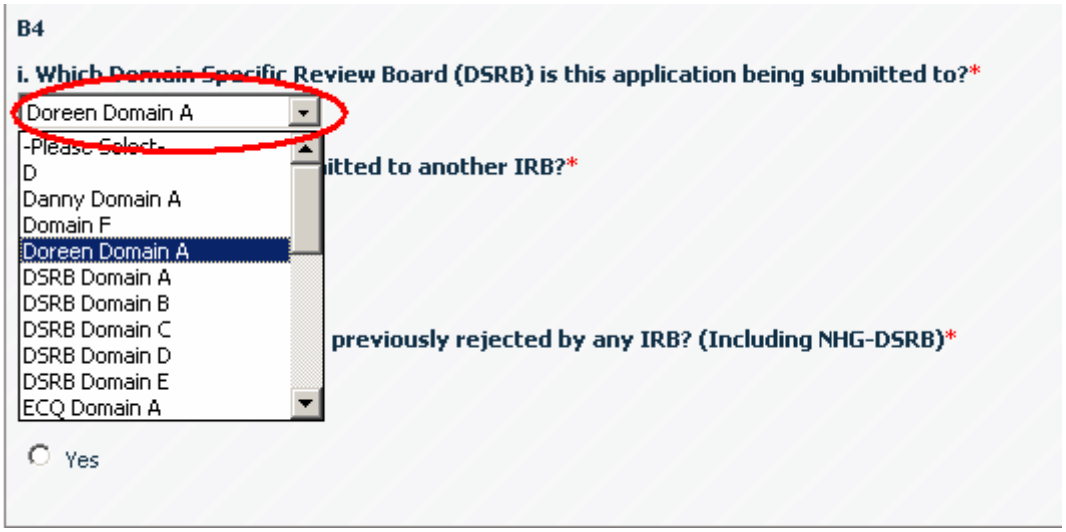


Figure 22 - Section B Question B4 Part I

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.
   - 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.

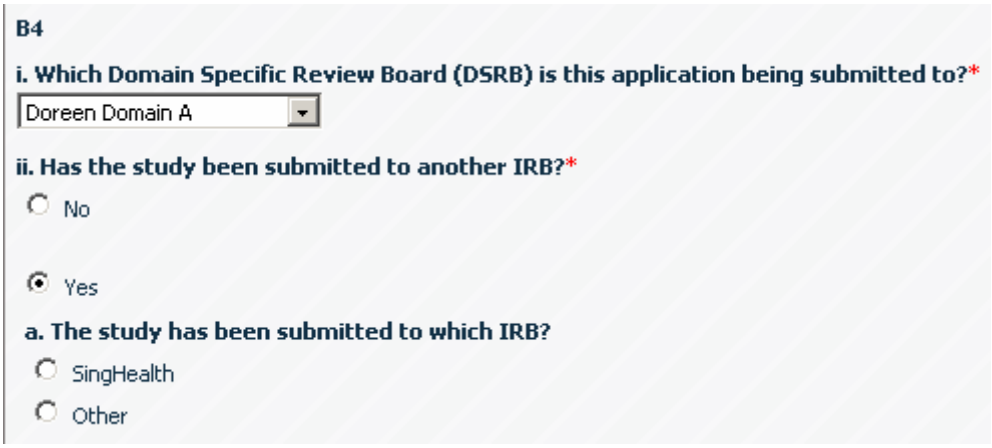


Figure 23 - Section B Question B4 Part II

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.

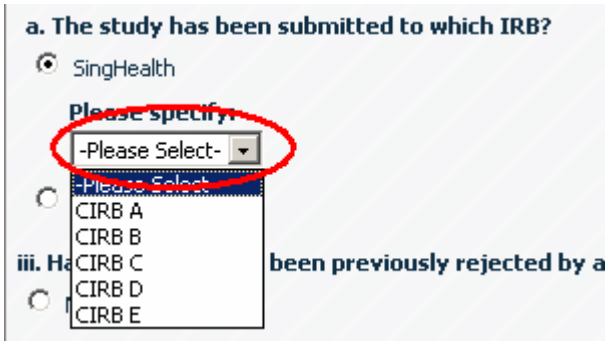


Figure 24 - Section B Question B4 Part II Question a

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

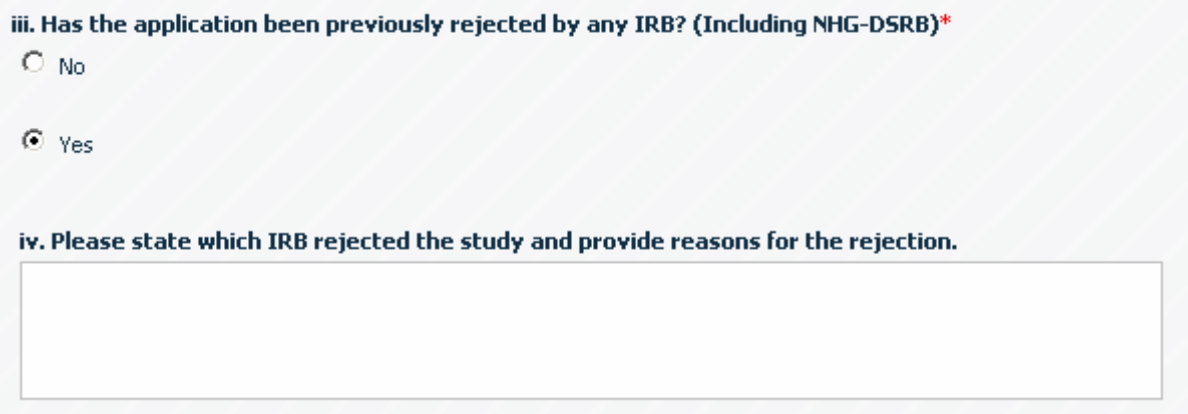


Figure 25 - Section B Question B4 Part III

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

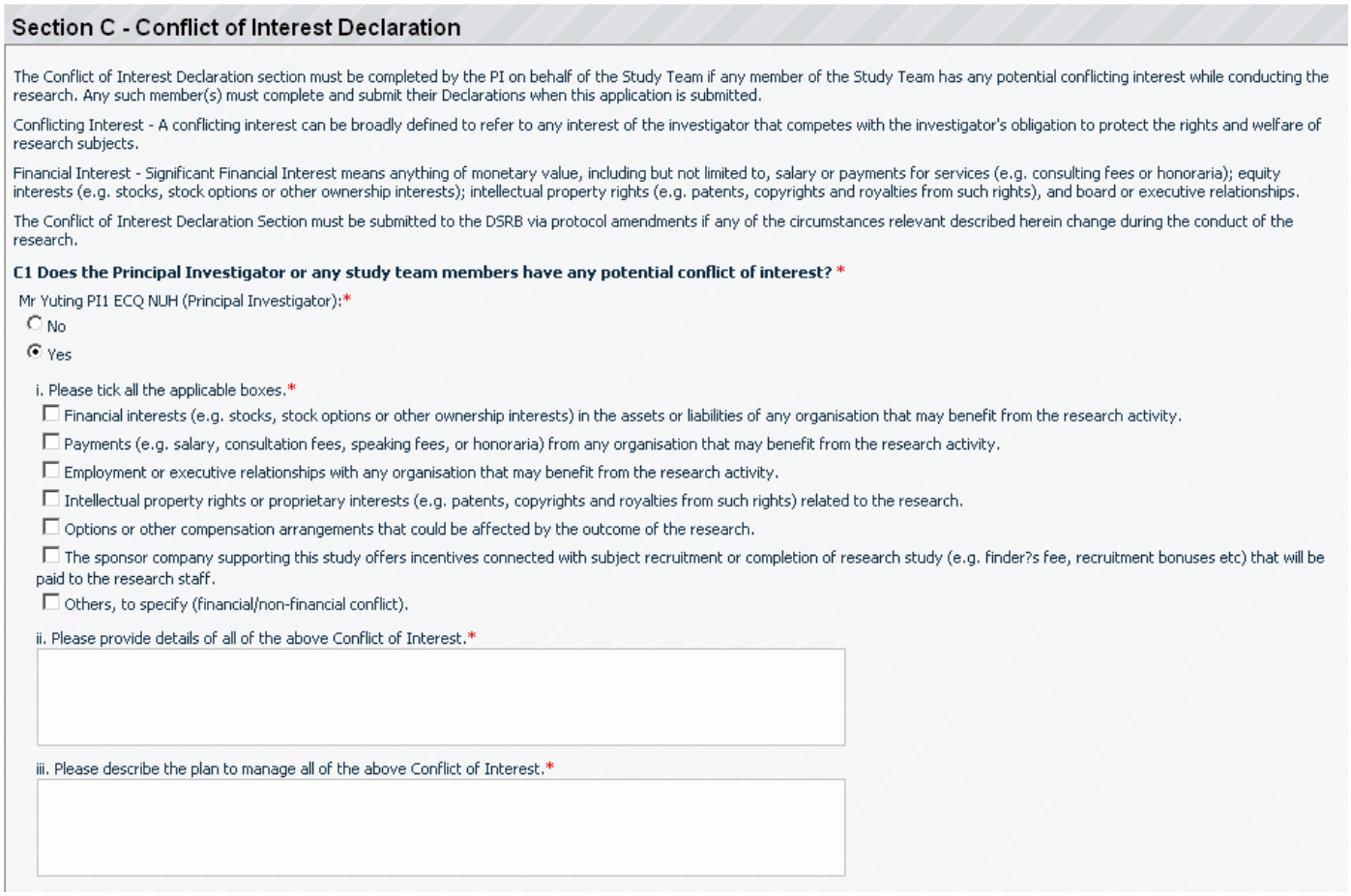


Figure 26 - Section C Question C1

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

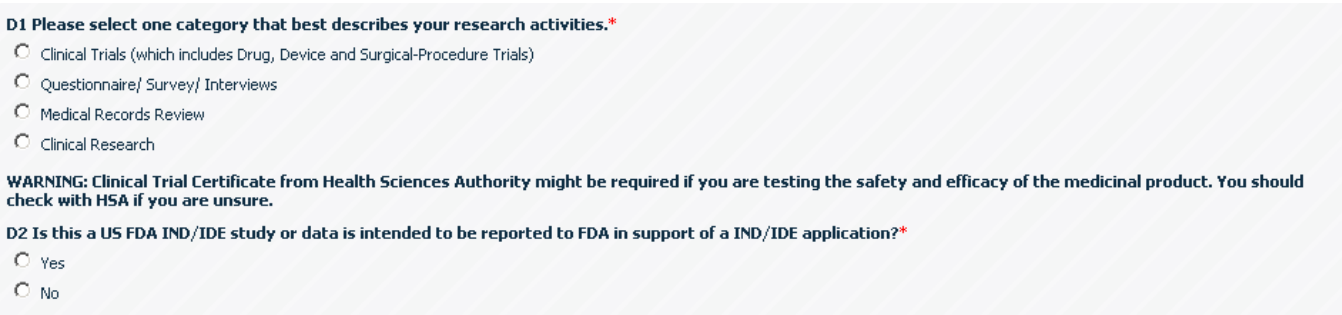


Figure 27 - Section D Question D1

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.

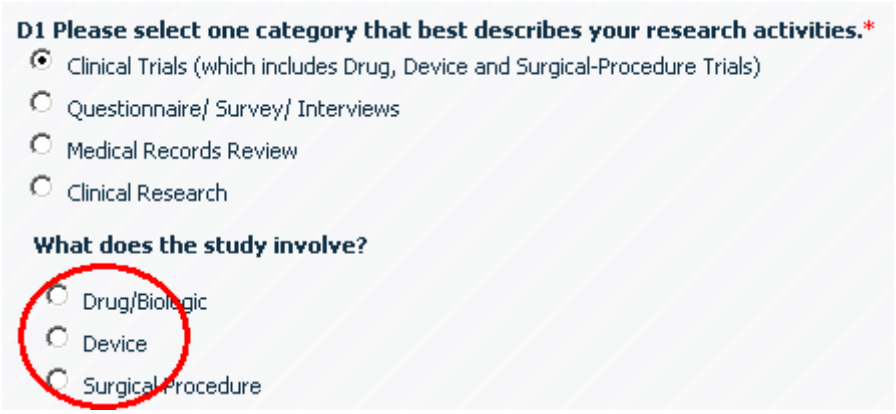


Figure 28

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

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.

Figure 30 - Section D Question D3

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

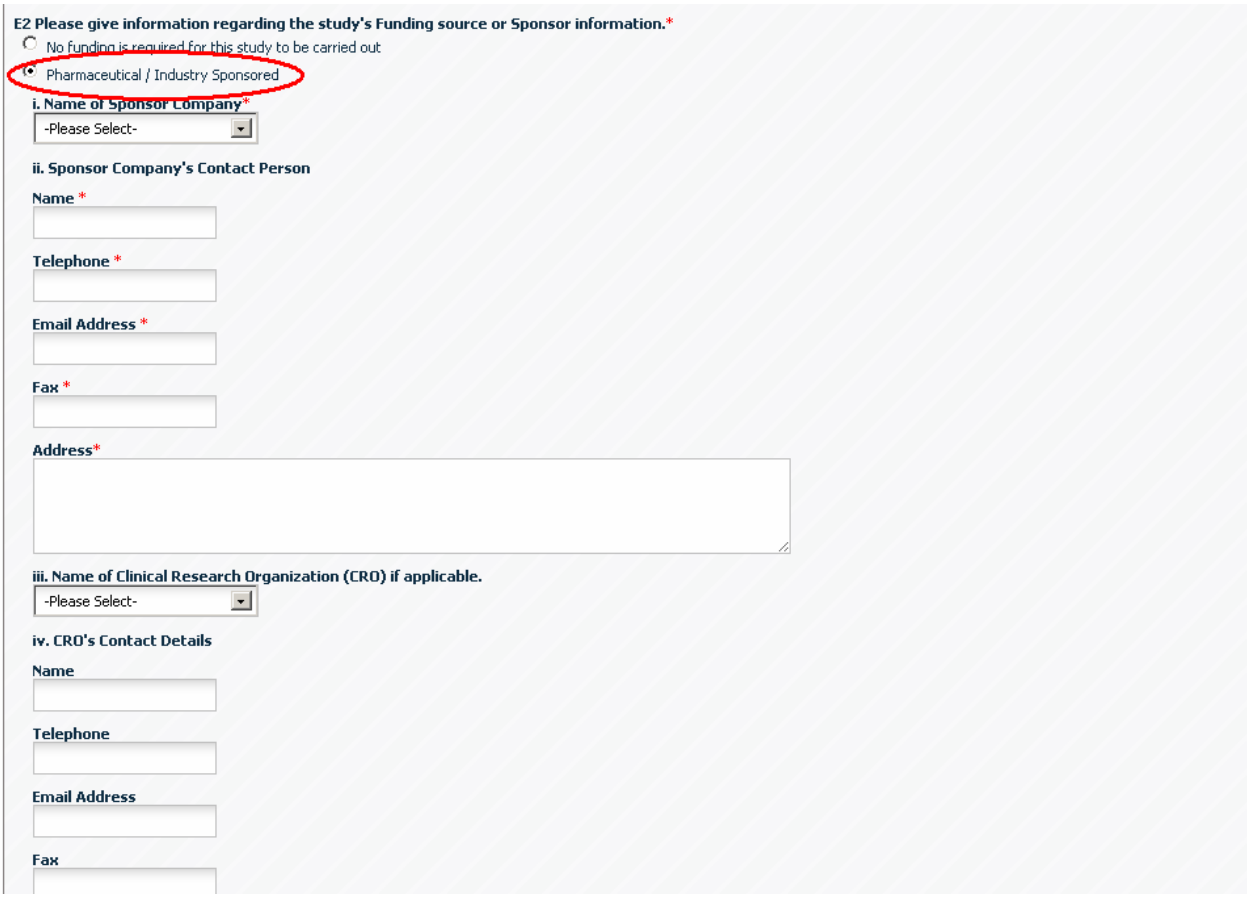


Figure 31 - Section E Question E2

2.2.4 For Section E Question E2;

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

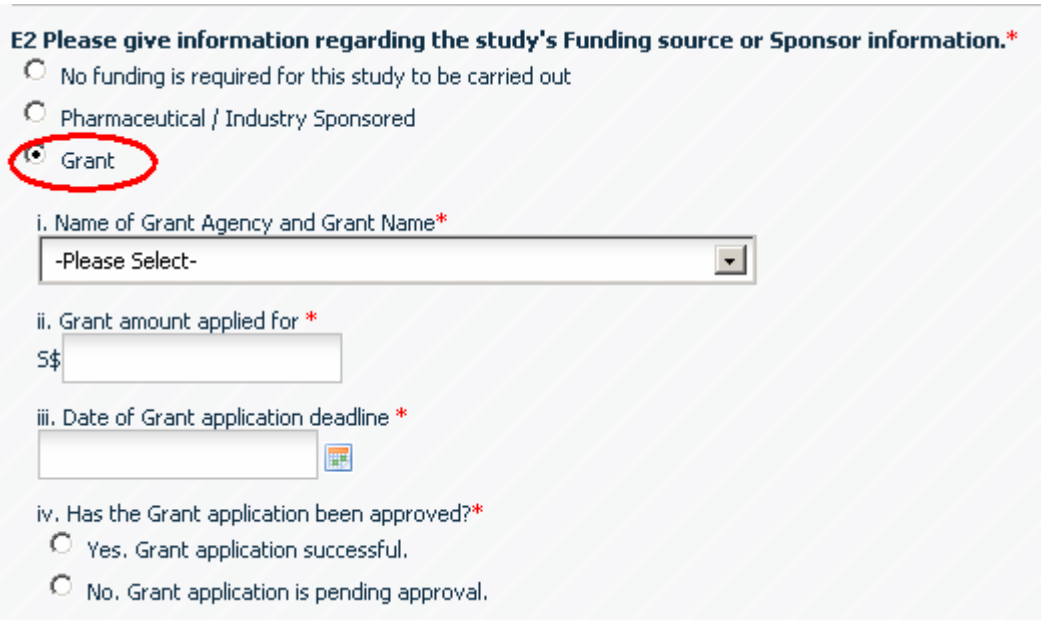


Figure 32 - Section E Question E2

2. For Section E Question E2;

3. If selection is 'Grant'; user will be required to fill in the details.

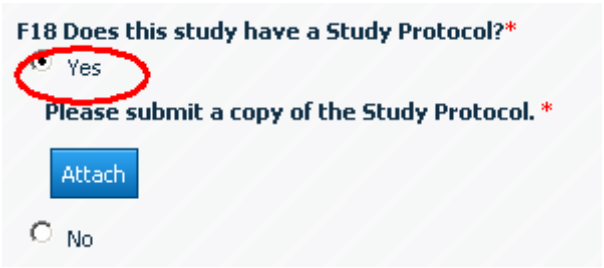


Figure 33 - Section F Question F18

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.

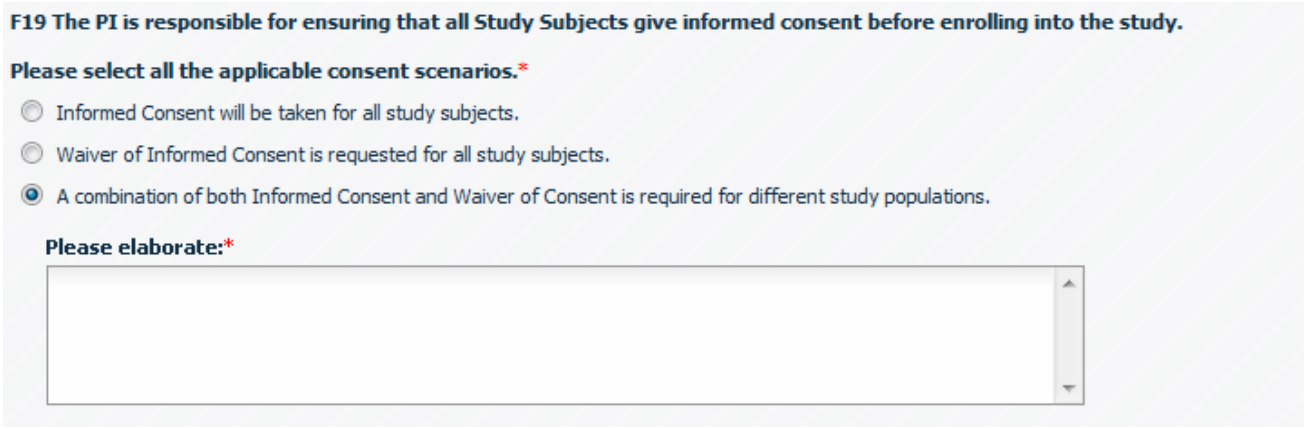


Figure 34 - Section F Question F19

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.

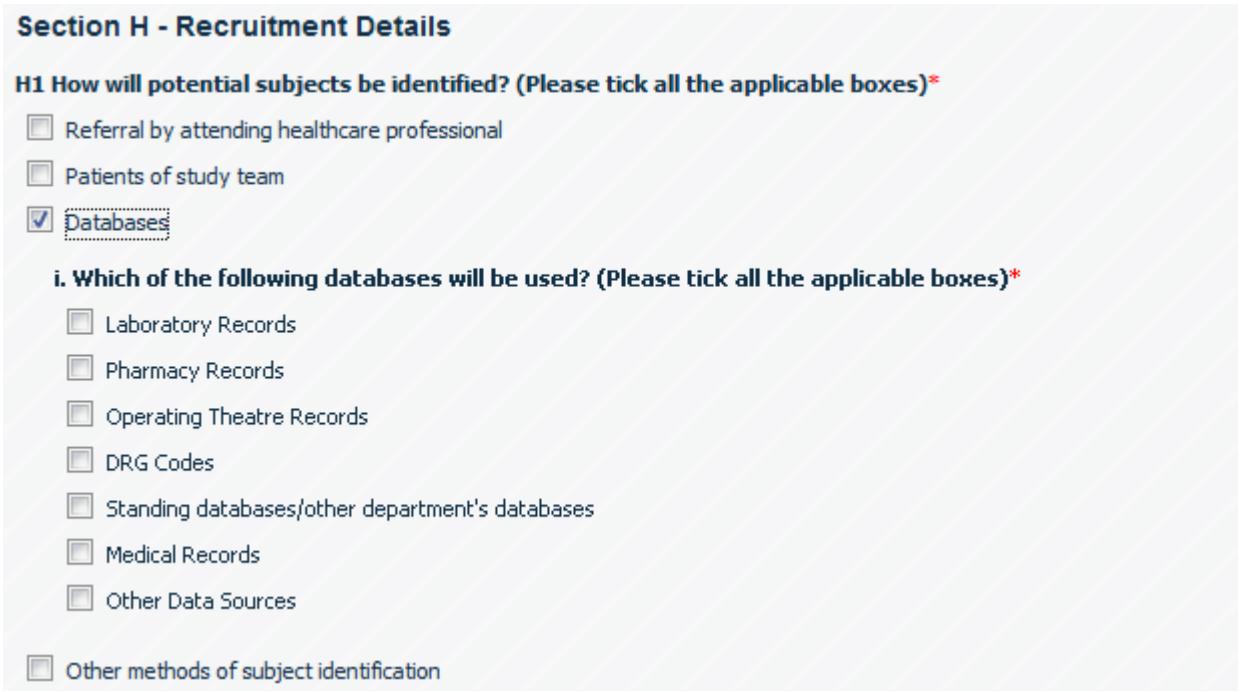


Figure 35 - Section H Question H1

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.

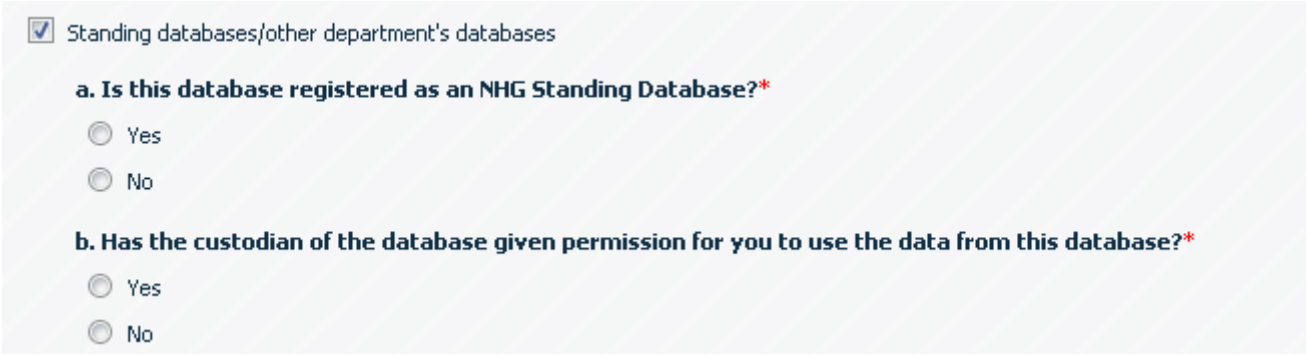


Figure 36 - Section H Question H1 Part I

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.

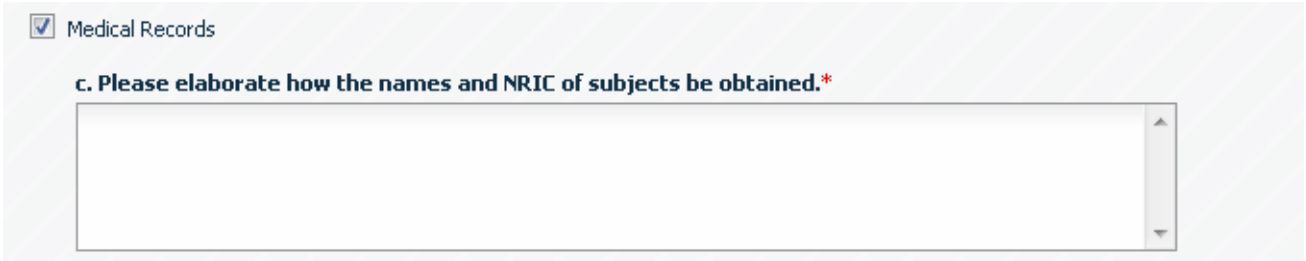


Figure 37 - Section H Question H1 Part I

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

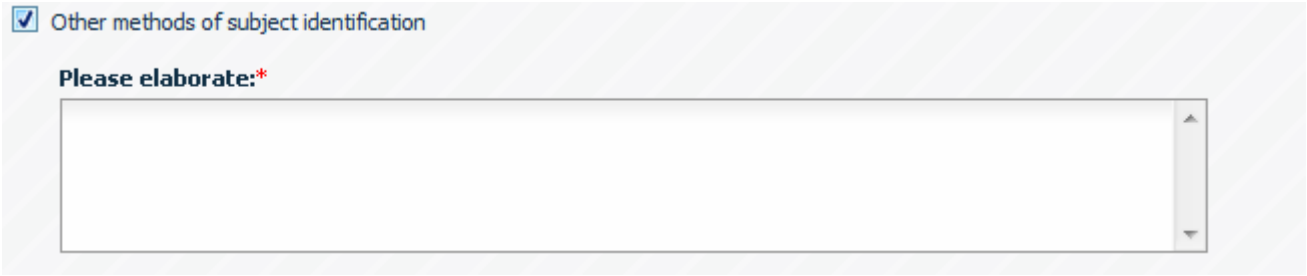


Figure 38 - Section H Question H1

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.

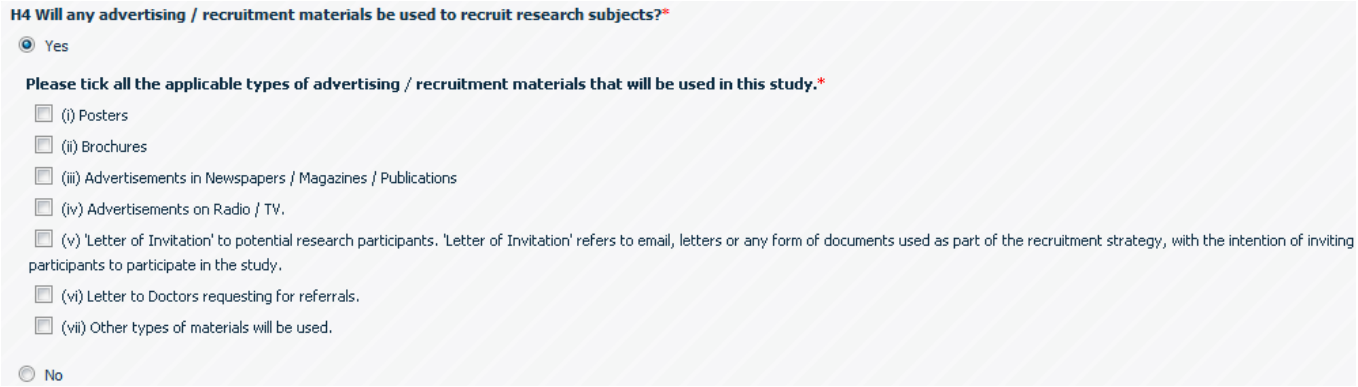


Figure 39 - Section H Question H4

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.

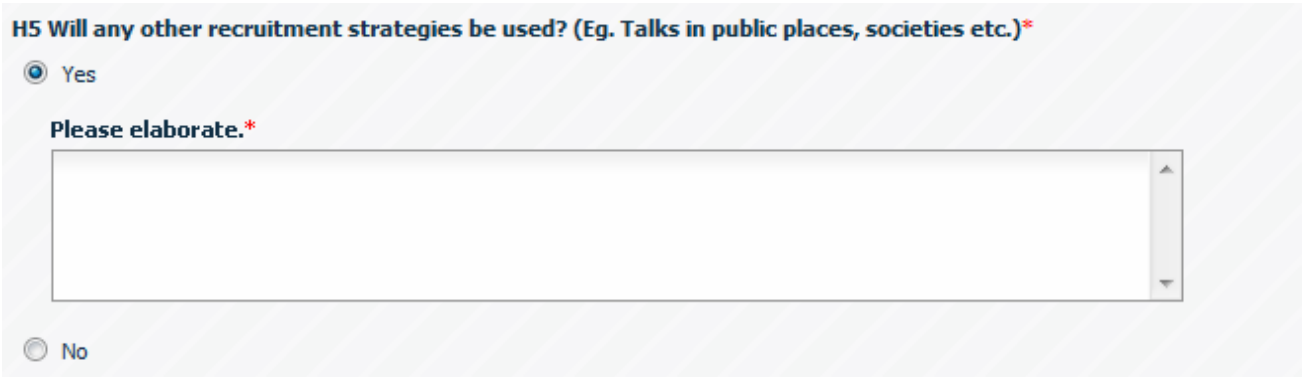


Figure 40 - Section H Question H5

21. For Section H Question H5;
22. If selection is 'Yes';
23. User will require elaborating more in the textbox provided.

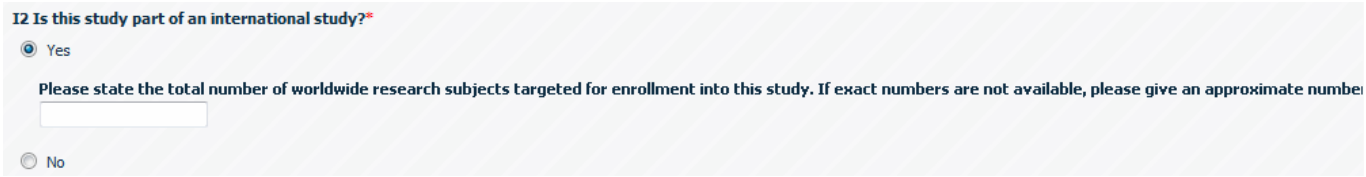


Figure 41 - Section I Question I2

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.

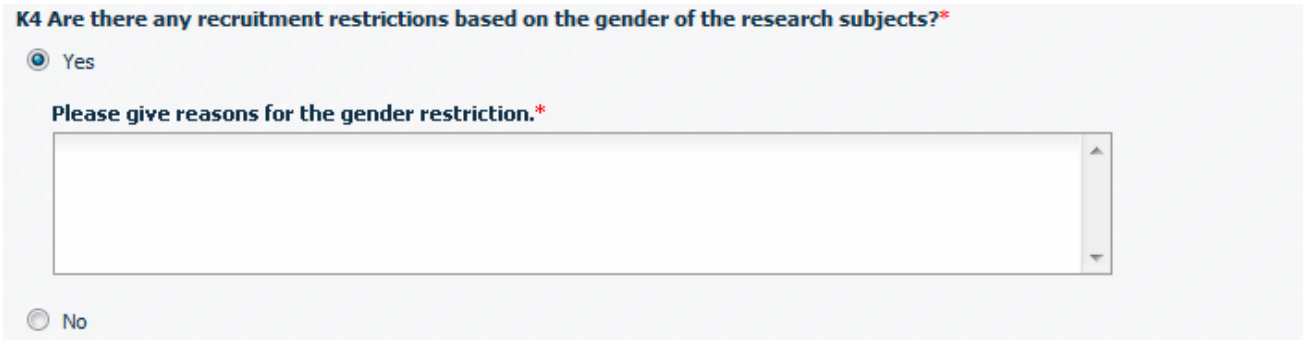


Figure 42 - Section K Question K4

2.2.8 For Section K Question K4;

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

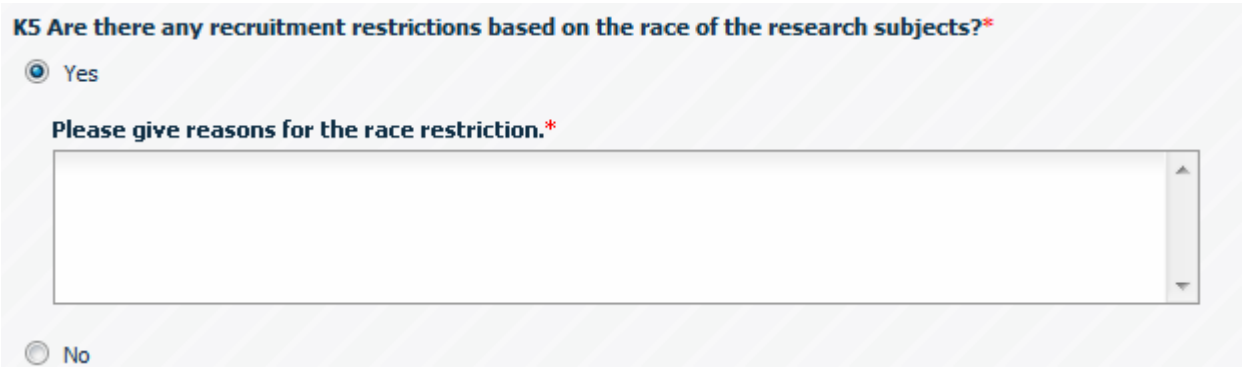


Figure 43 - Section K Question K5

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

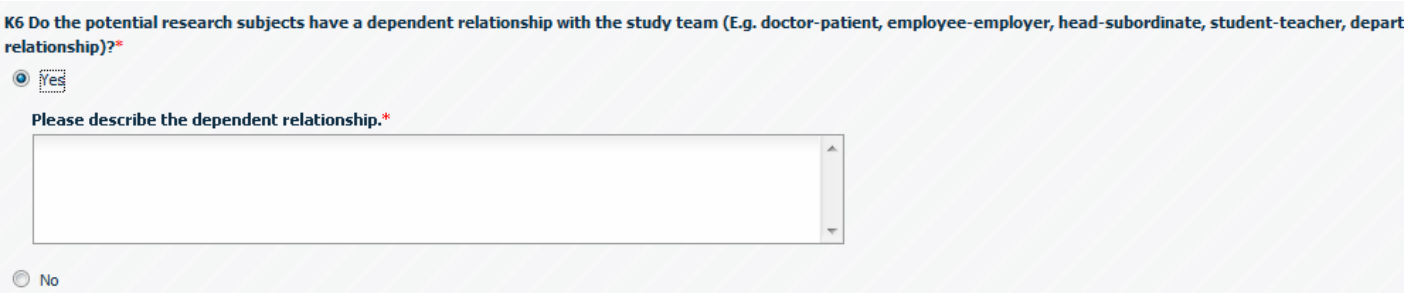


Figure 44 - Section K Question K6

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

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.

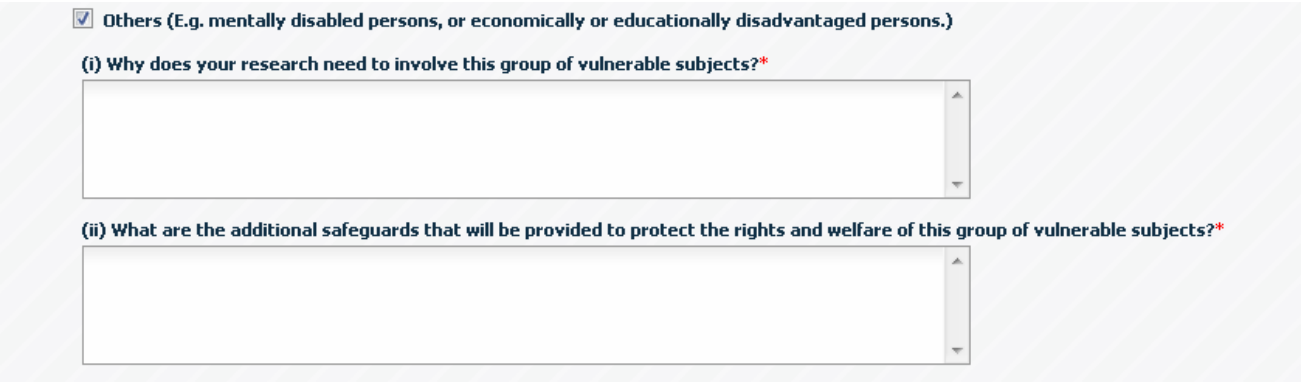


Figure 46 - Section K Question K7 (Others)

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.

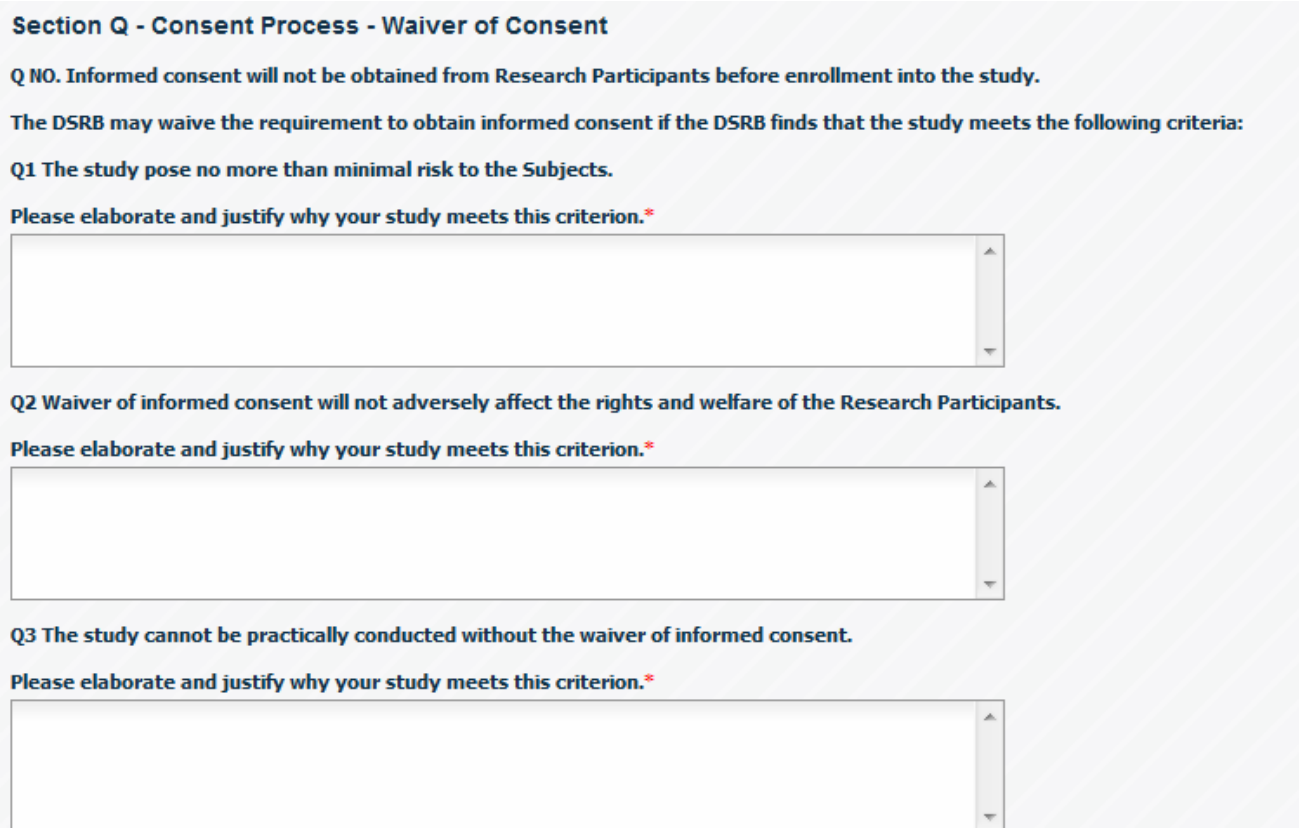


Figure 47 - Section Q

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.

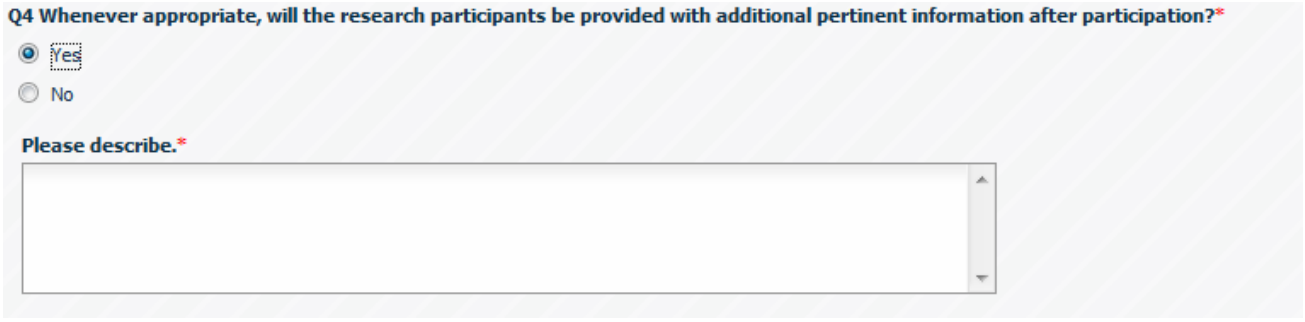


Figure 48 - Section Q Question Q4

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

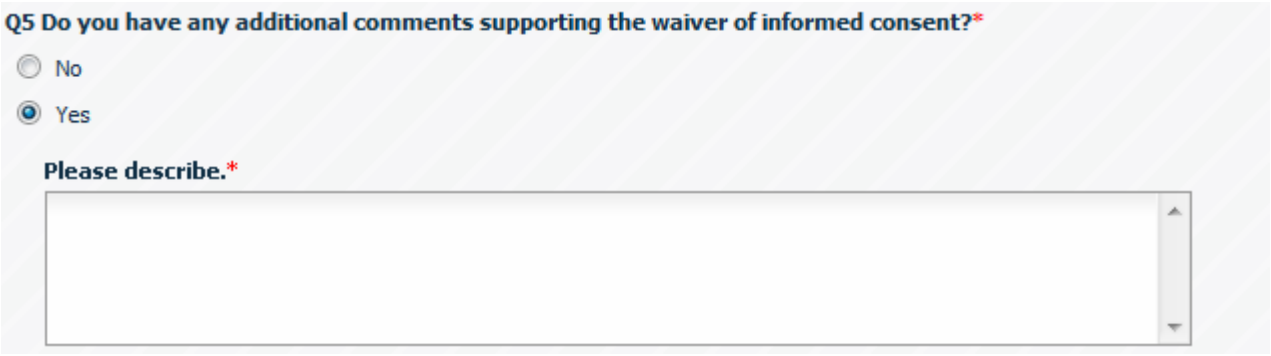


Figure 49 - Section Q Question Q5

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

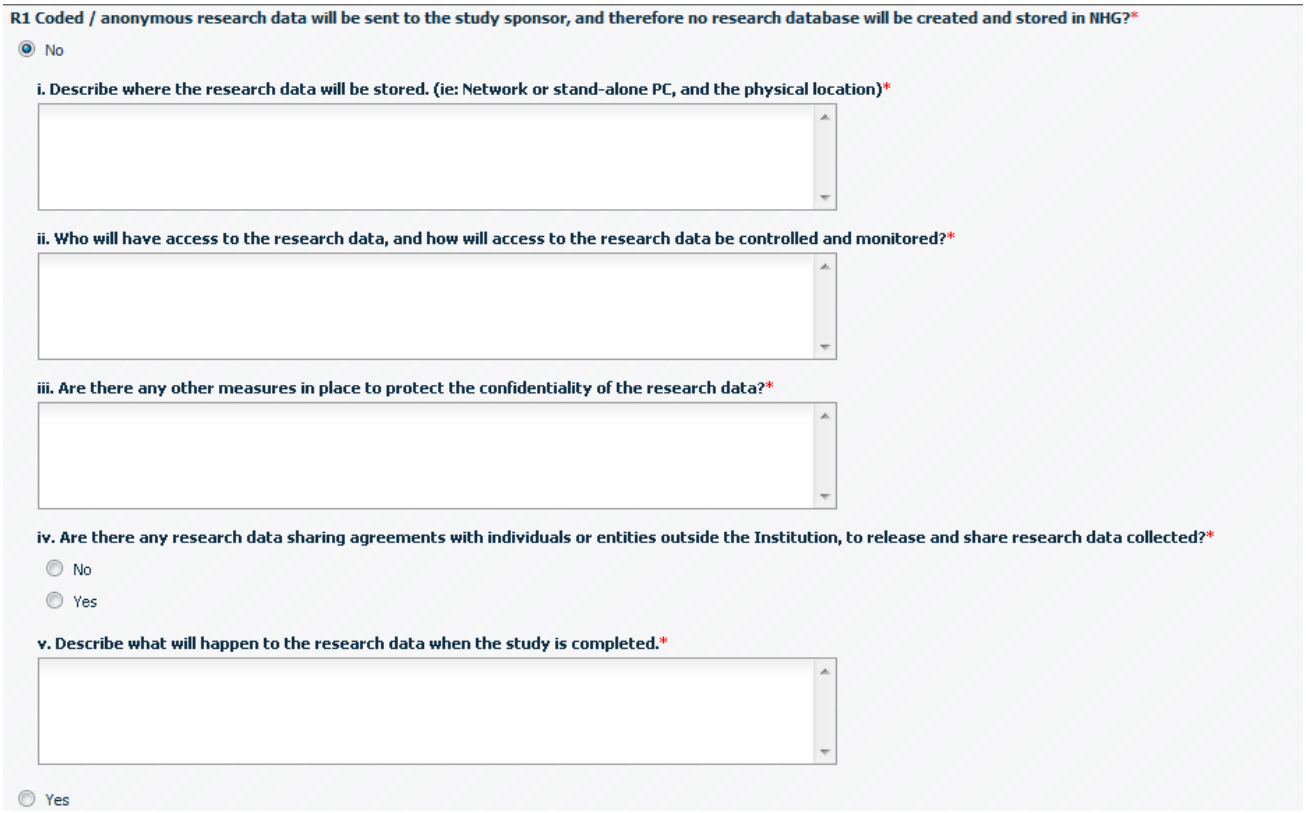


Figure 50 - Section R Question R1

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.

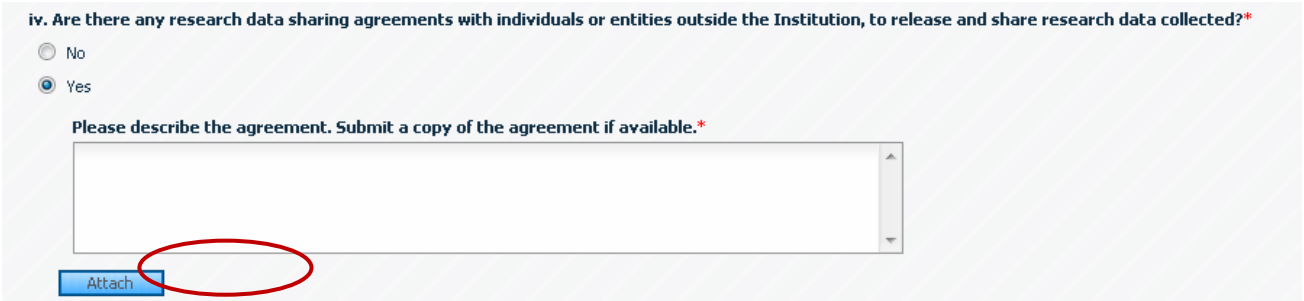


Figure 51 - Section R Question R1 Part IV

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.

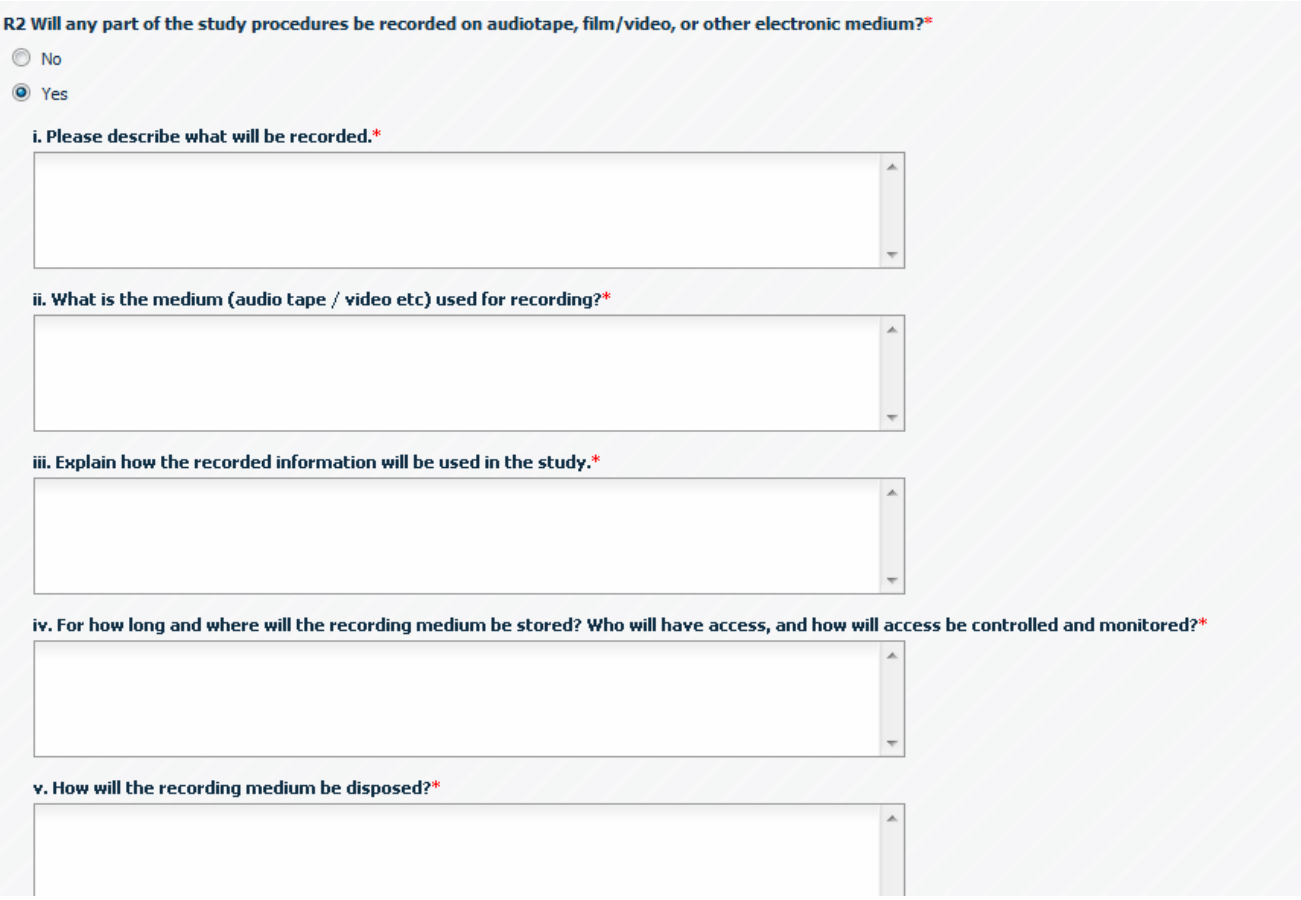


Figure 52 - Section R Question R2

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

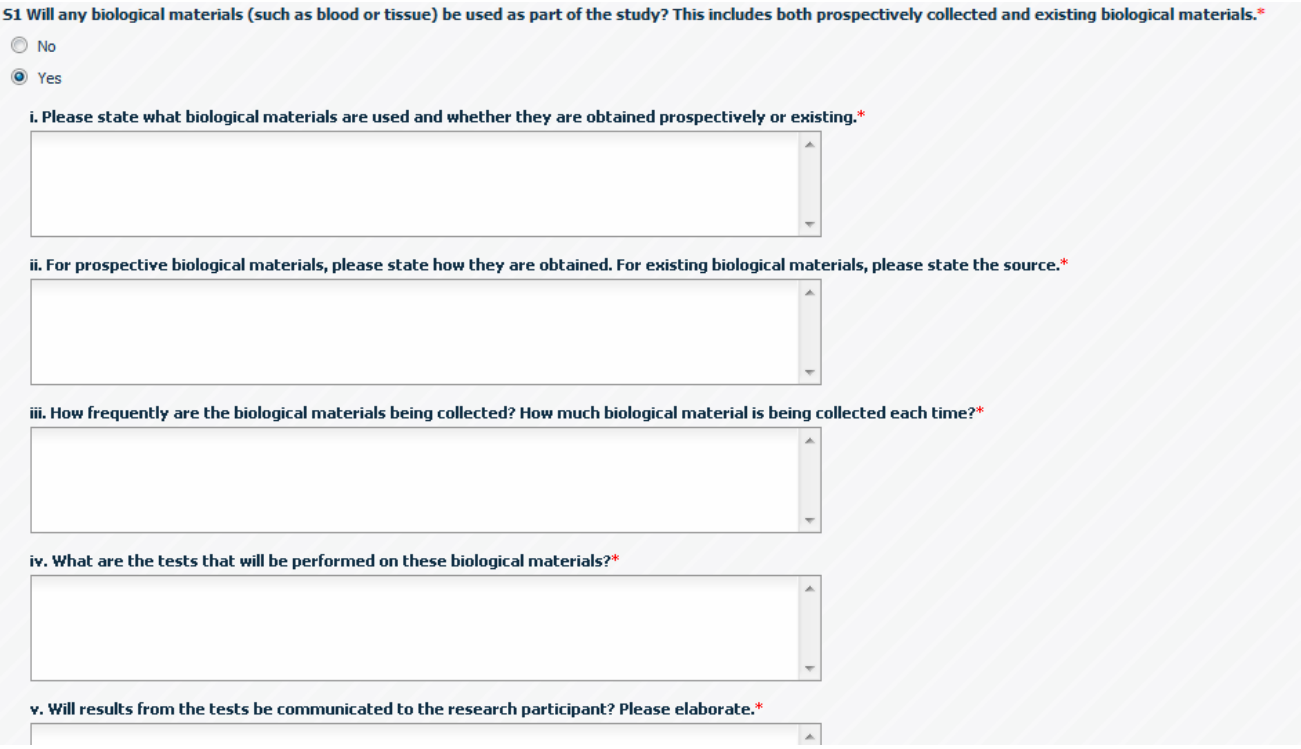


Figure 53 - Section S Question S1

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.

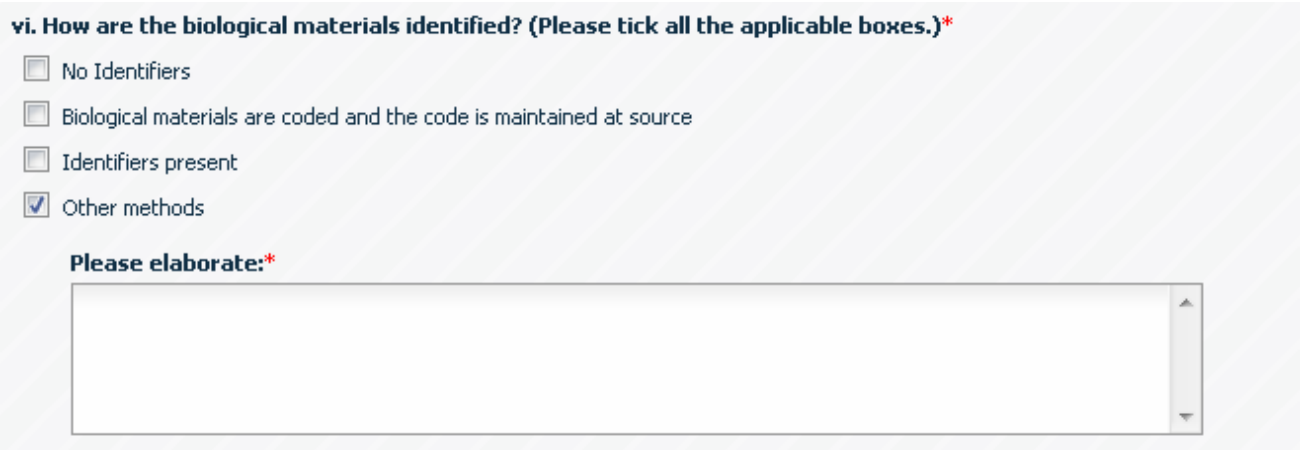


Figure 54 - Section S Question S1 (Yes) Part VI (Other methods)

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.

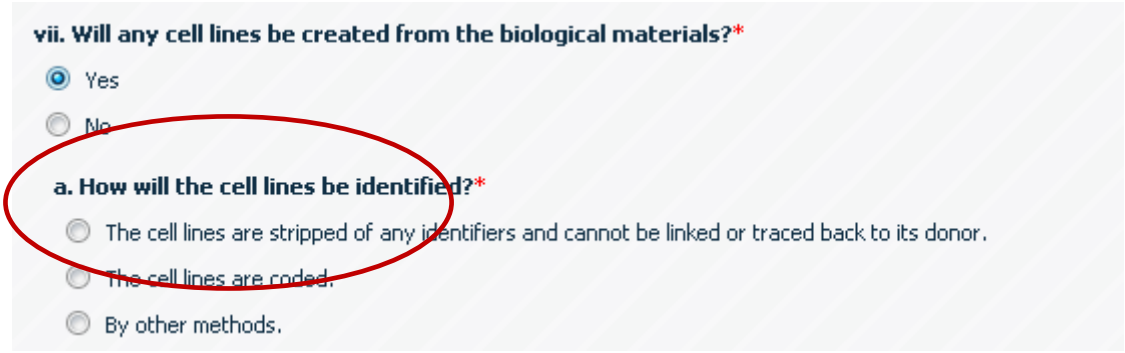


Figure 55 - Section S Question S1 (Yes) Part VII (Yes)

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

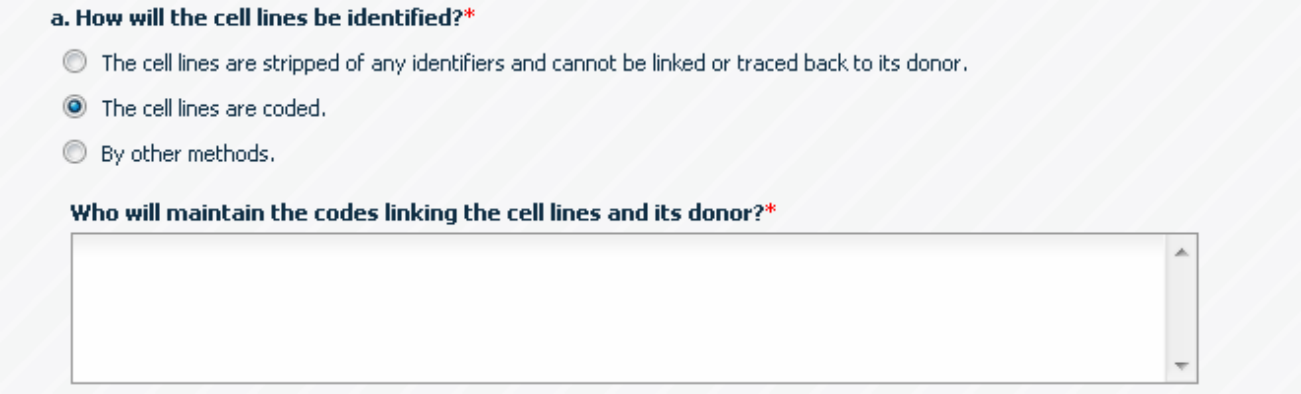


Figure 56 - Section S Question S1 (Yes) Part VII (Yes) Qn. A

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.

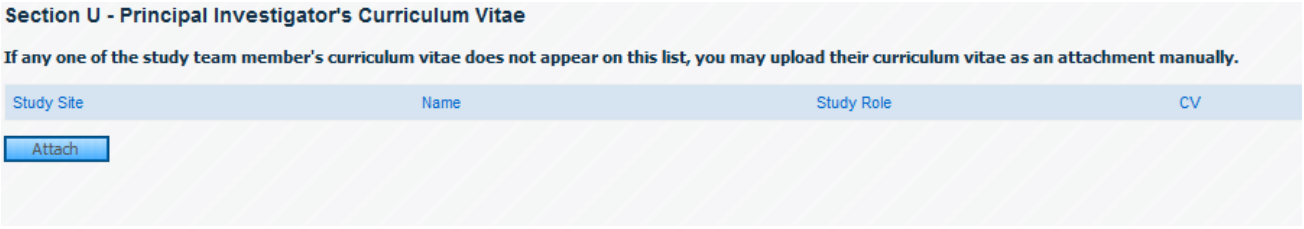


Figure 57 - Section U

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;

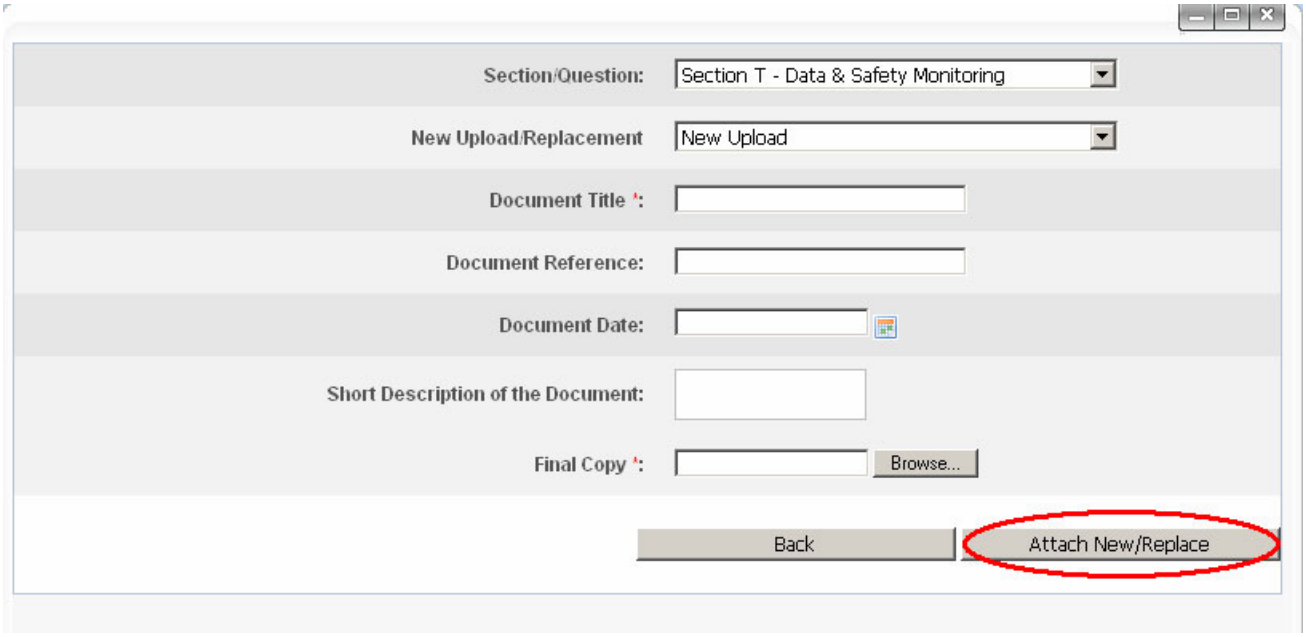


Figure 58 - Section U Attaching file

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

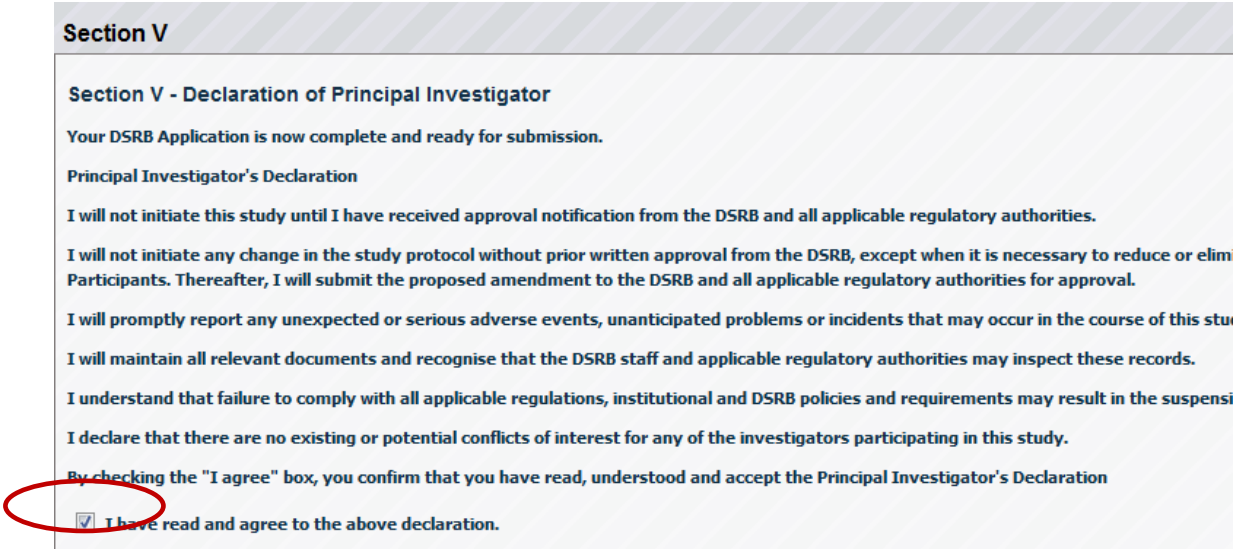


Figure 59 - Section V

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.

Figure 60 - Section V Submitting Form

2.3 Finding and Editing Drafts

1. If a new Study is not submitted the first time, it is saved as a draft in the main interface My Studies. To retrieve it for editing, just click on the icon on the extreme right of the same row.

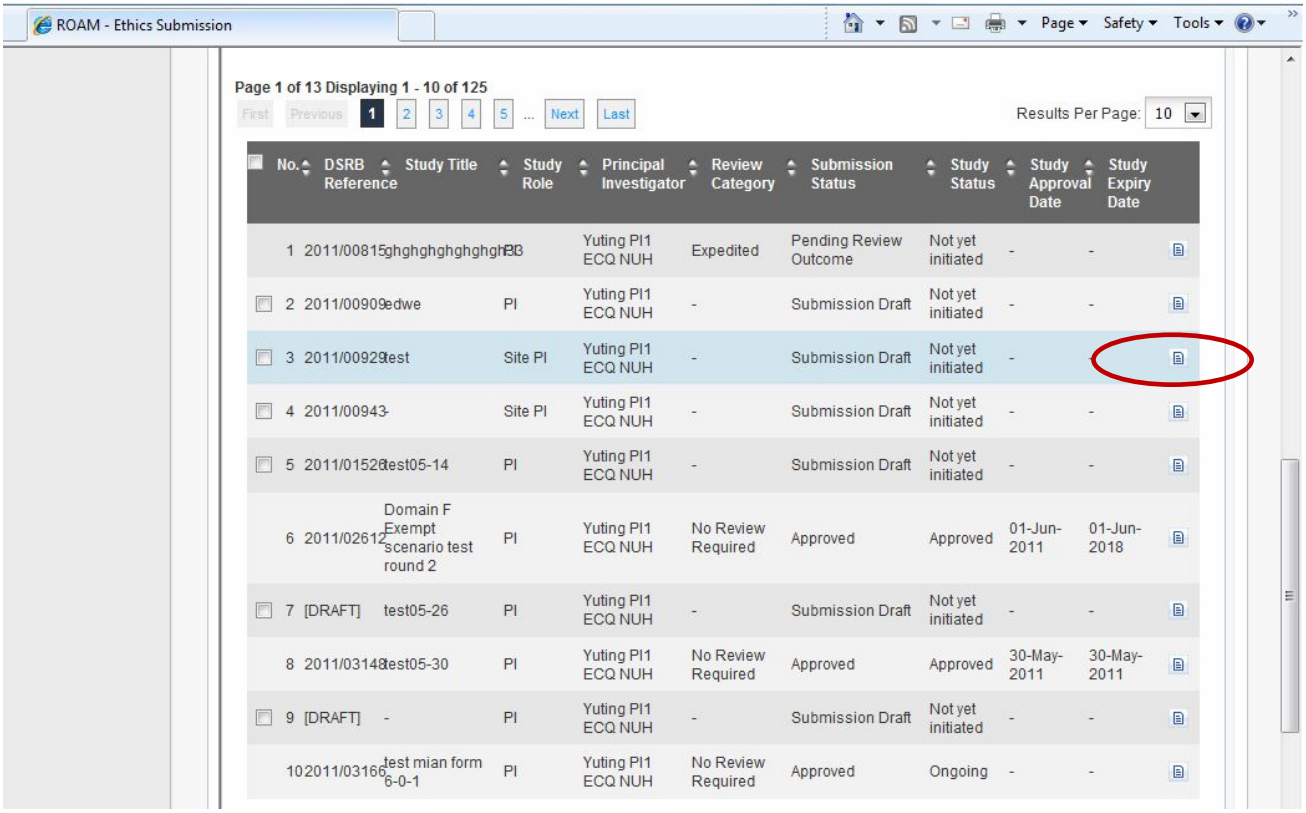


Figure 61 Finding and Editing a Draft

2. To remove the draft permanently, please tick the leftmost checkbox and click on the Delete Submission button on the bottom.
   Note: There is no Undo function, so deleted drafts cannot be retrieved.

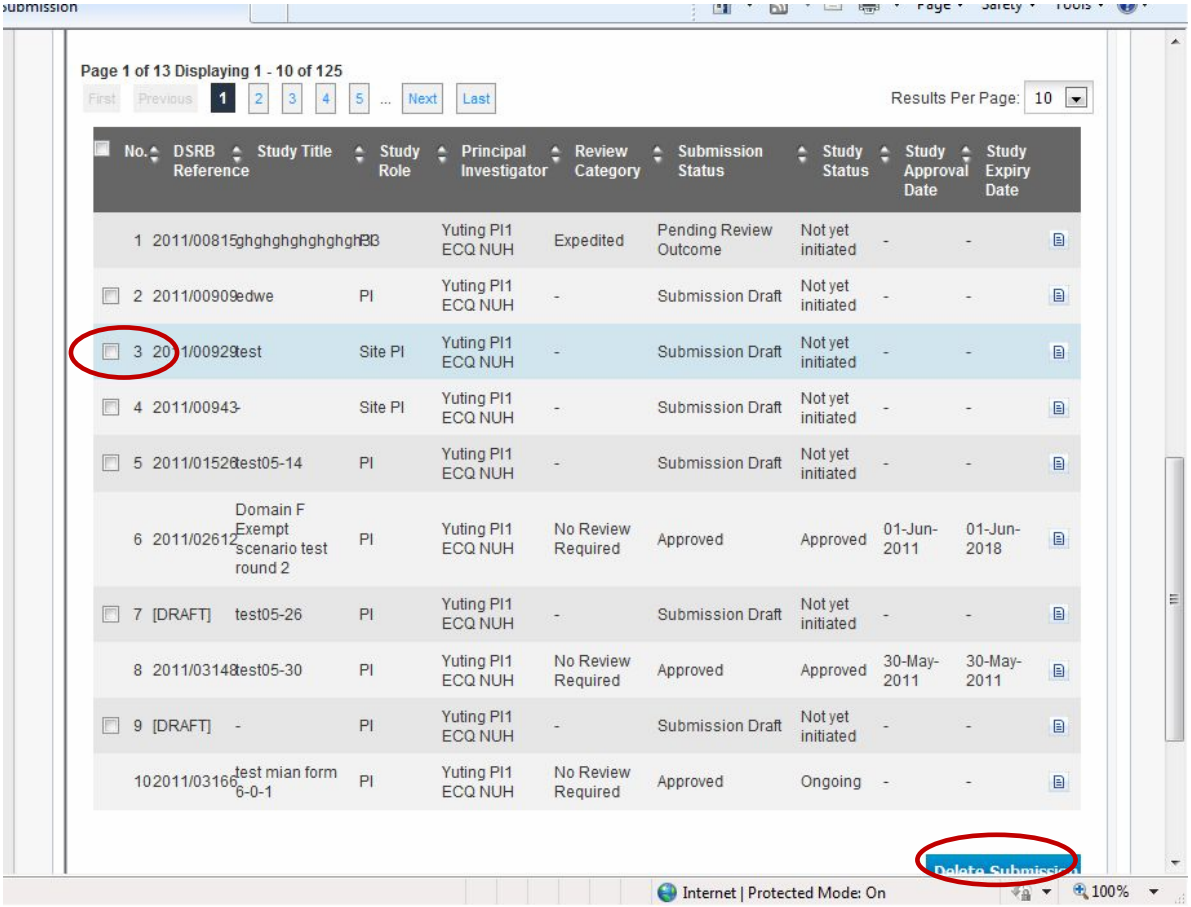


Figure 62 Marking a Draft for Deletion

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.

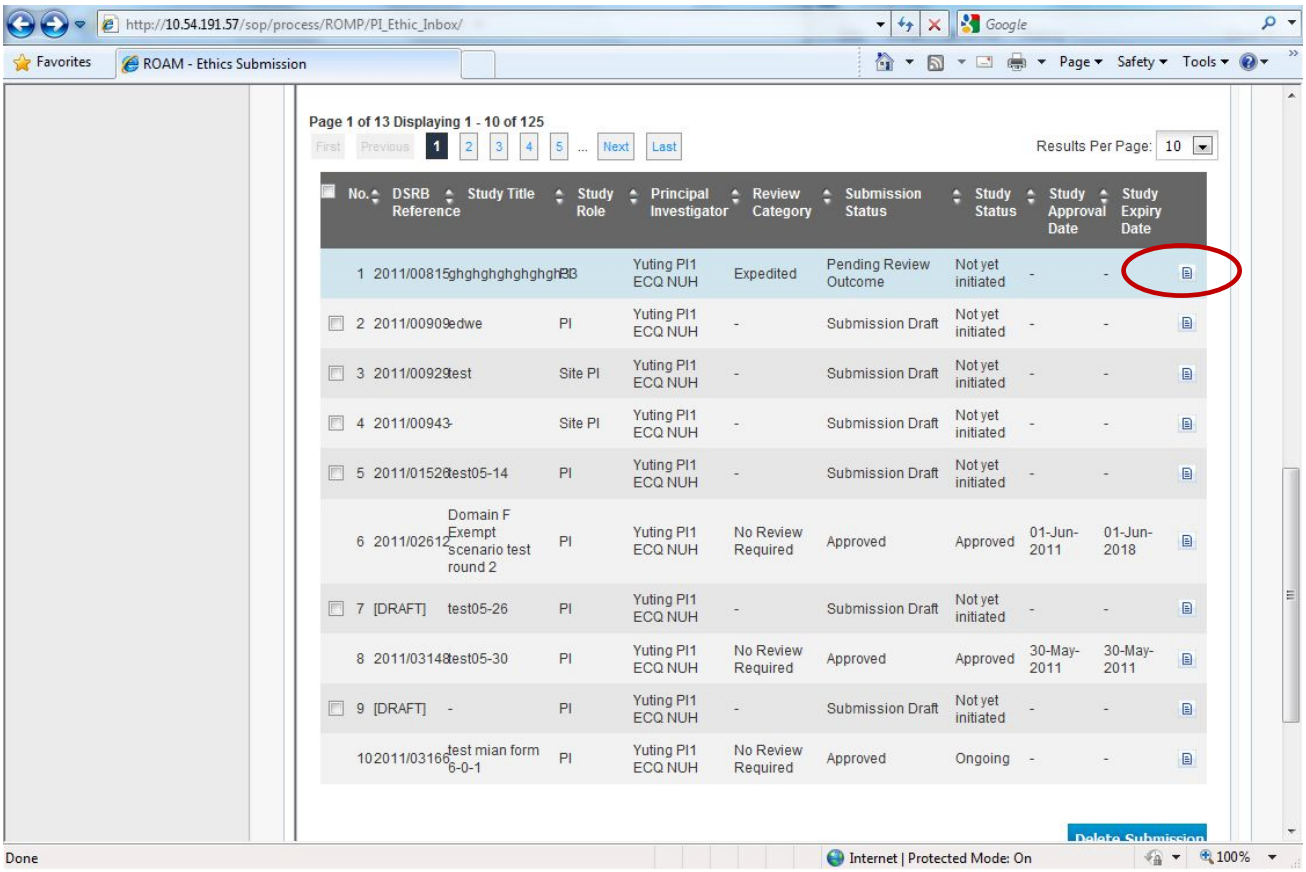


Figure 63 After a Draft becomes a Submitted Study

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.

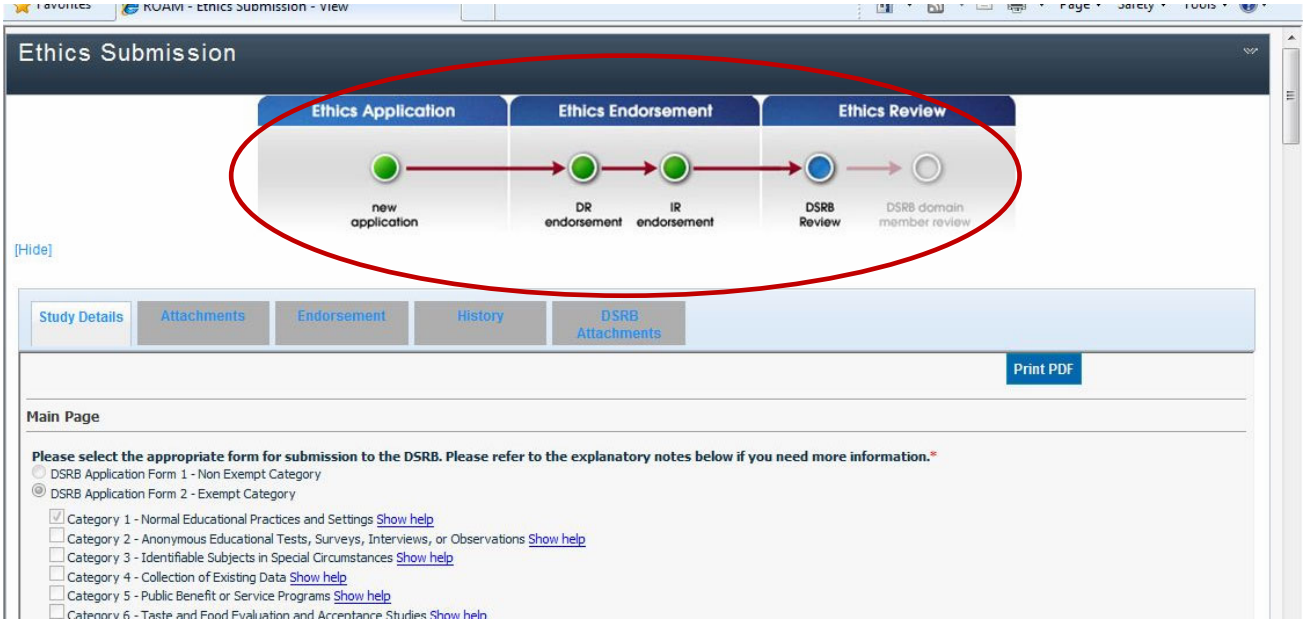


Figure 64 Submission Status Screen.

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.

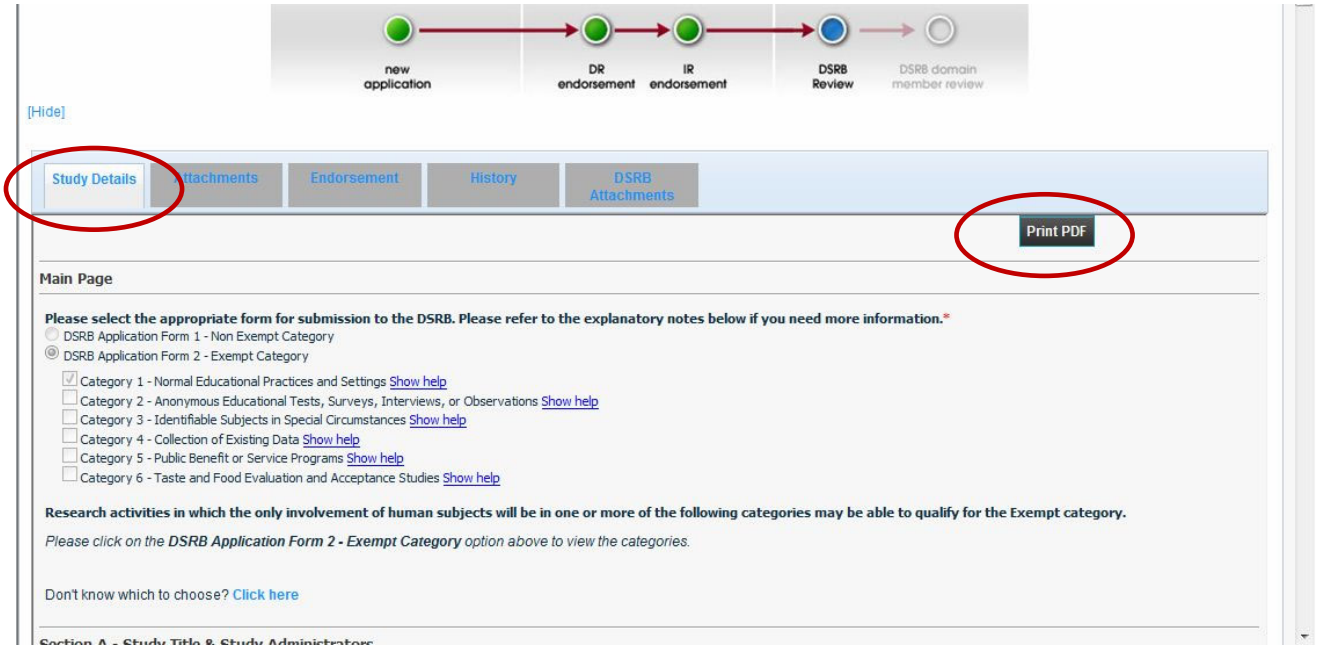


Figure 65 Study Details and Print PDF

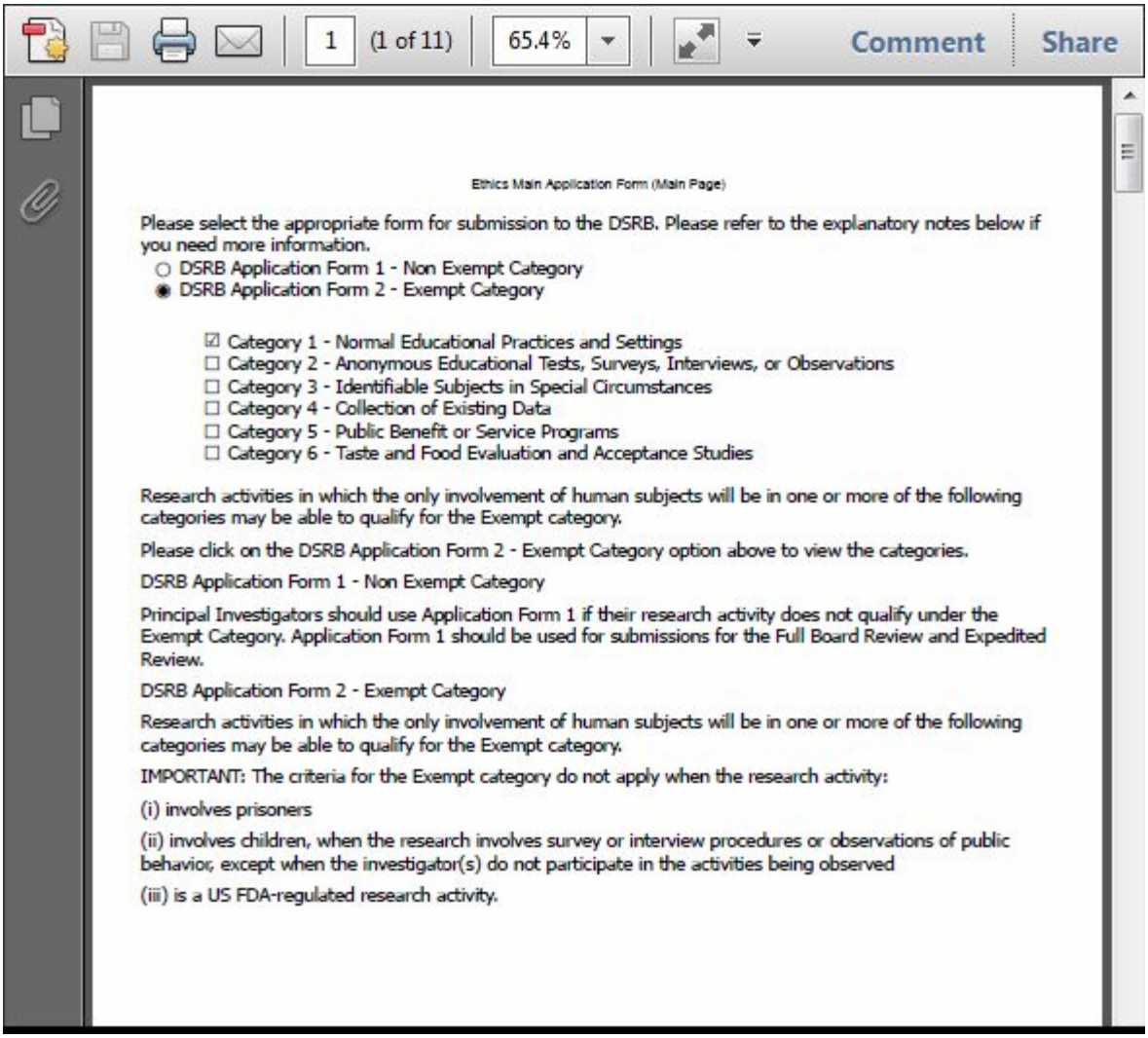


Figure 66 PDF Sample

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.

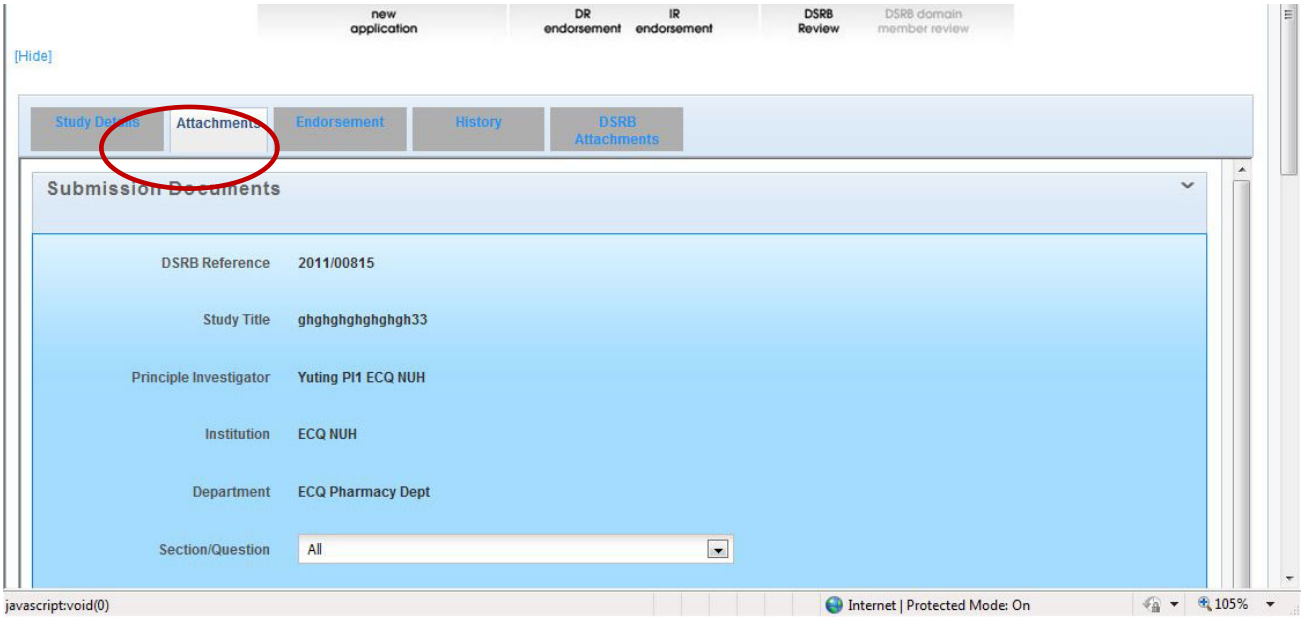


Figure 67 Attachments Panel

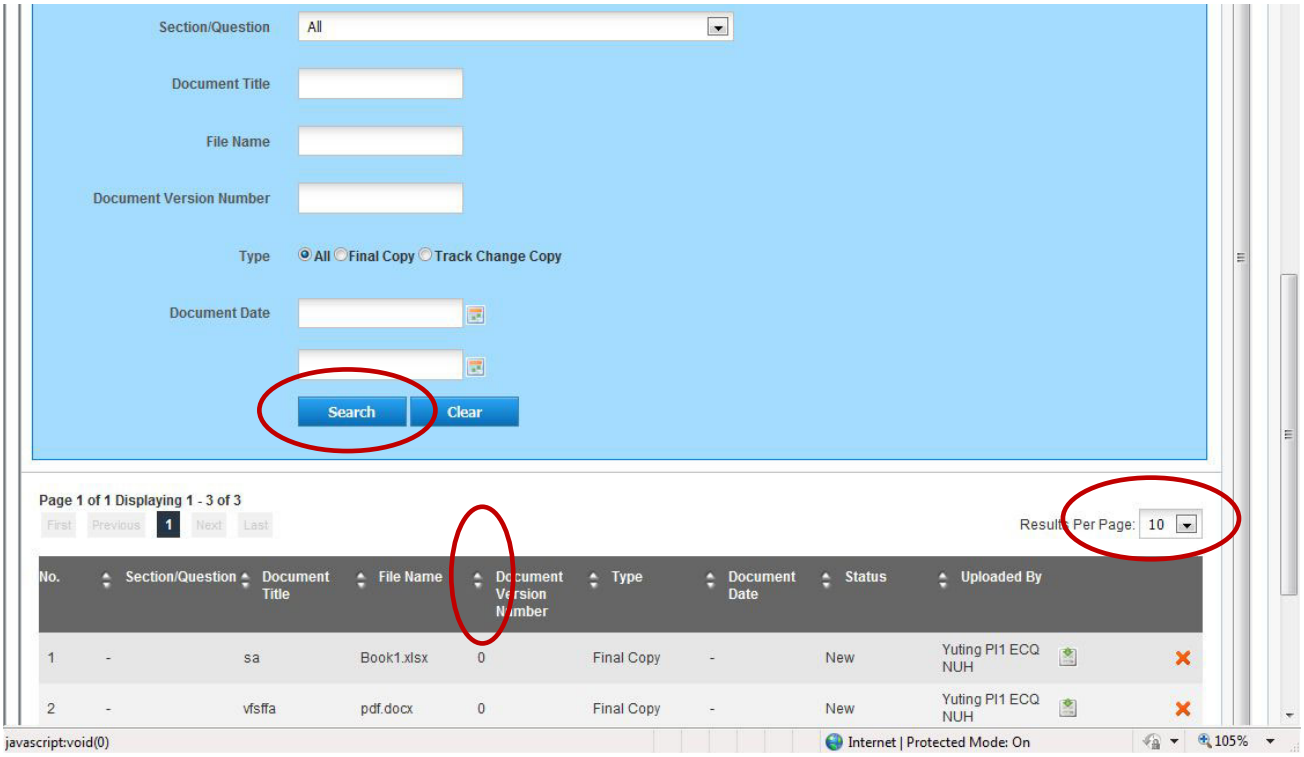


Figure 68 Search, Sort and Paginate functions.

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.

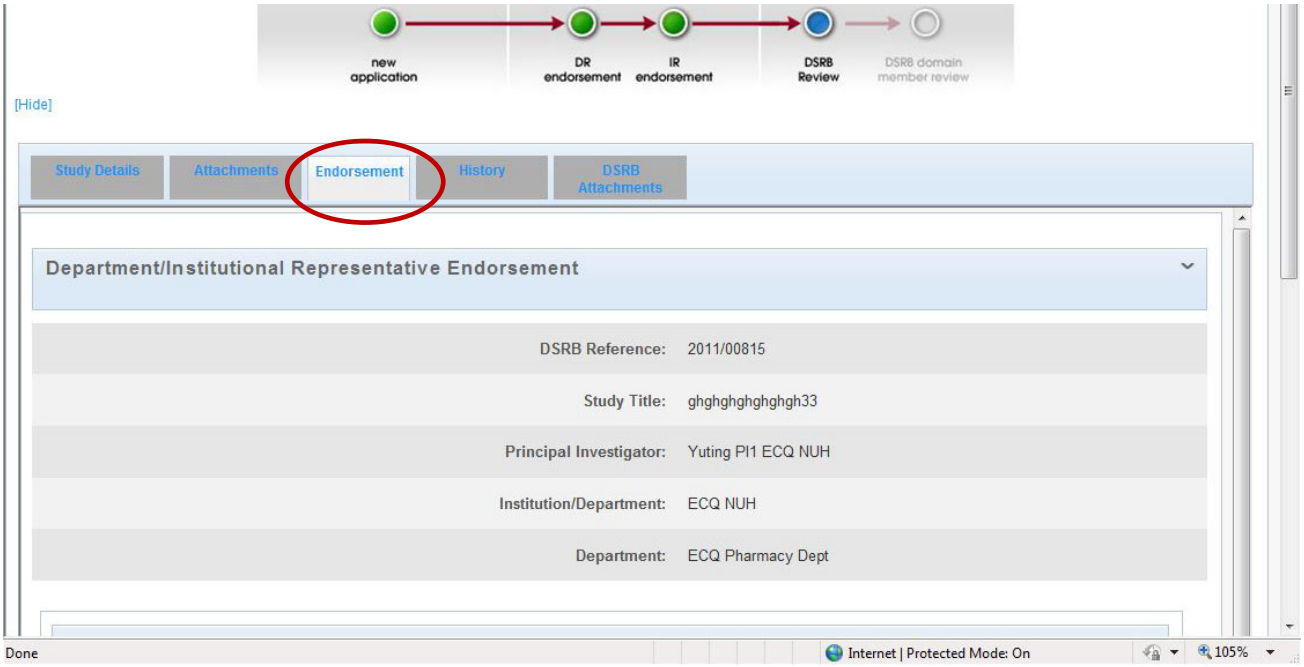


Figure 69 Endorsements

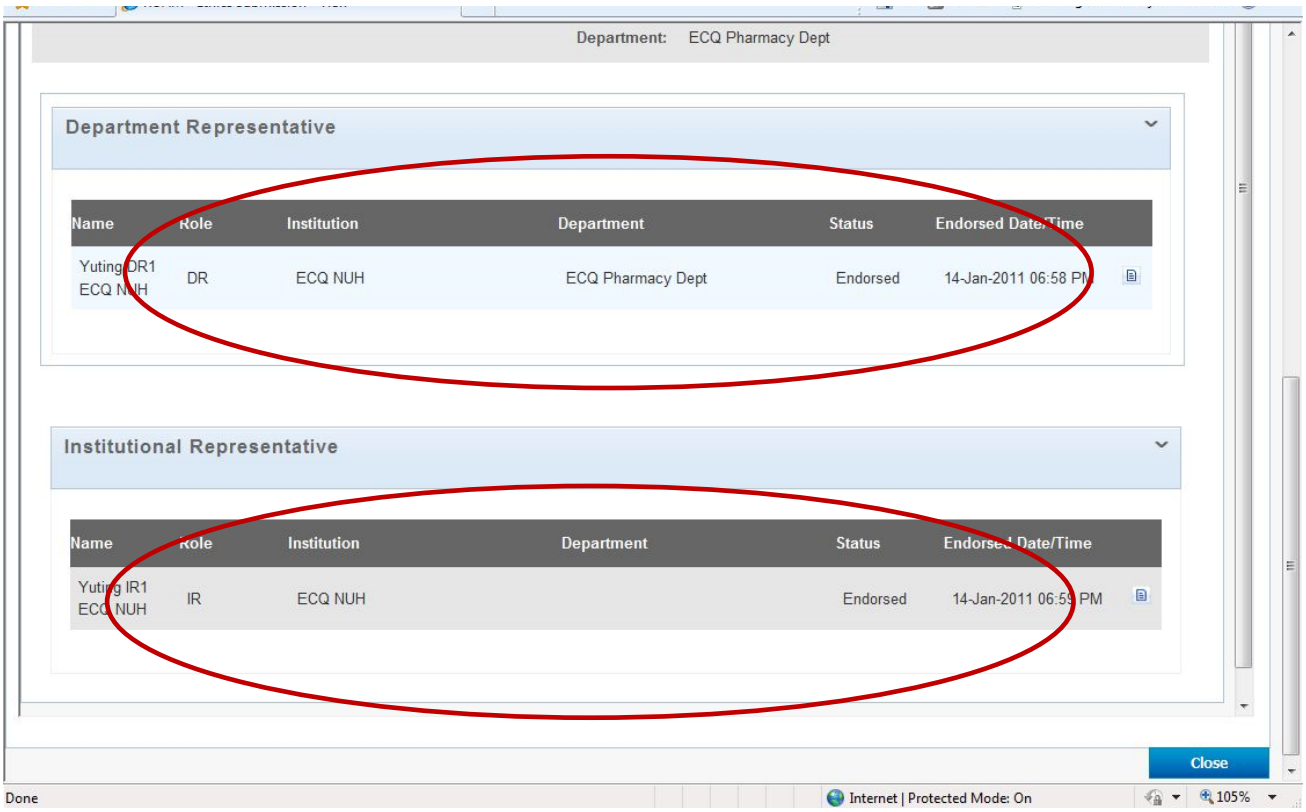


Figure 70 Endorsements II

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.

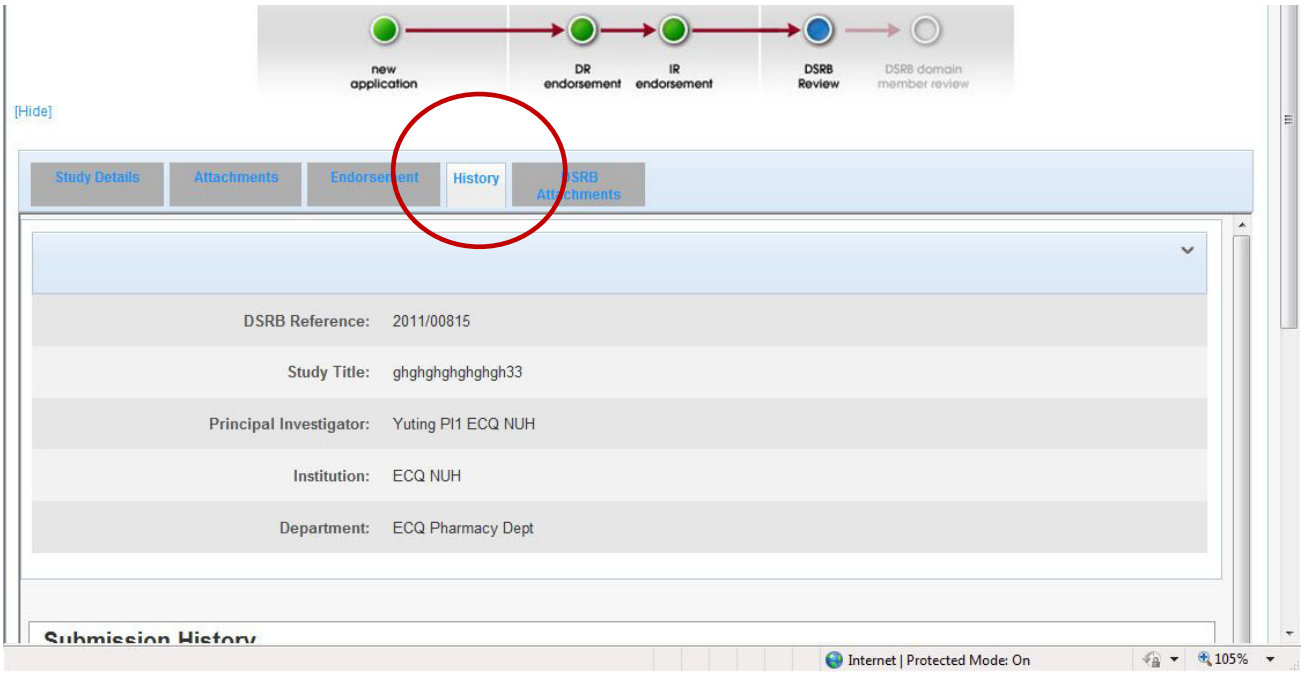


Figure 71 History

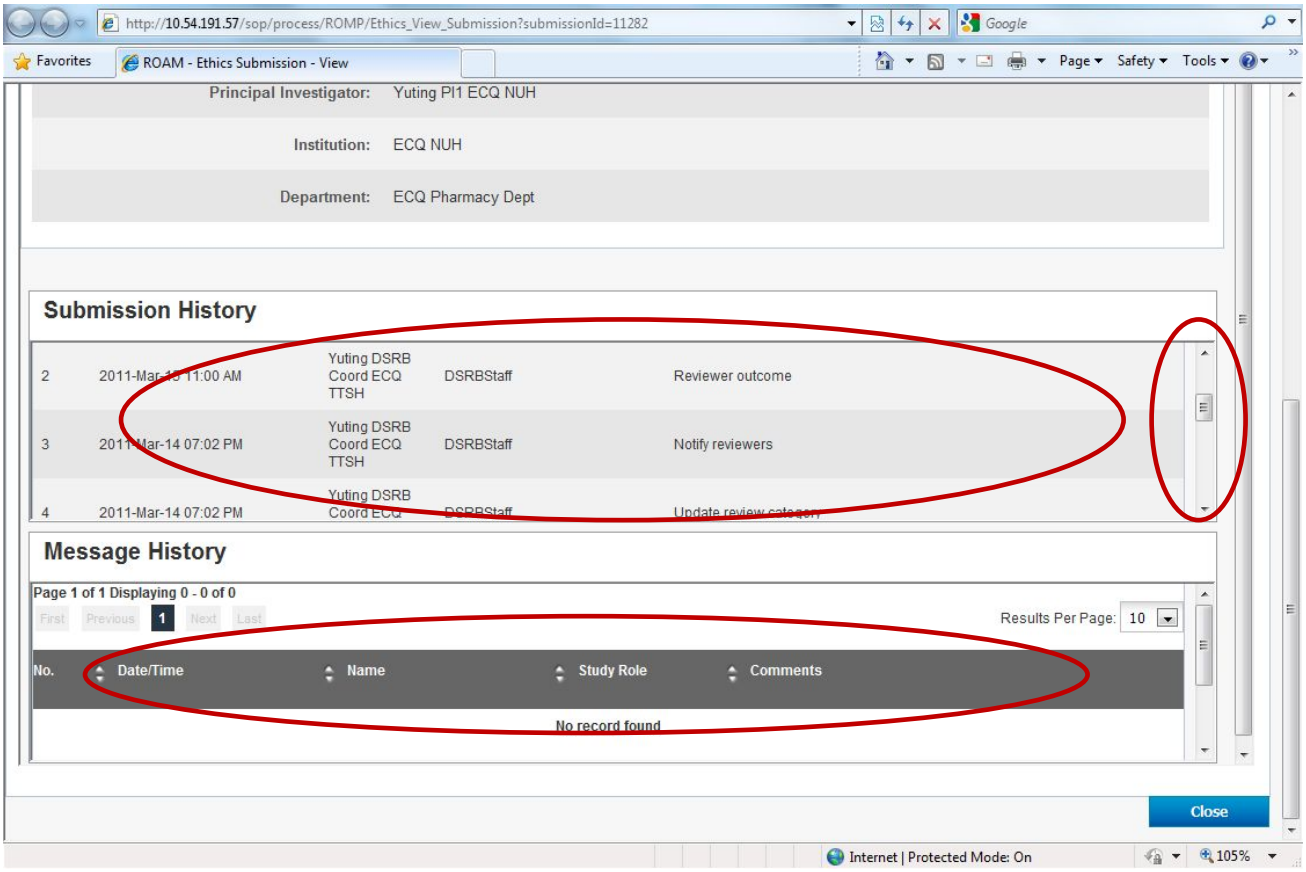


Figure 72 History II

3.8 DSRB Attachments Panel

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

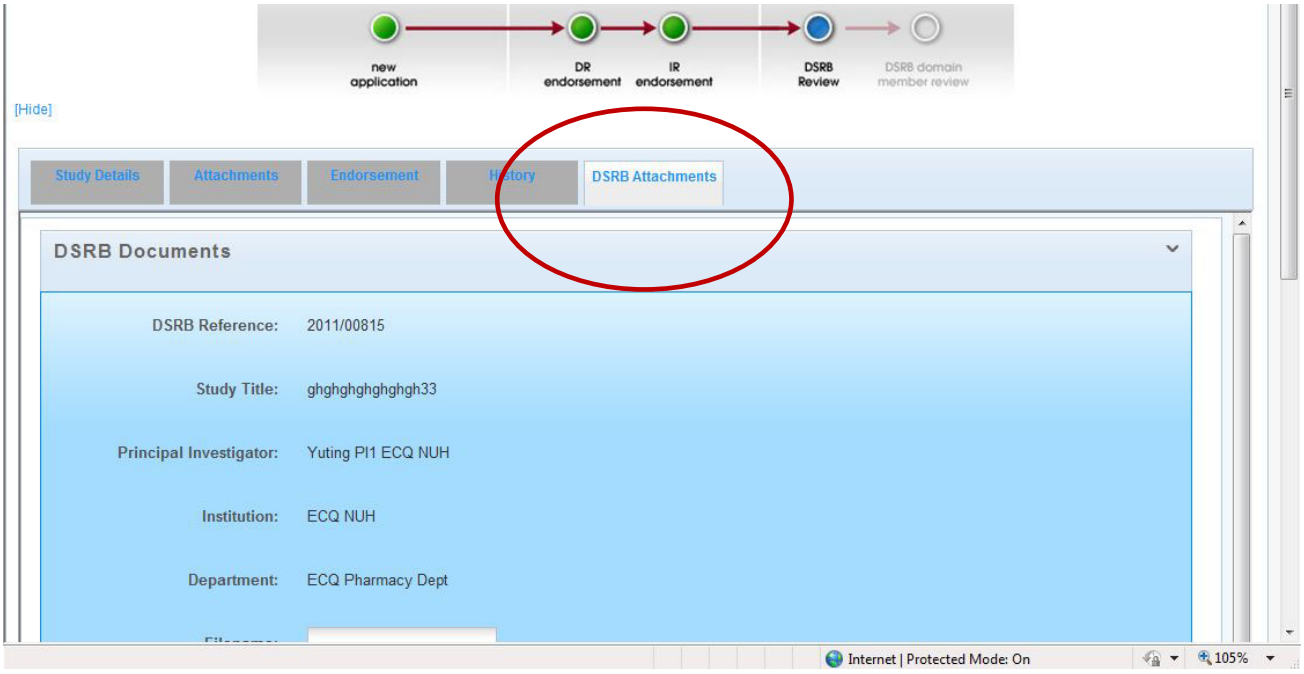


Figure 73 DSRB Attachments

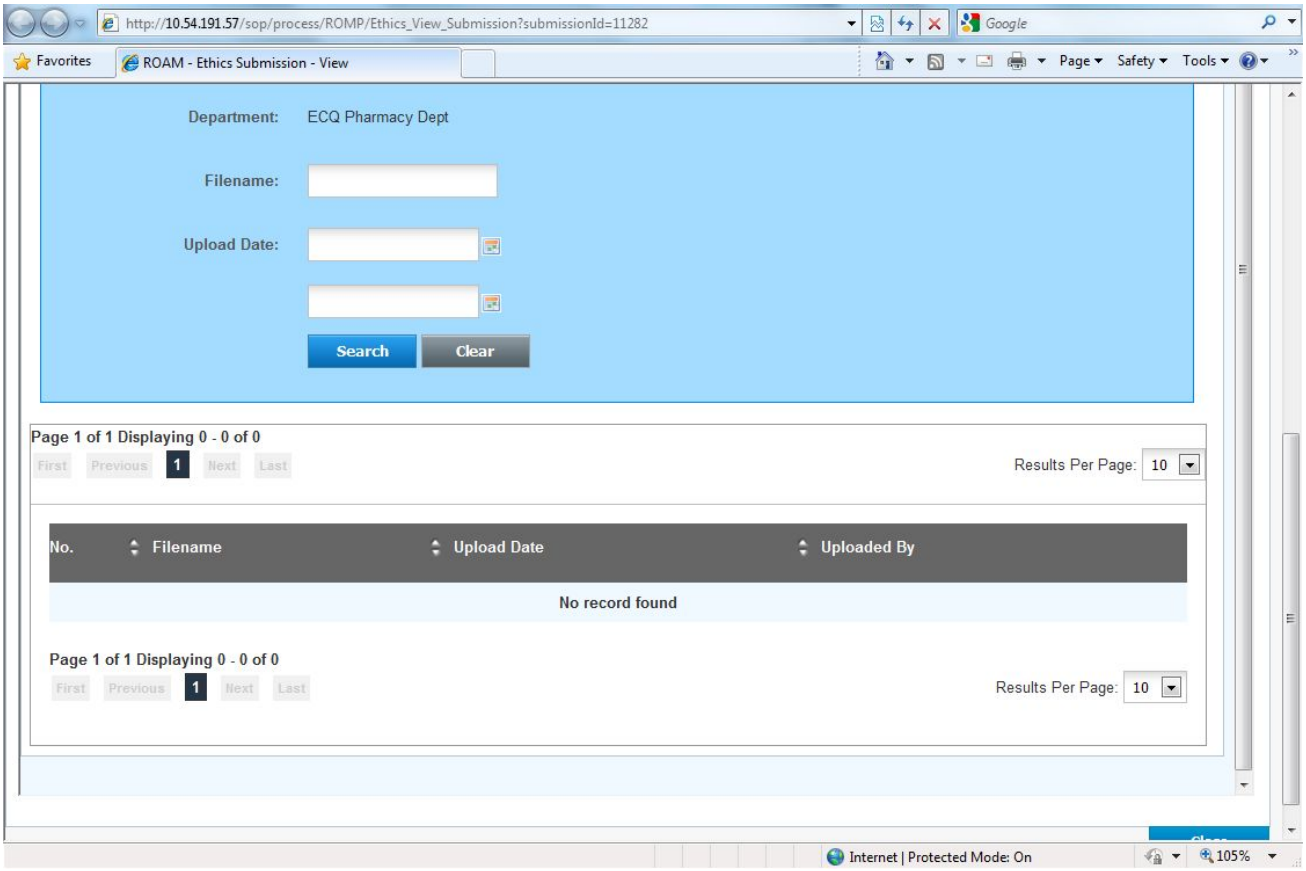


Figure 74 DSRB Attachments II

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.

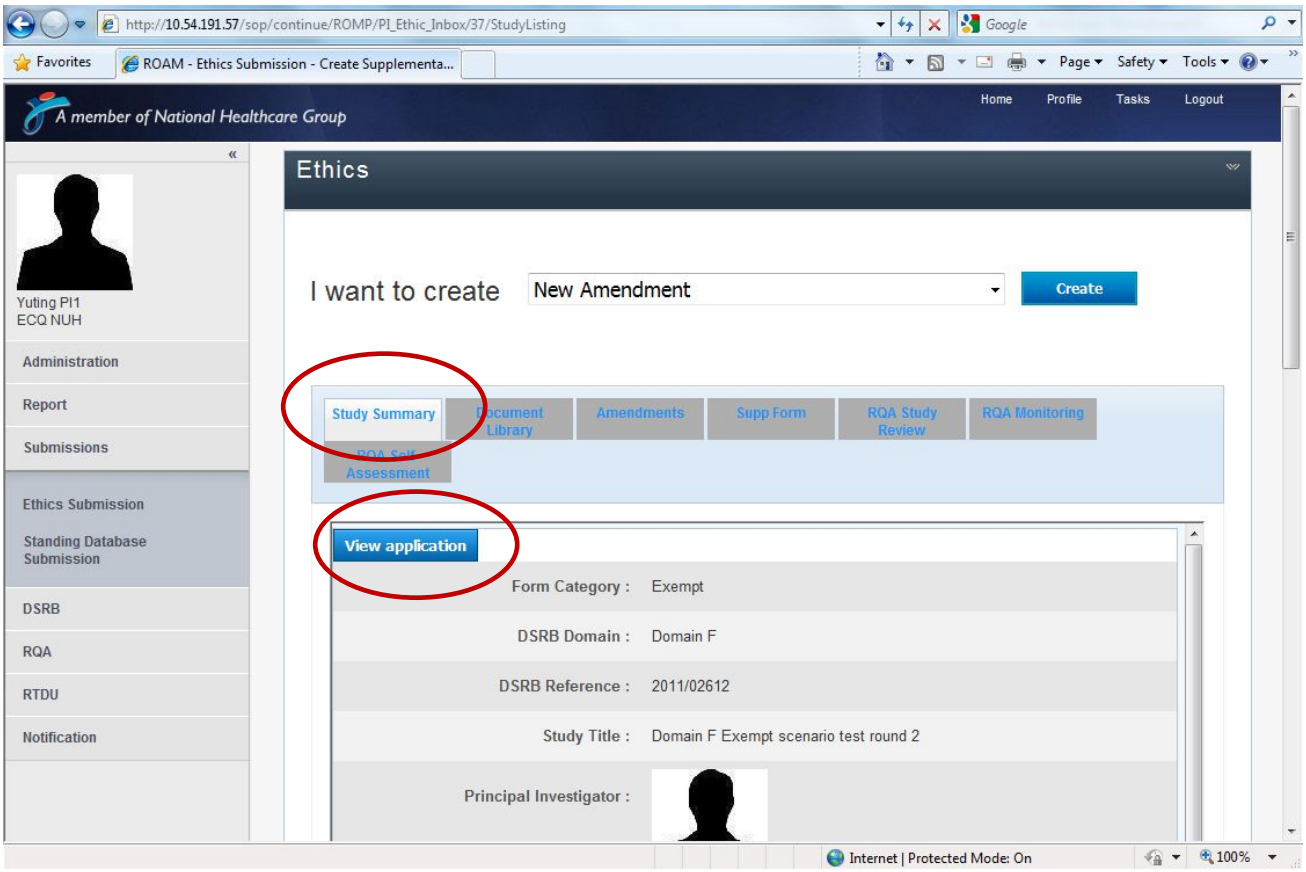


Figure 75 Study Summary

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

Figure 76 Study Summary II

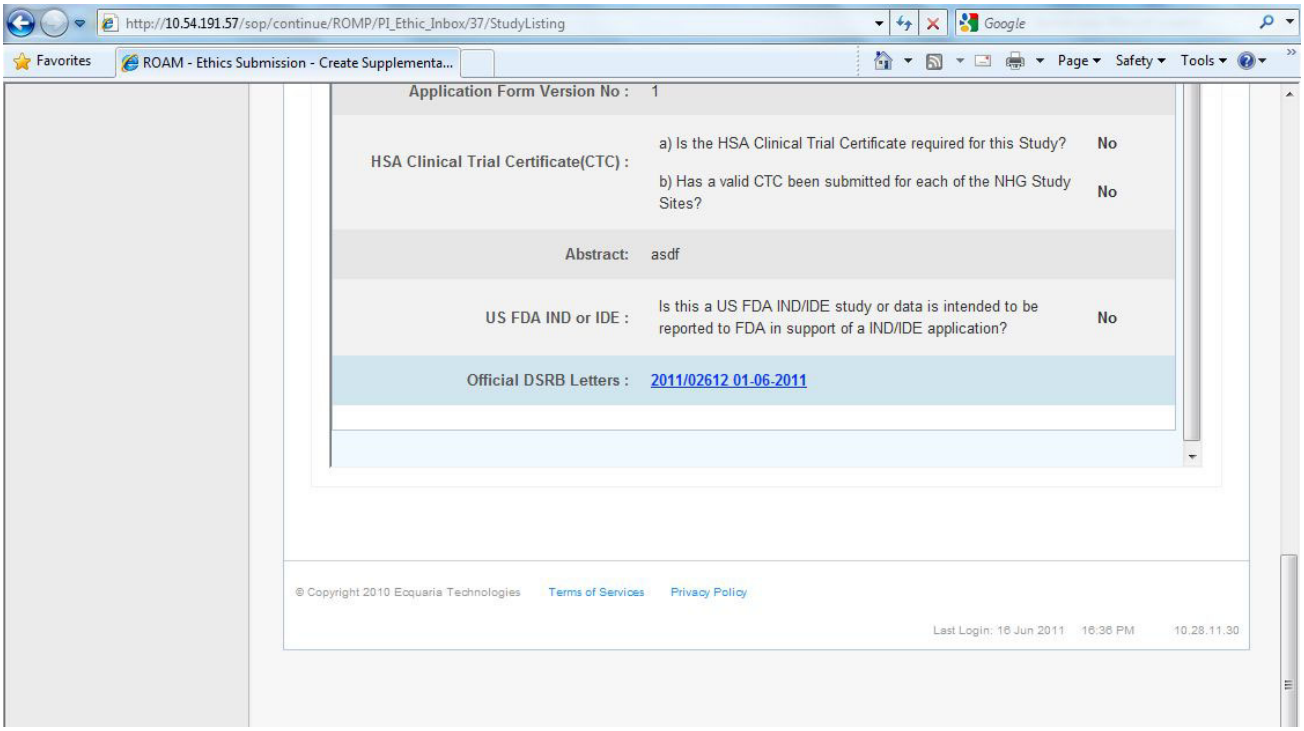


Figure 77 Study Summary III

4.1.2 Document Library

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

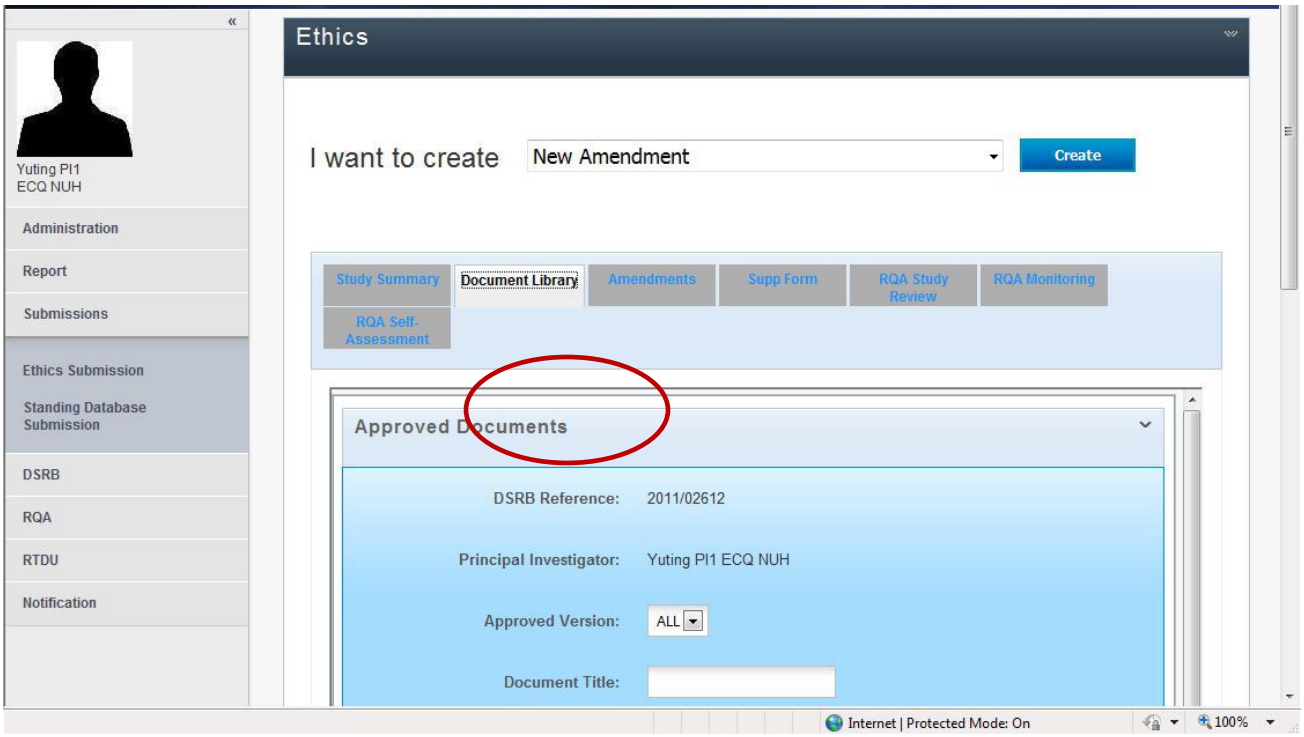


Figure 78 Document Library

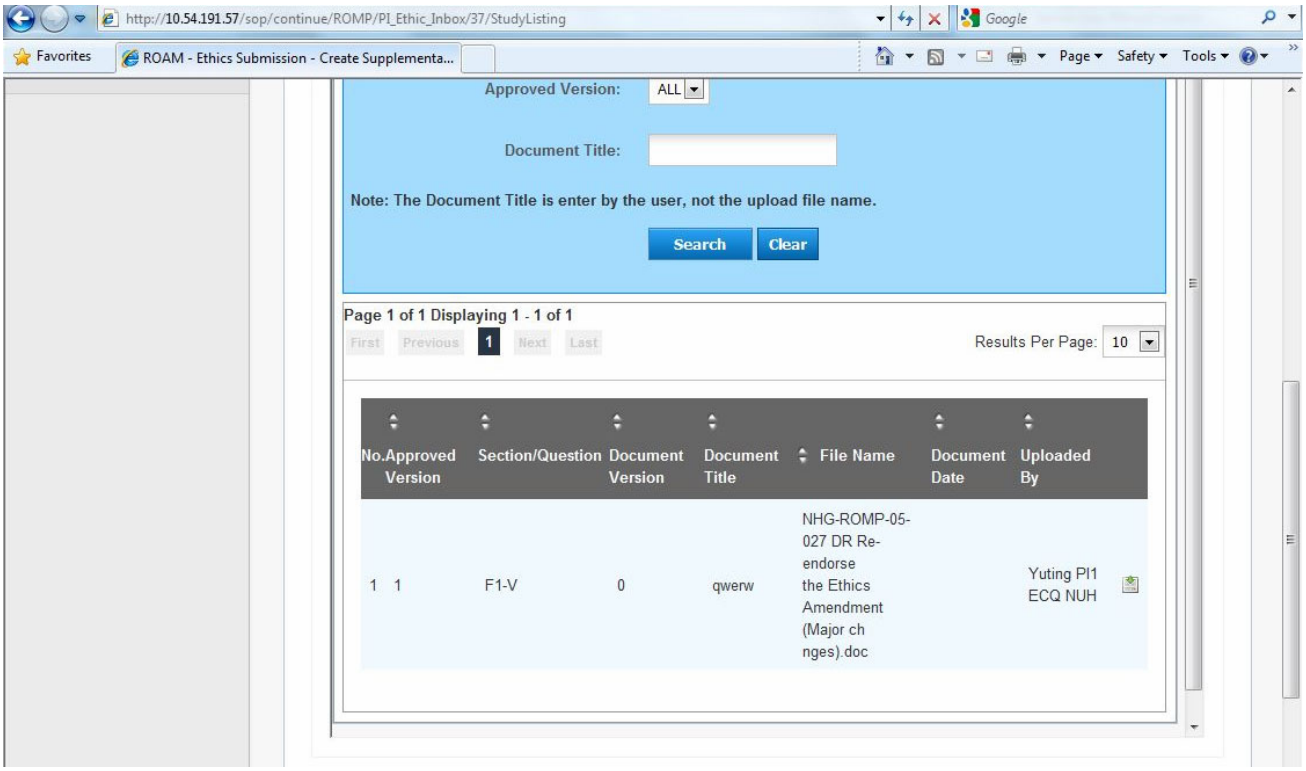


Figure 79 Document Library II

4.1.3 Amendments

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

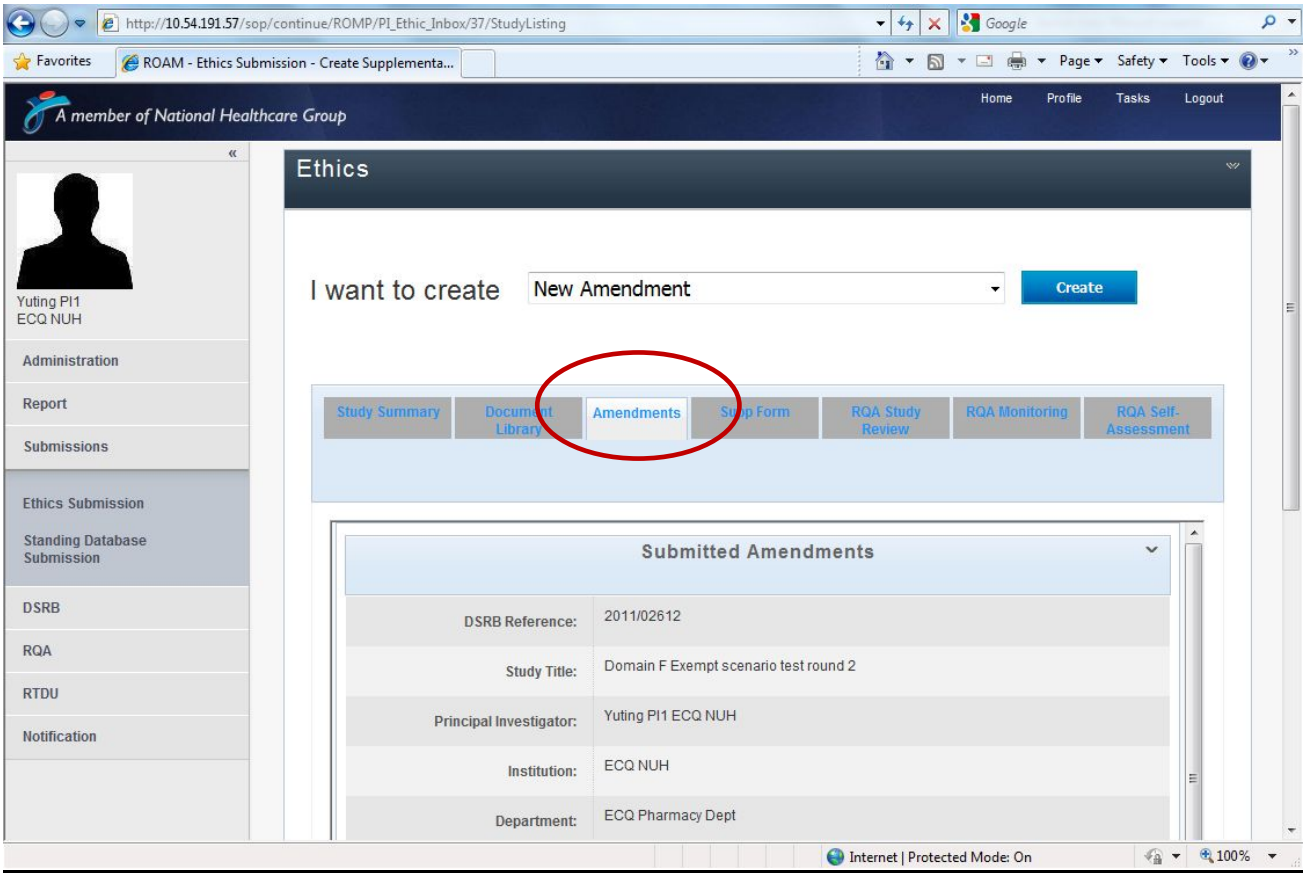


Figure 80 Amendments

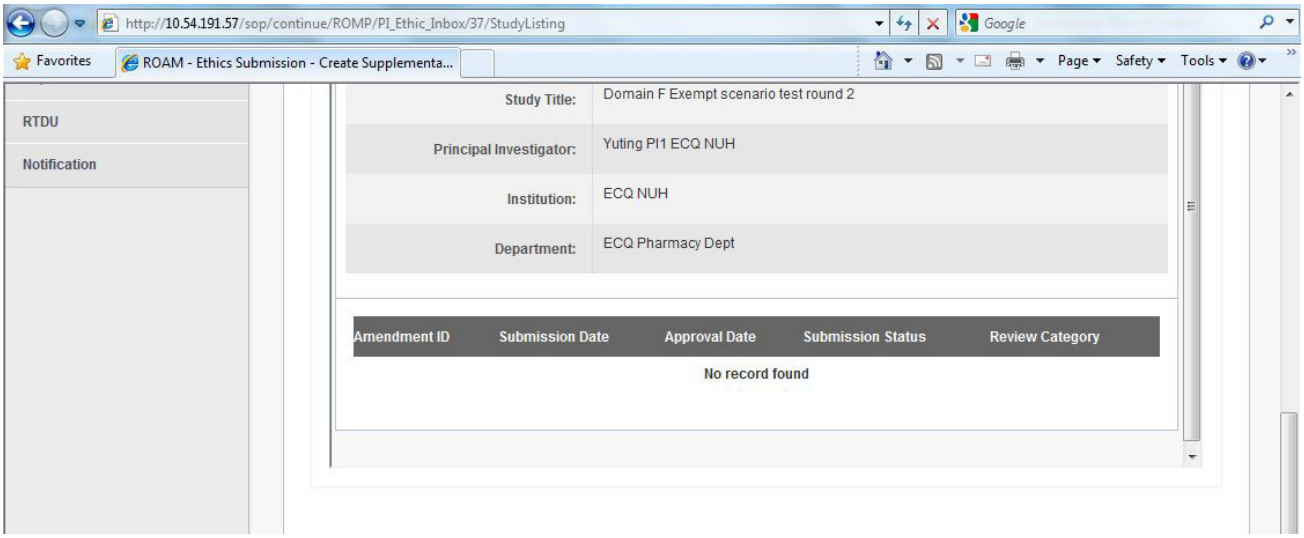


Figure 81 Amendments II

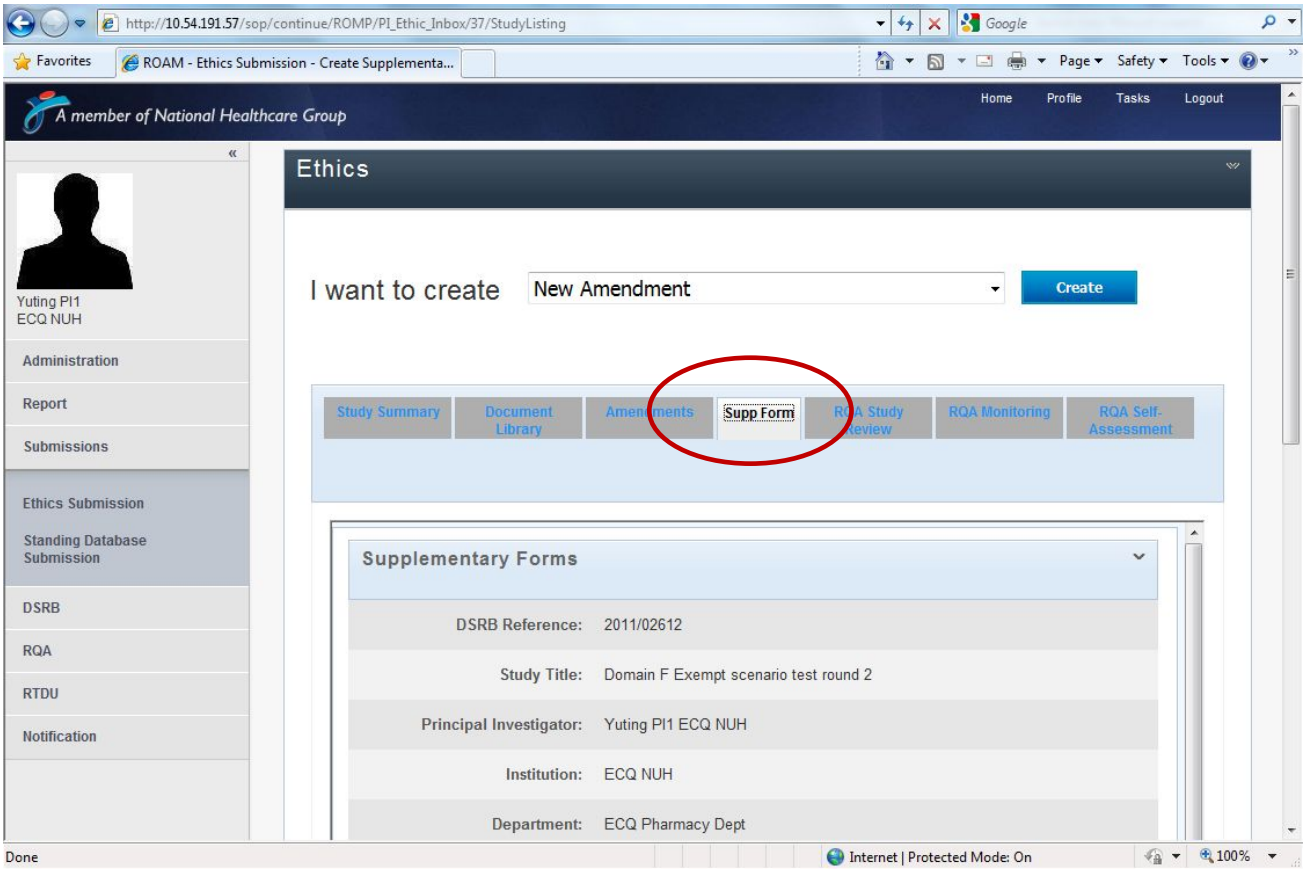


Figure 82 Supplementary Forms

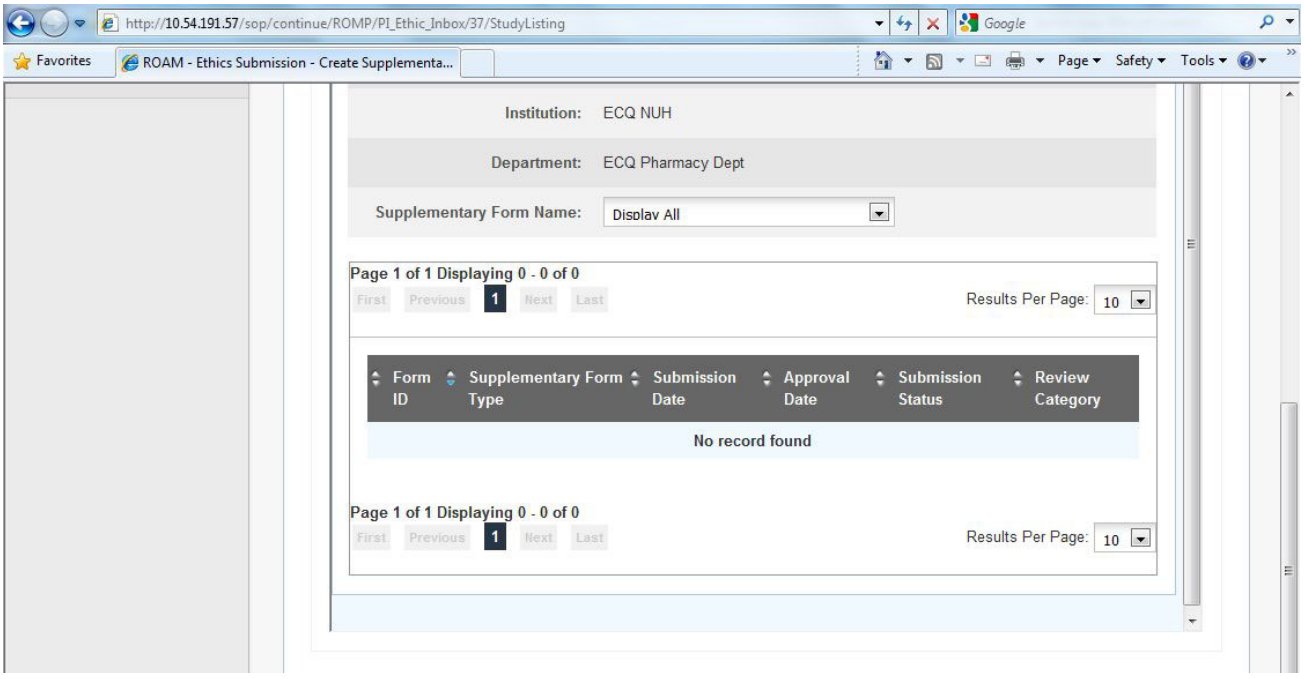


Figure 83 Supplementary Forms II

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.

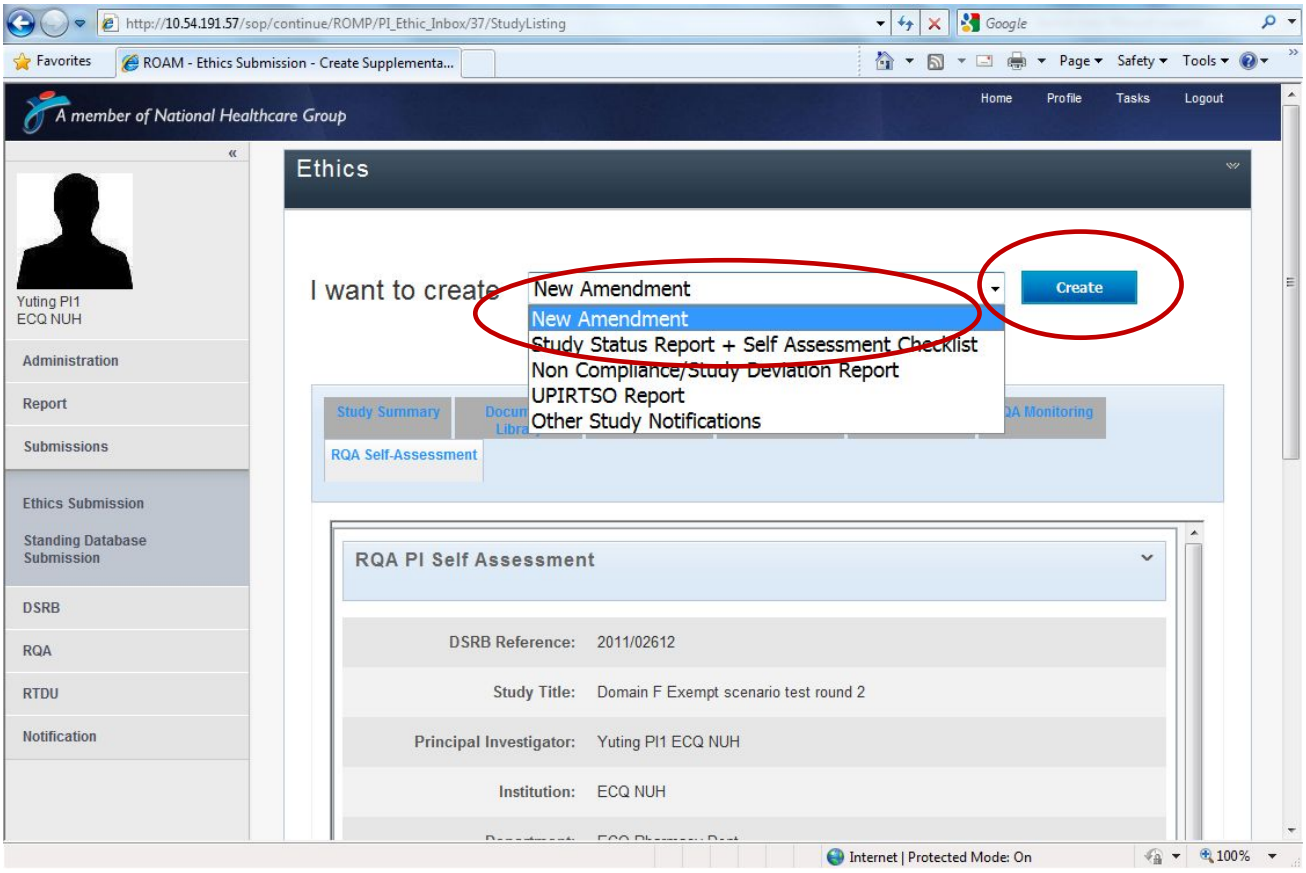


Figure 84 New Amendment drop down list

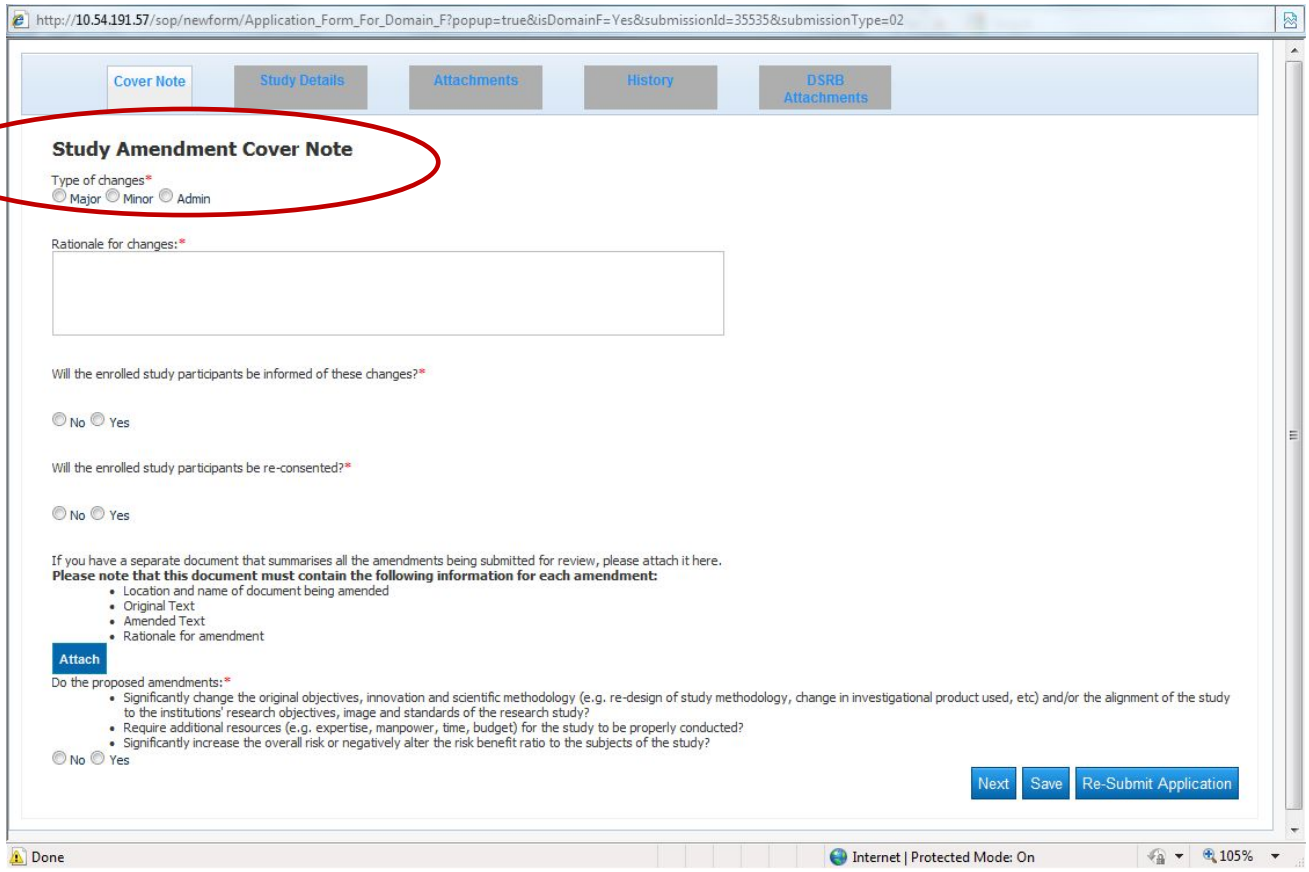


Figure 85 Study Amendment Cover Note

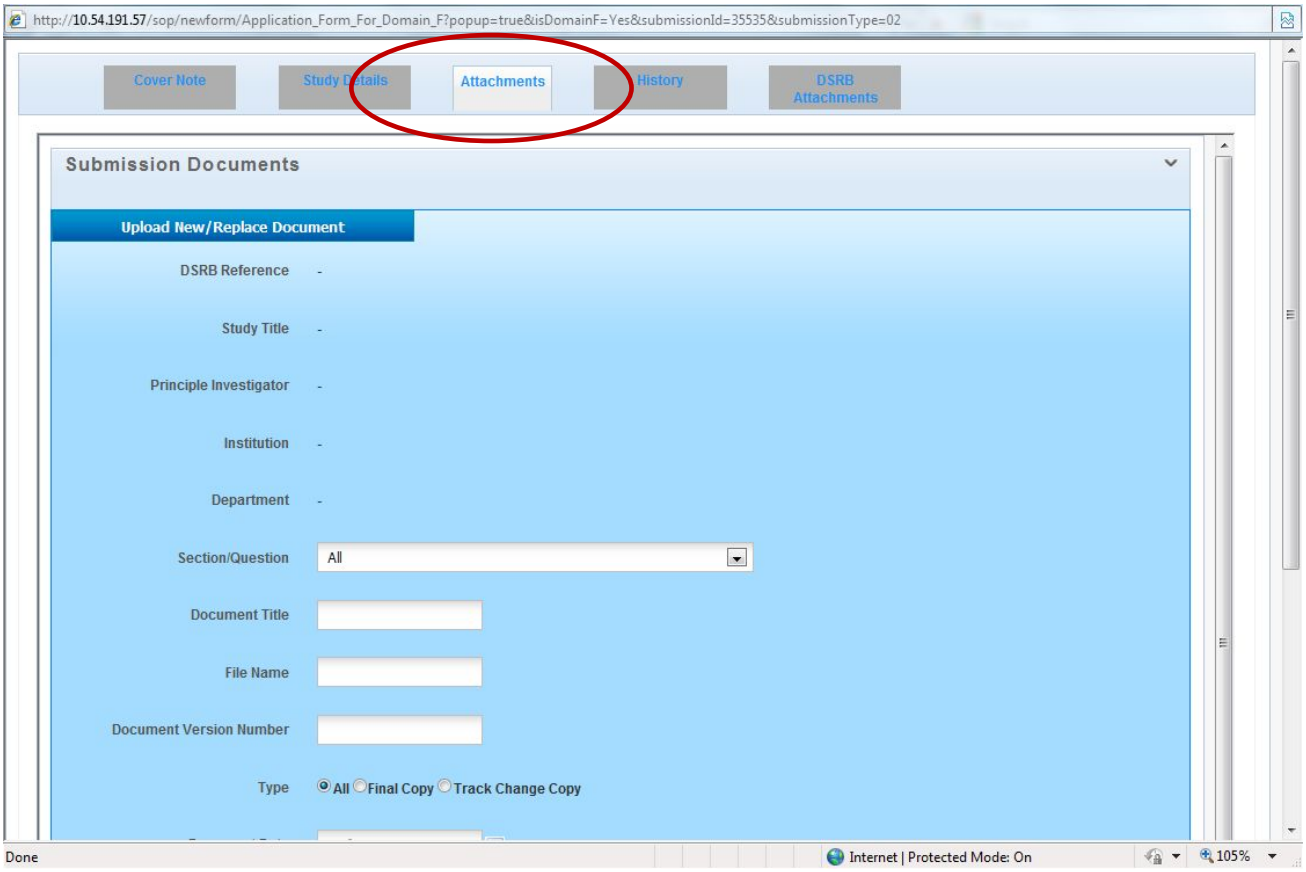
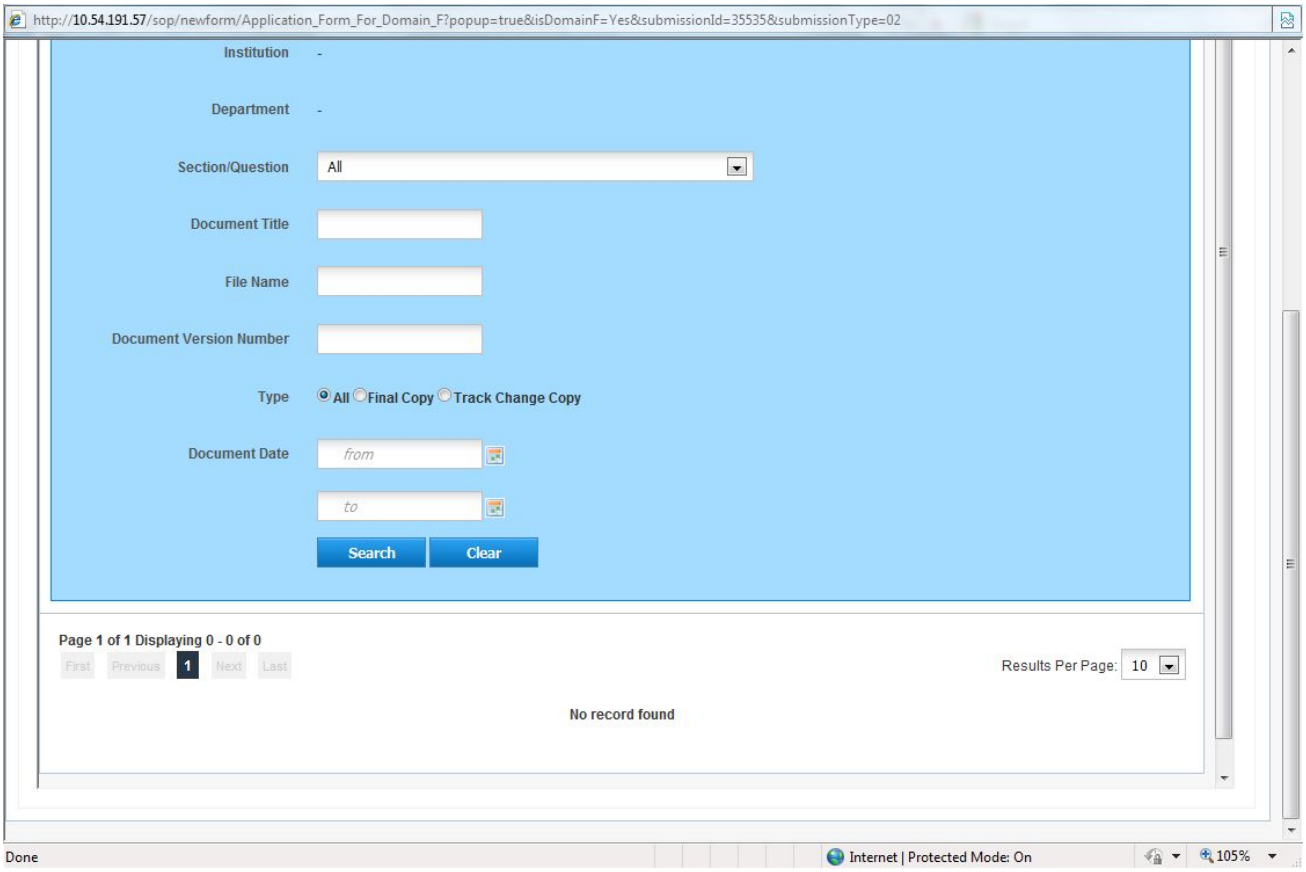


Figure 86 Study Amendment Attachments



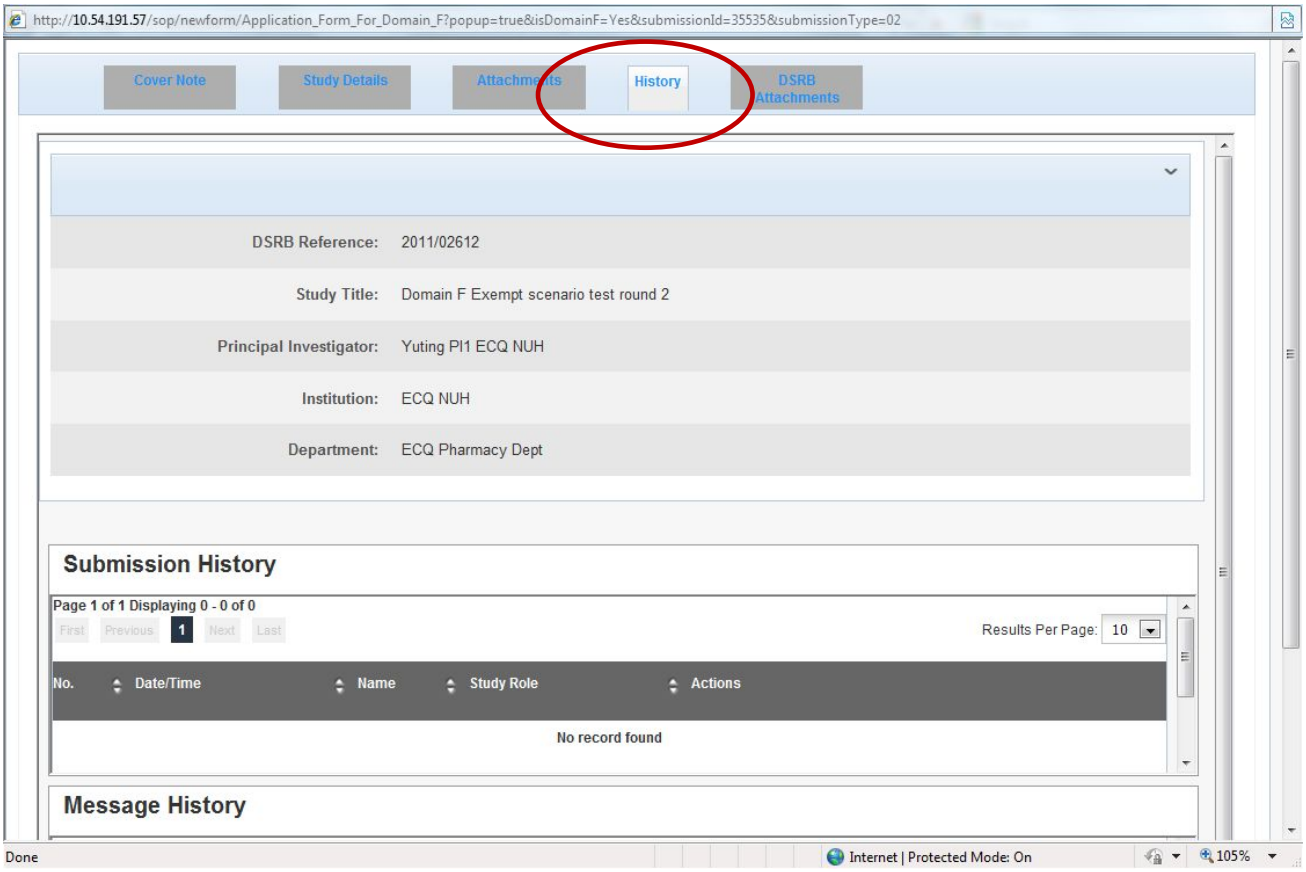


Figure 87 Study Amendment History

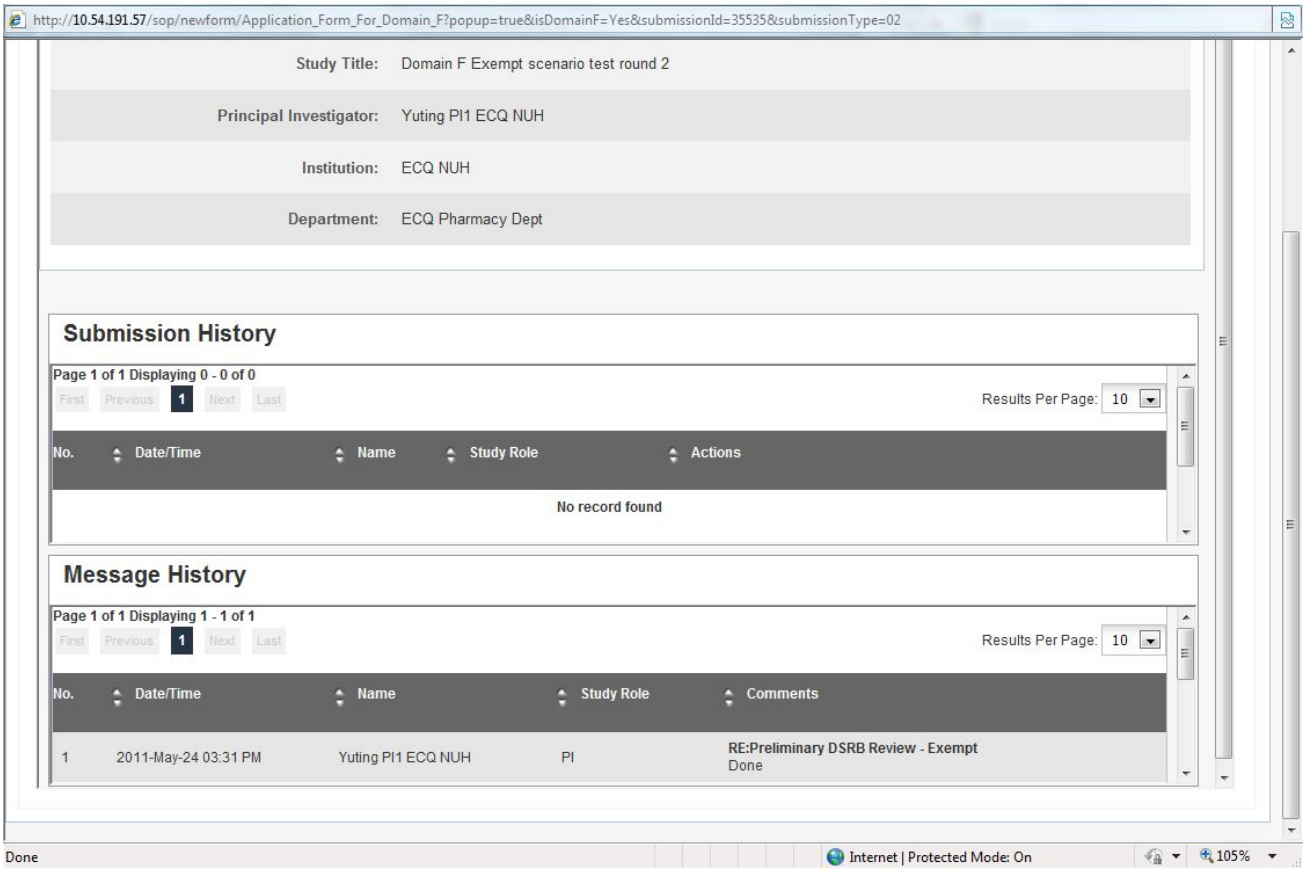


Figure 88 Study Amendment History II

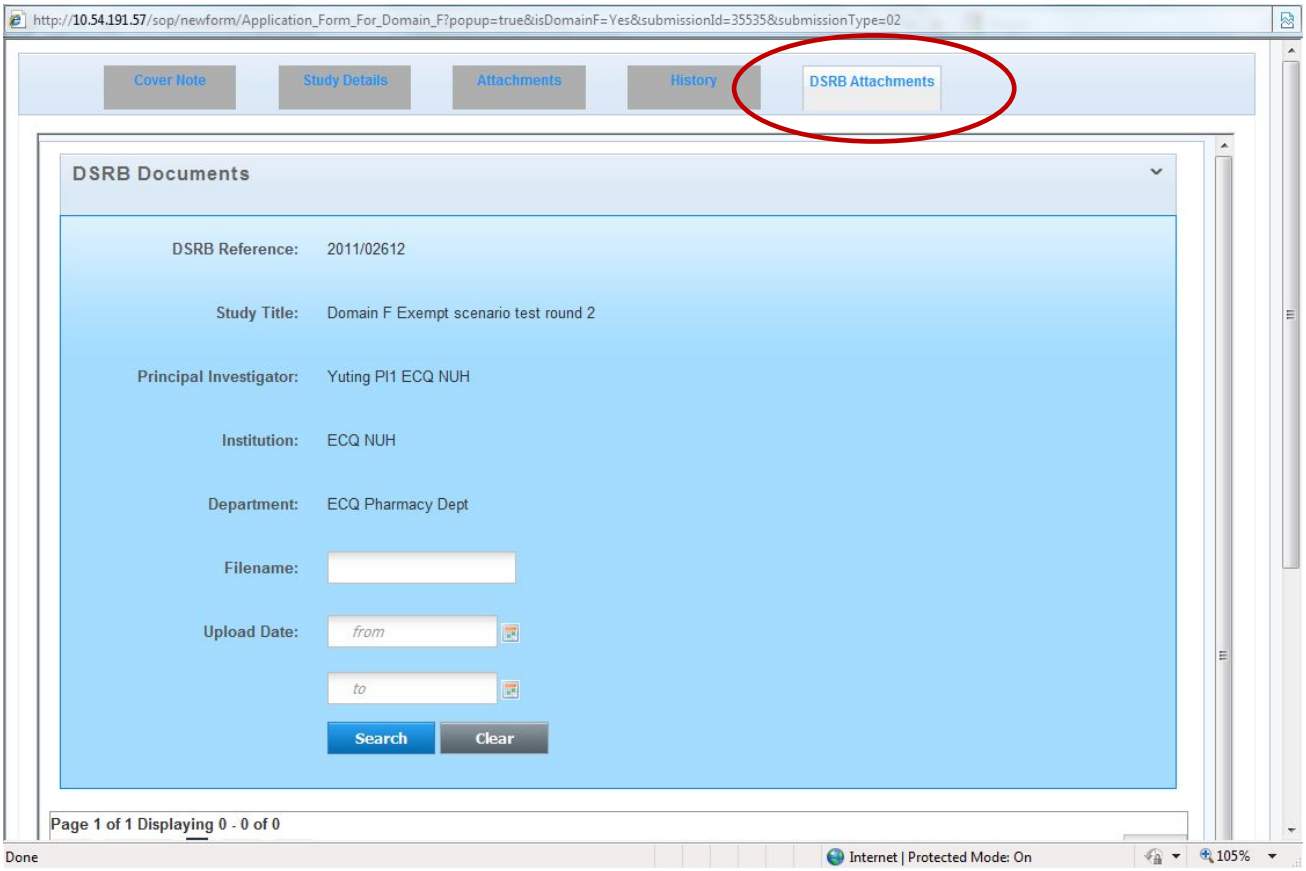


Figure 89 Study Amendment DSRB Attachments

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.

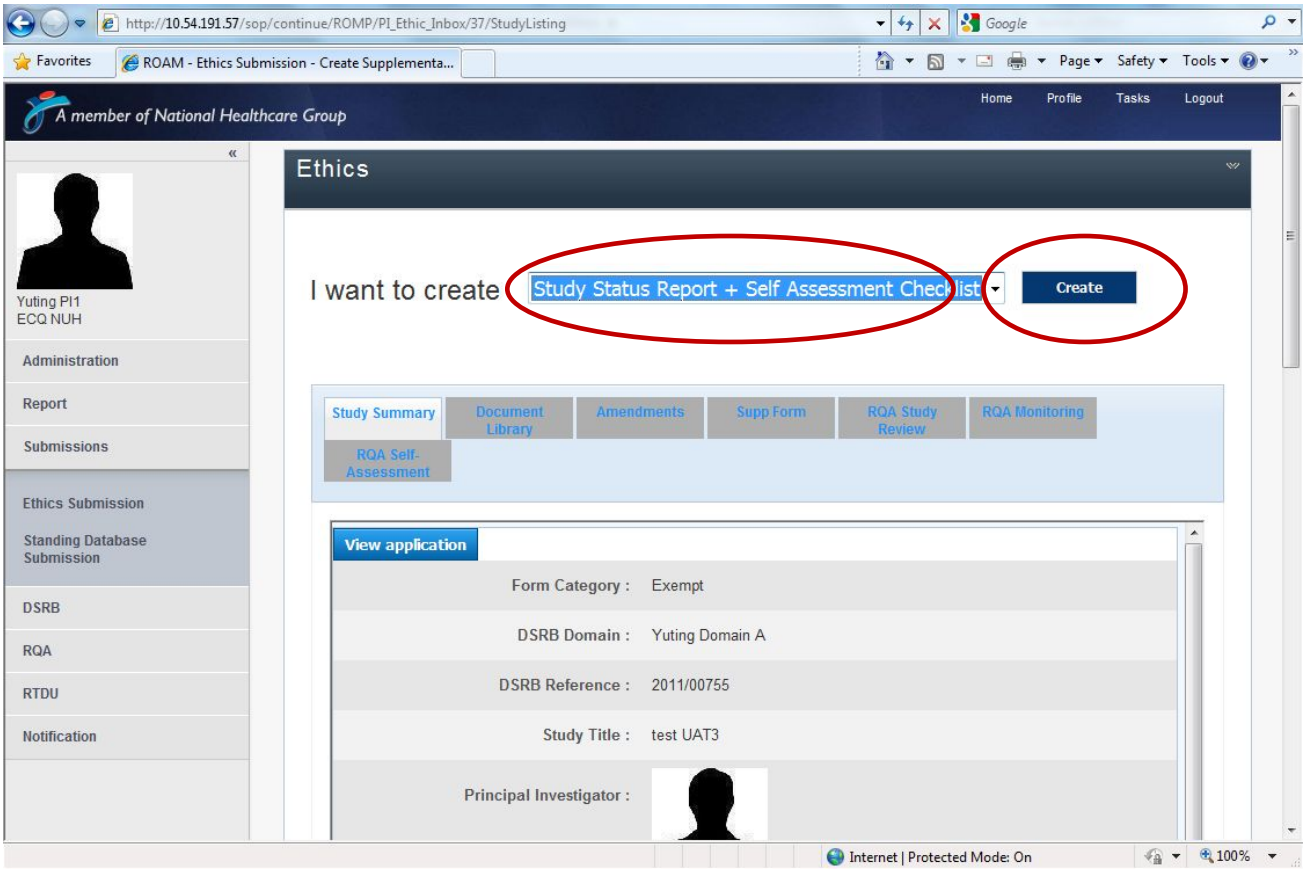


Figure 90 Creating a new Study Status Report

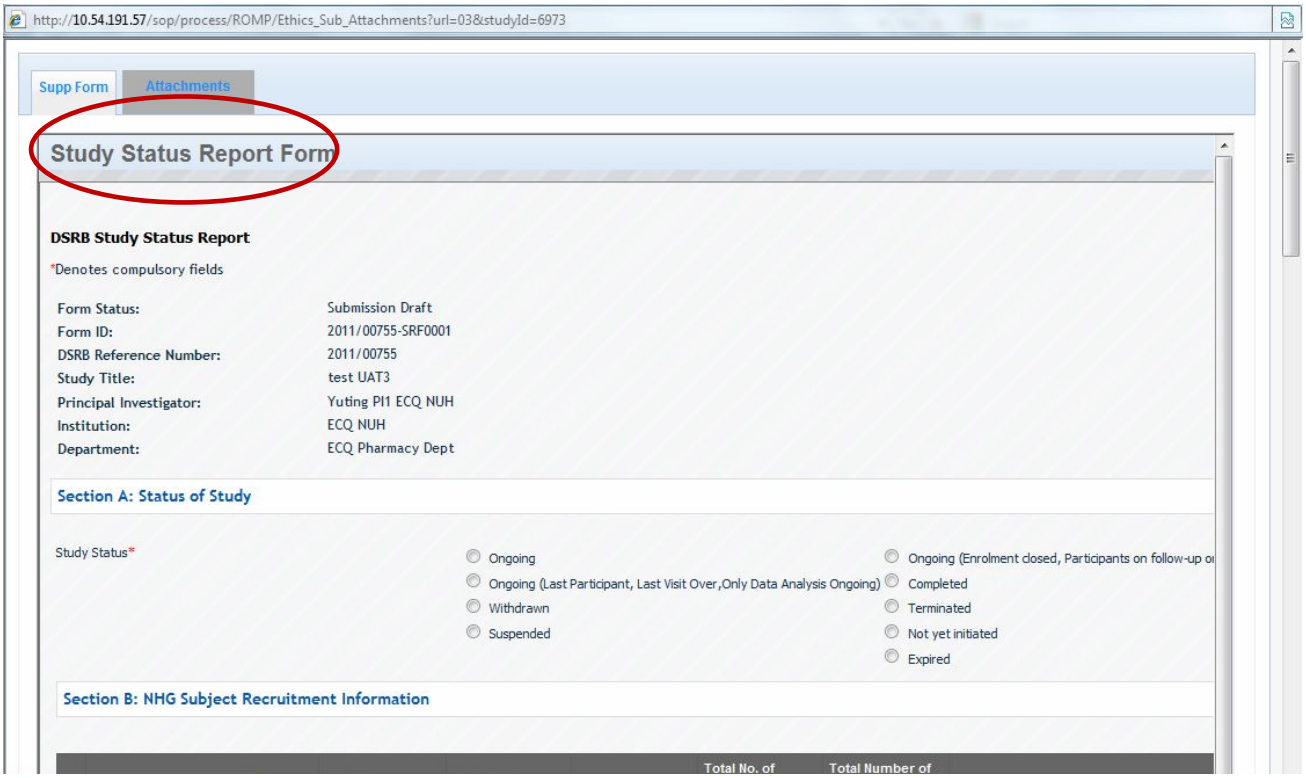


Figure 91 Study Status Report Form

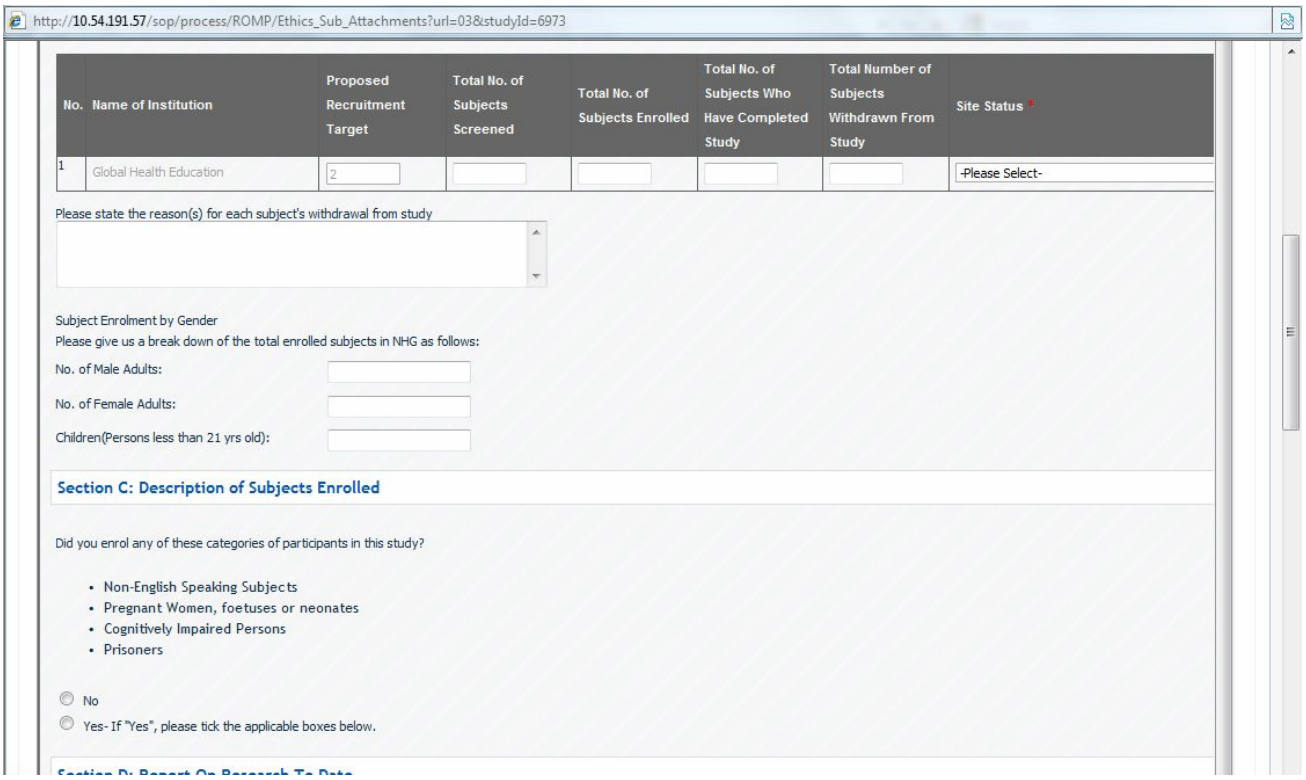


Figure 92 Study Status Report Form II

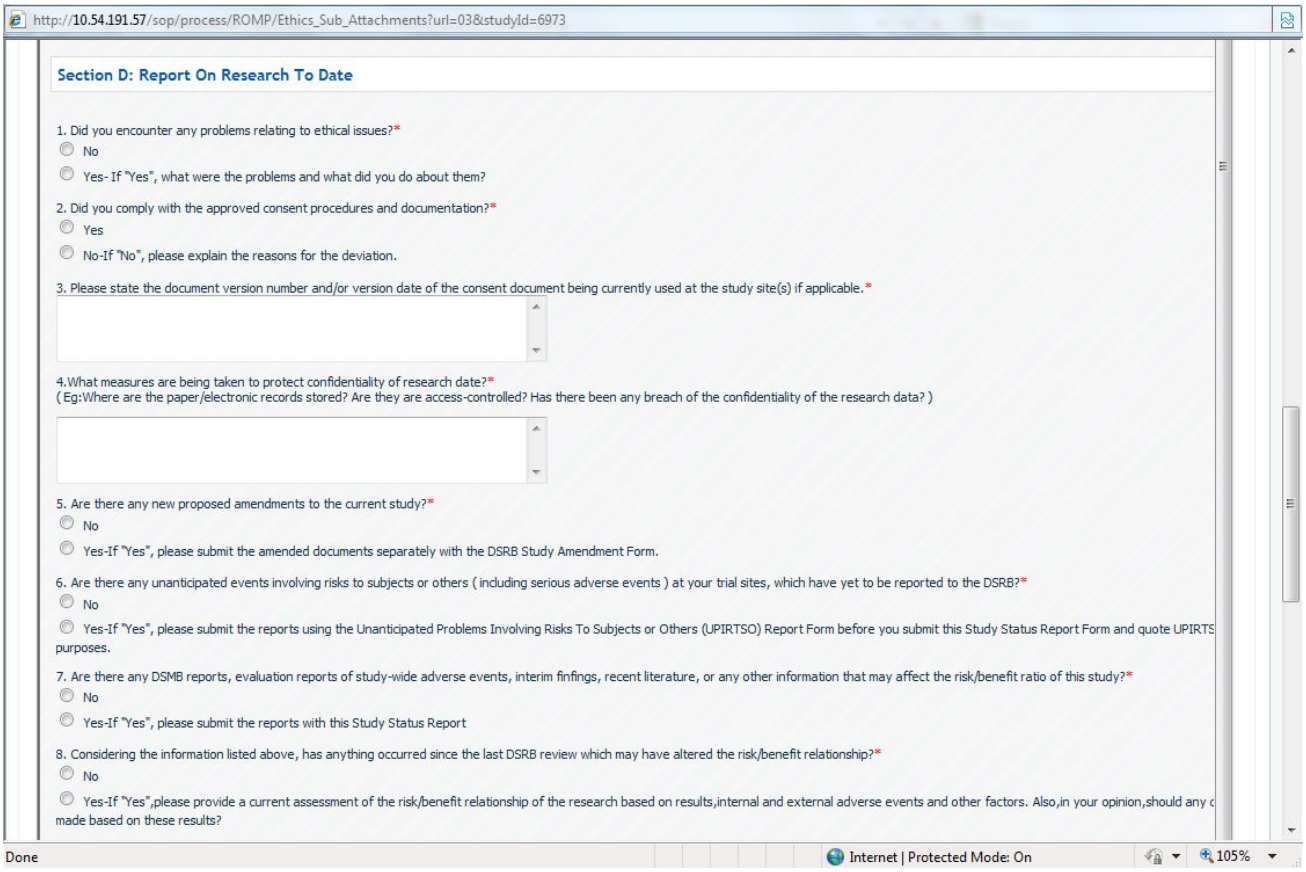


Figure 93 Study Status Report Form III

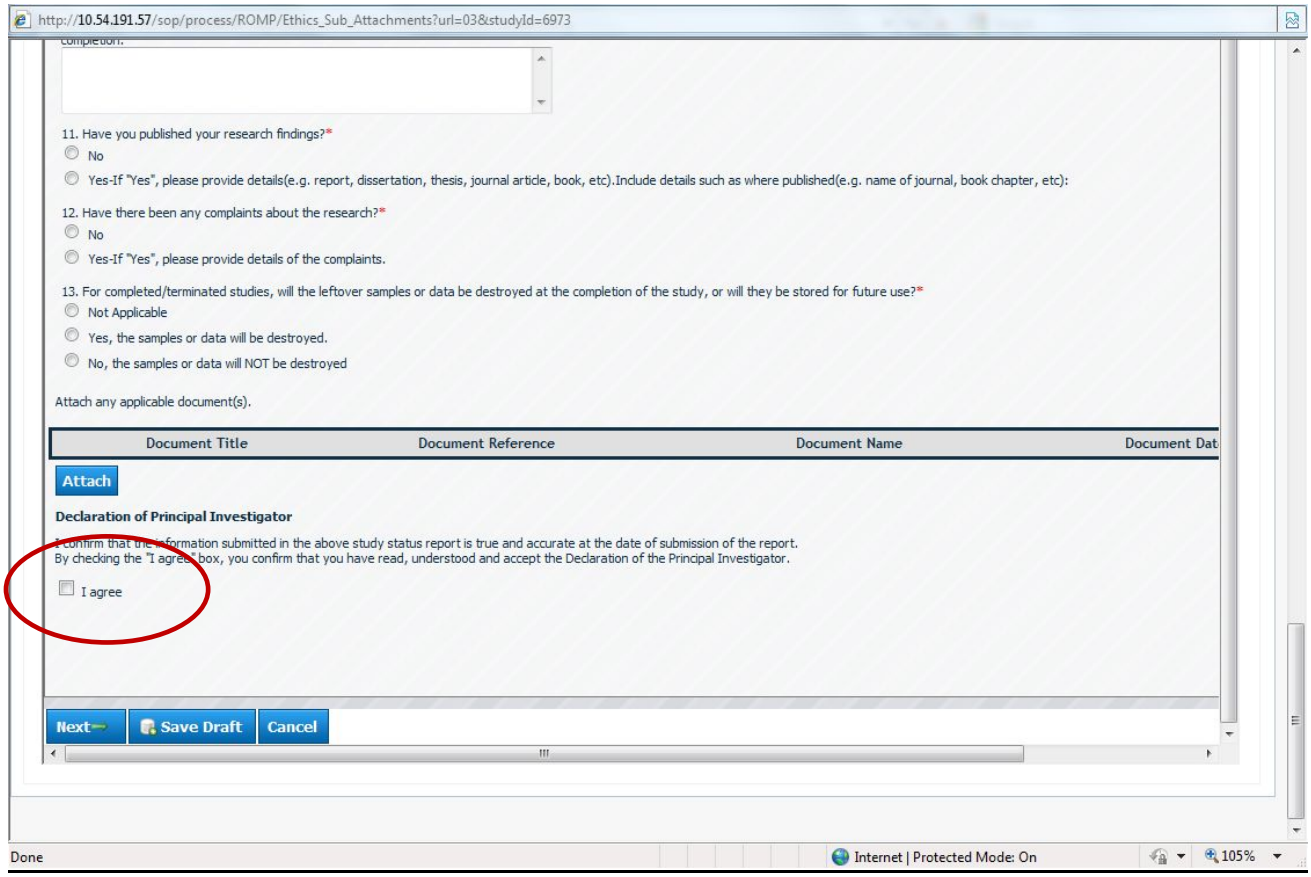


Figure 94 Study Status Report Form IV

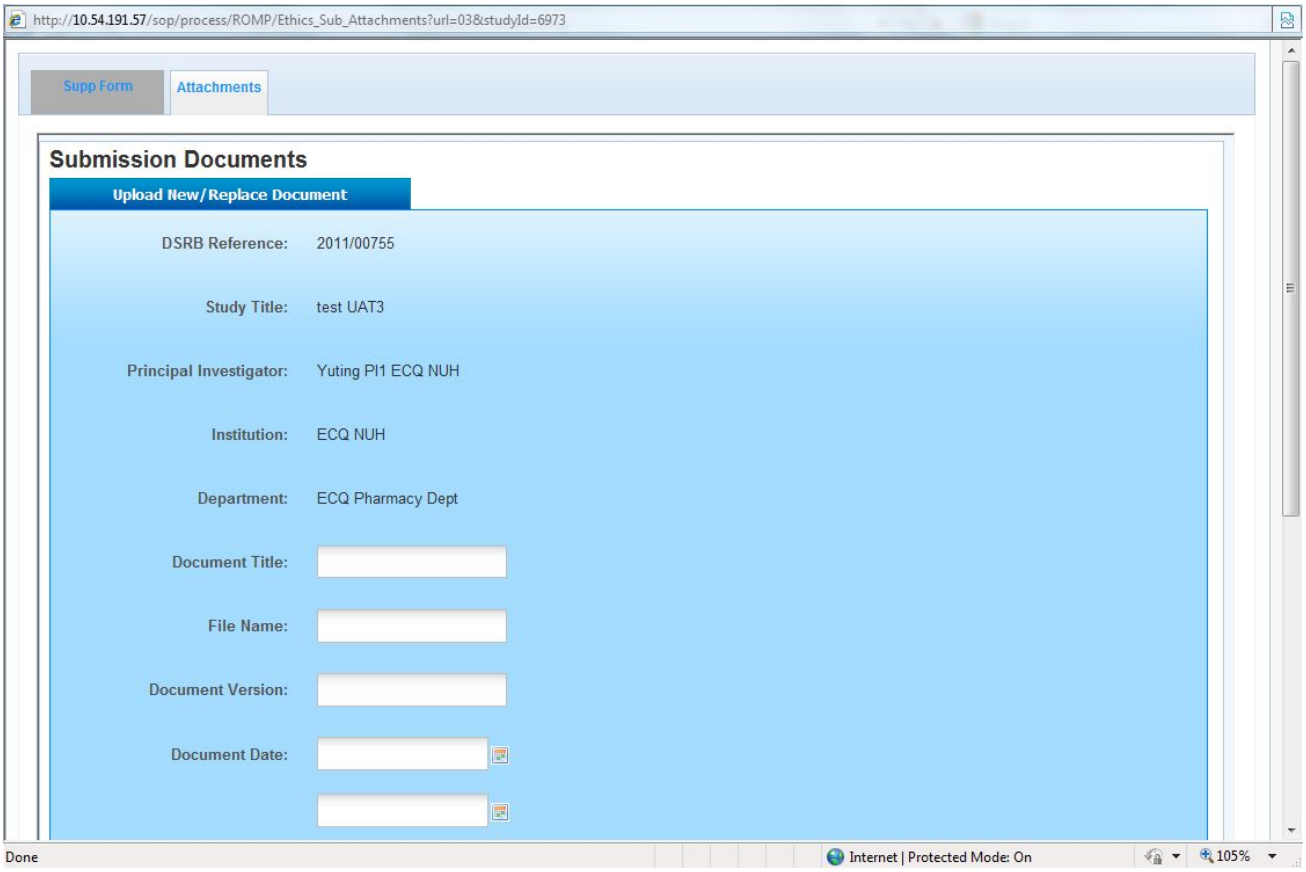


Figure 95 Study Status Attachments

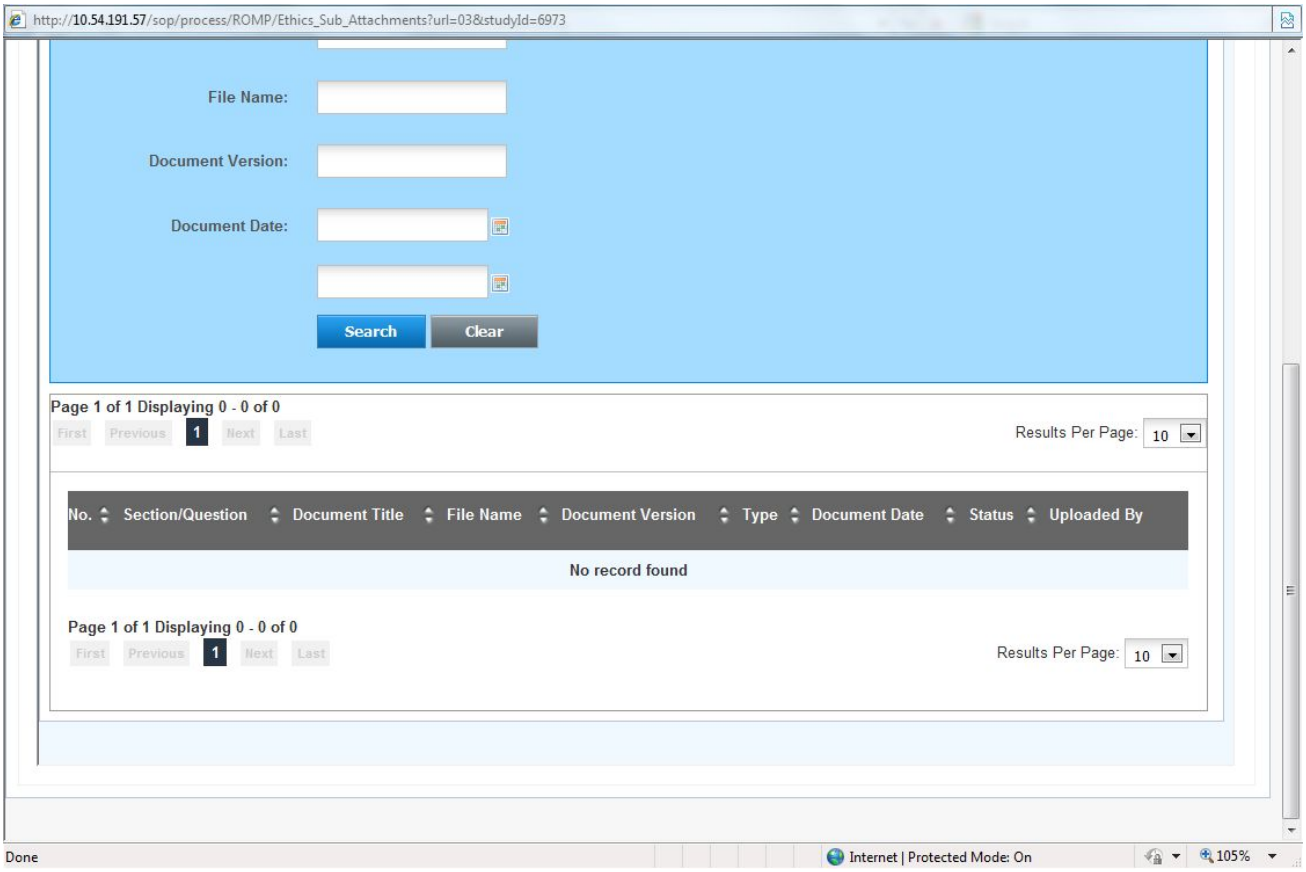


Figure 96 Study Status Attachments II

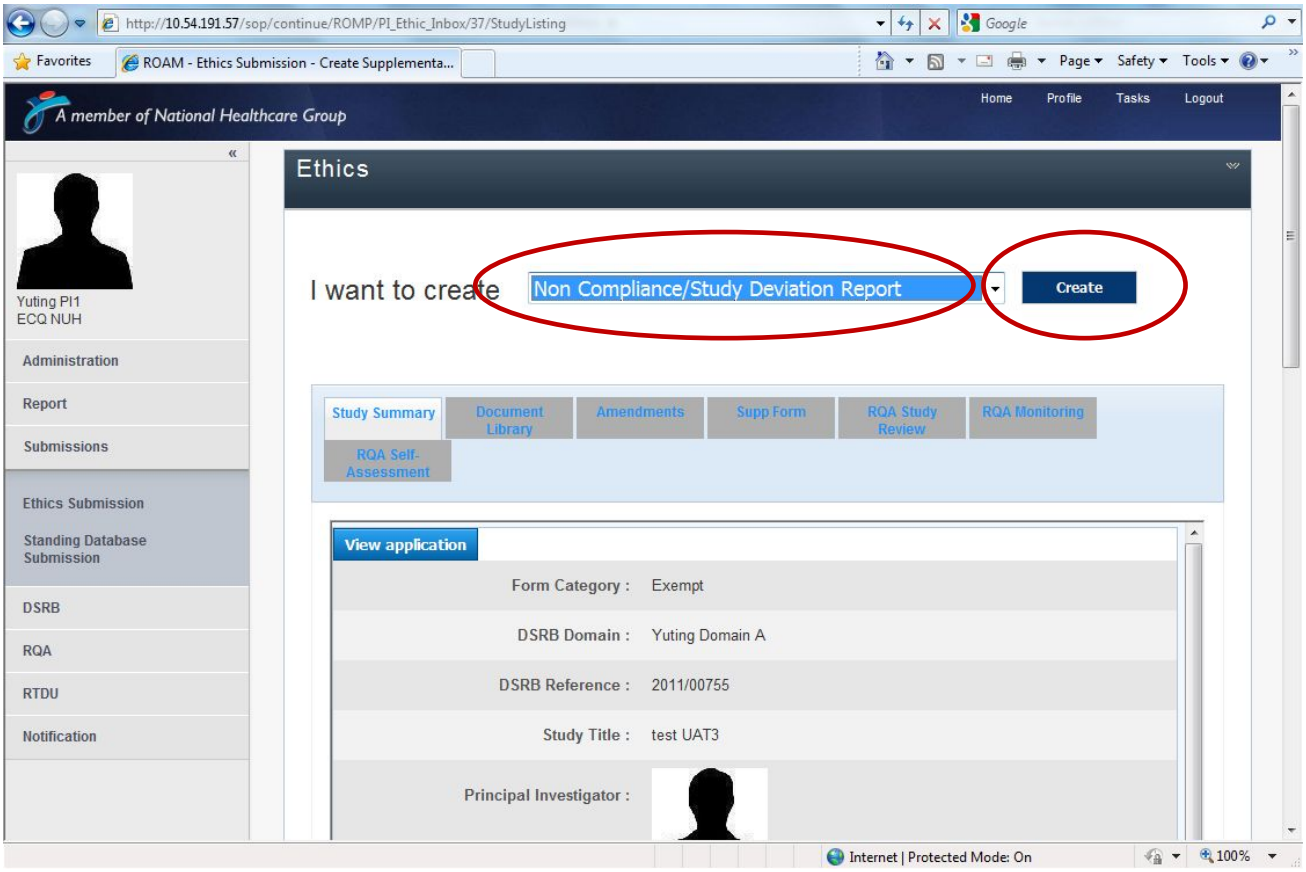


Figure 97 Creating a Non-compliance/ Study Deviation Report (NCR)

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.

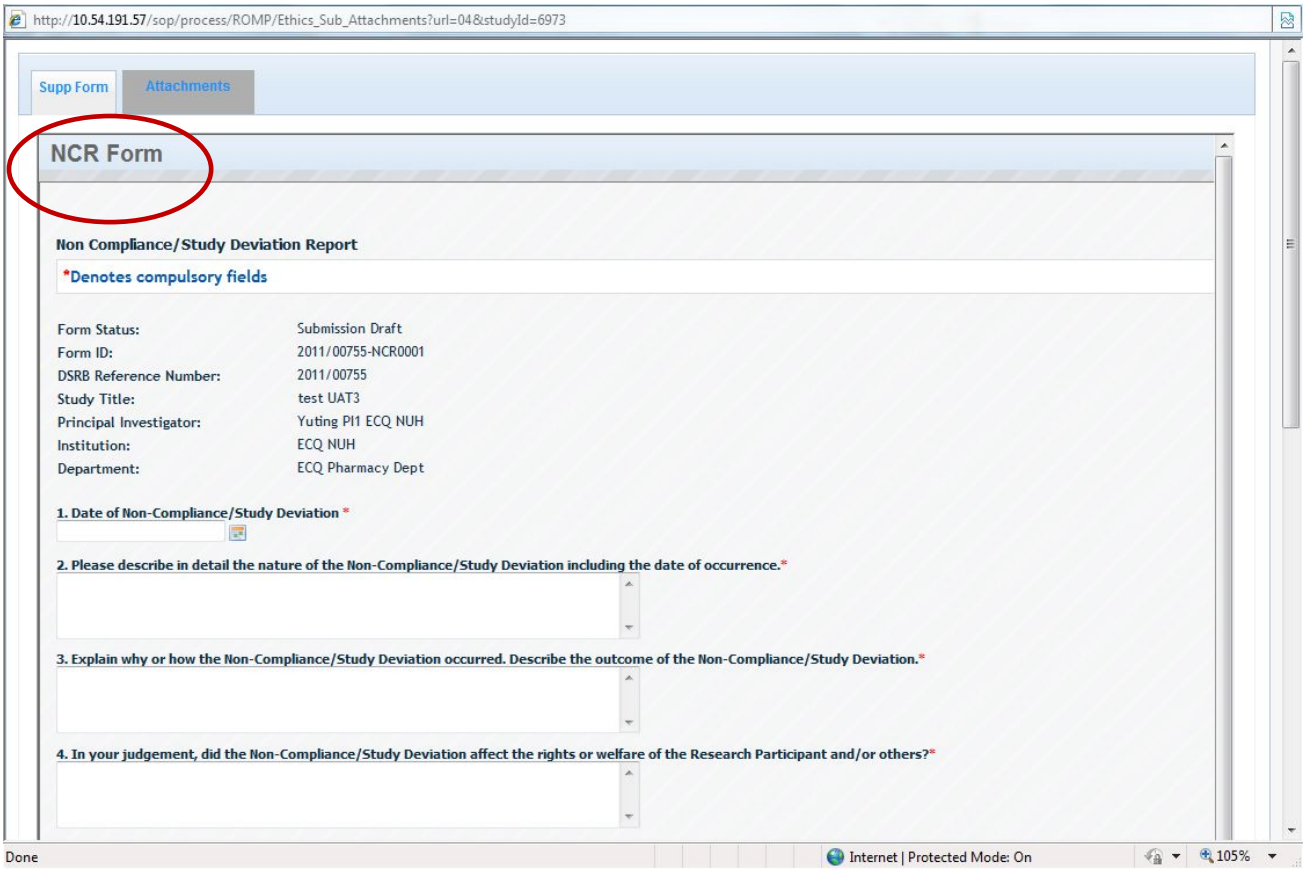


Figure 98 Non-compliance Report Form

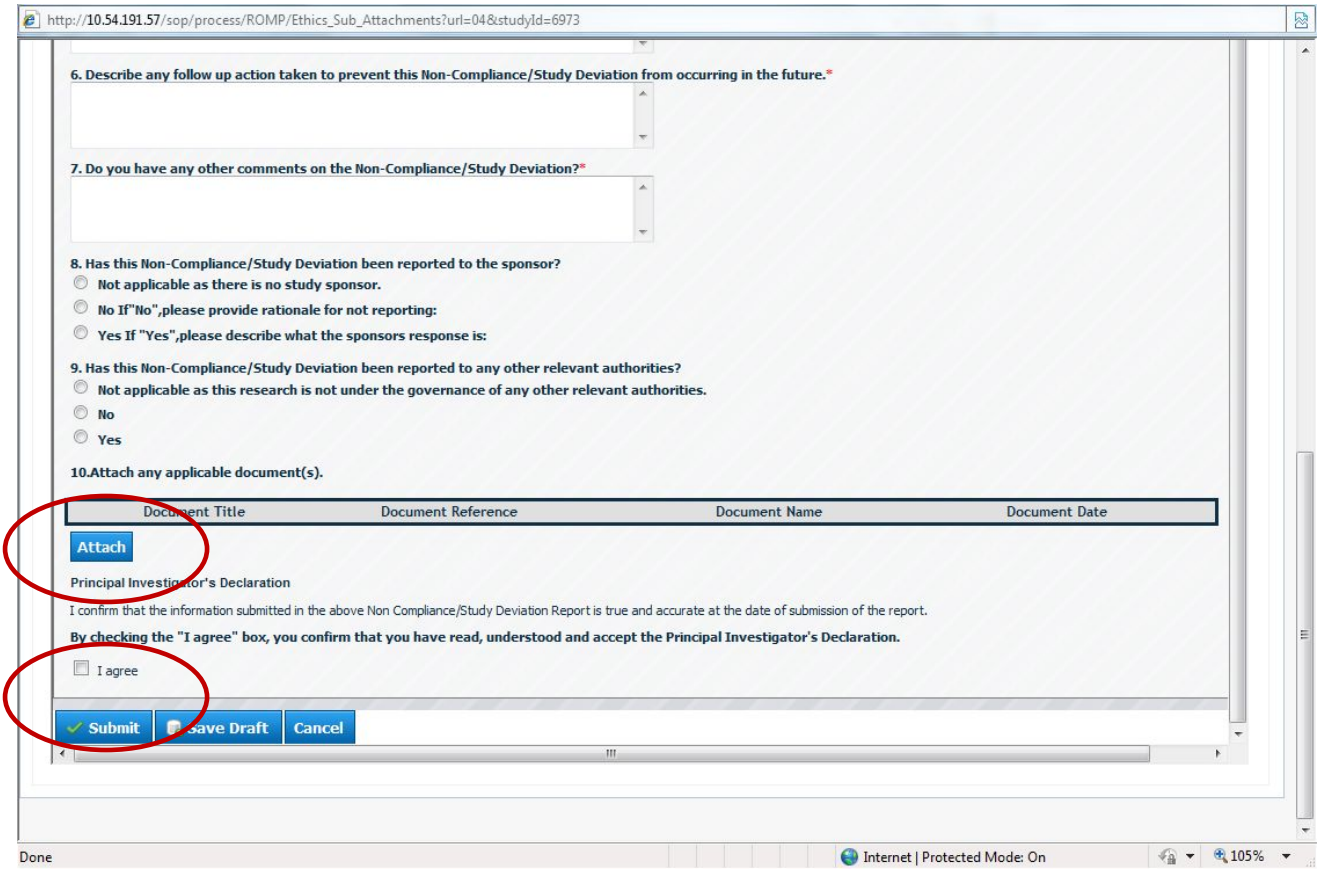


Figure 99 NCR Form II

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.

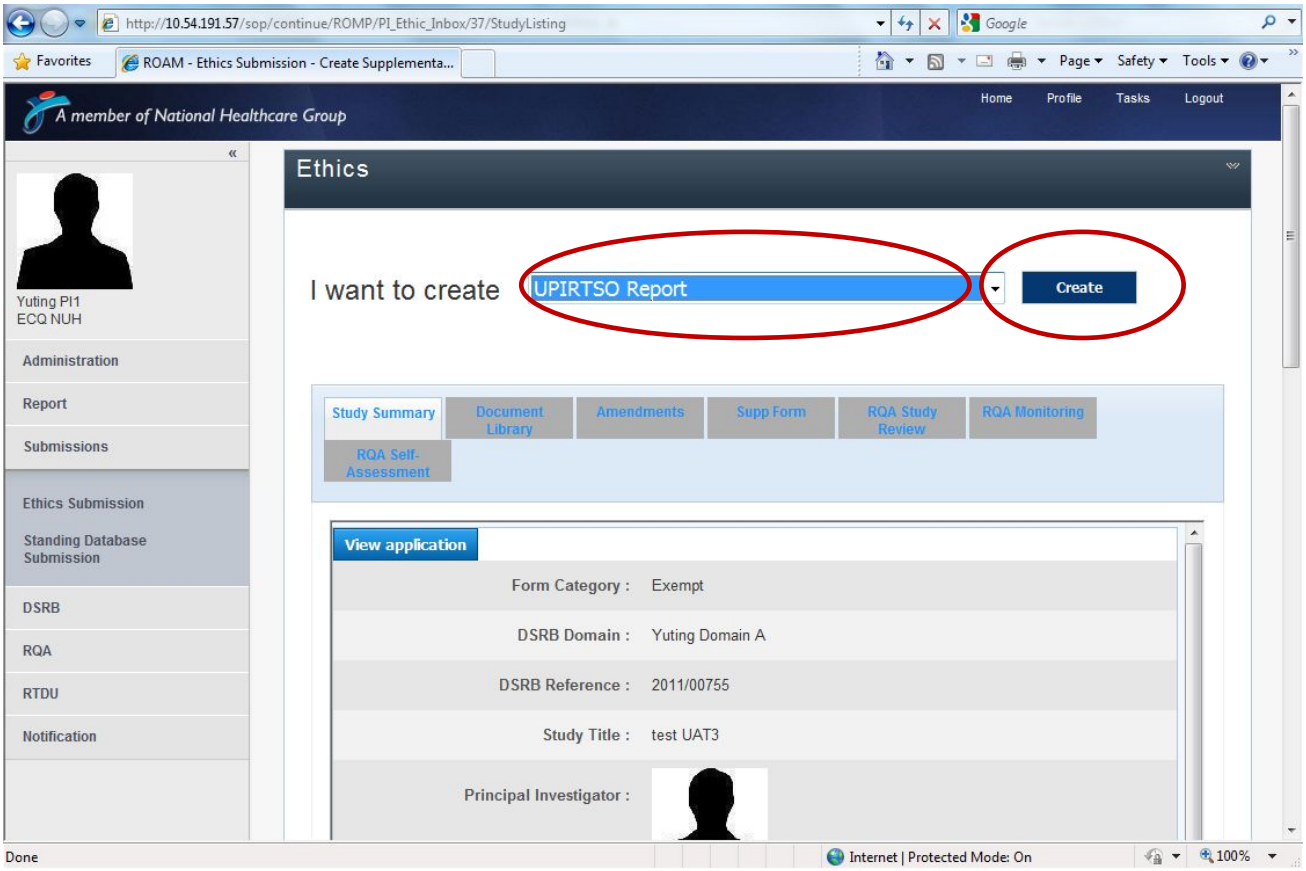


Figure 101 Creating an UPIRTSO Report

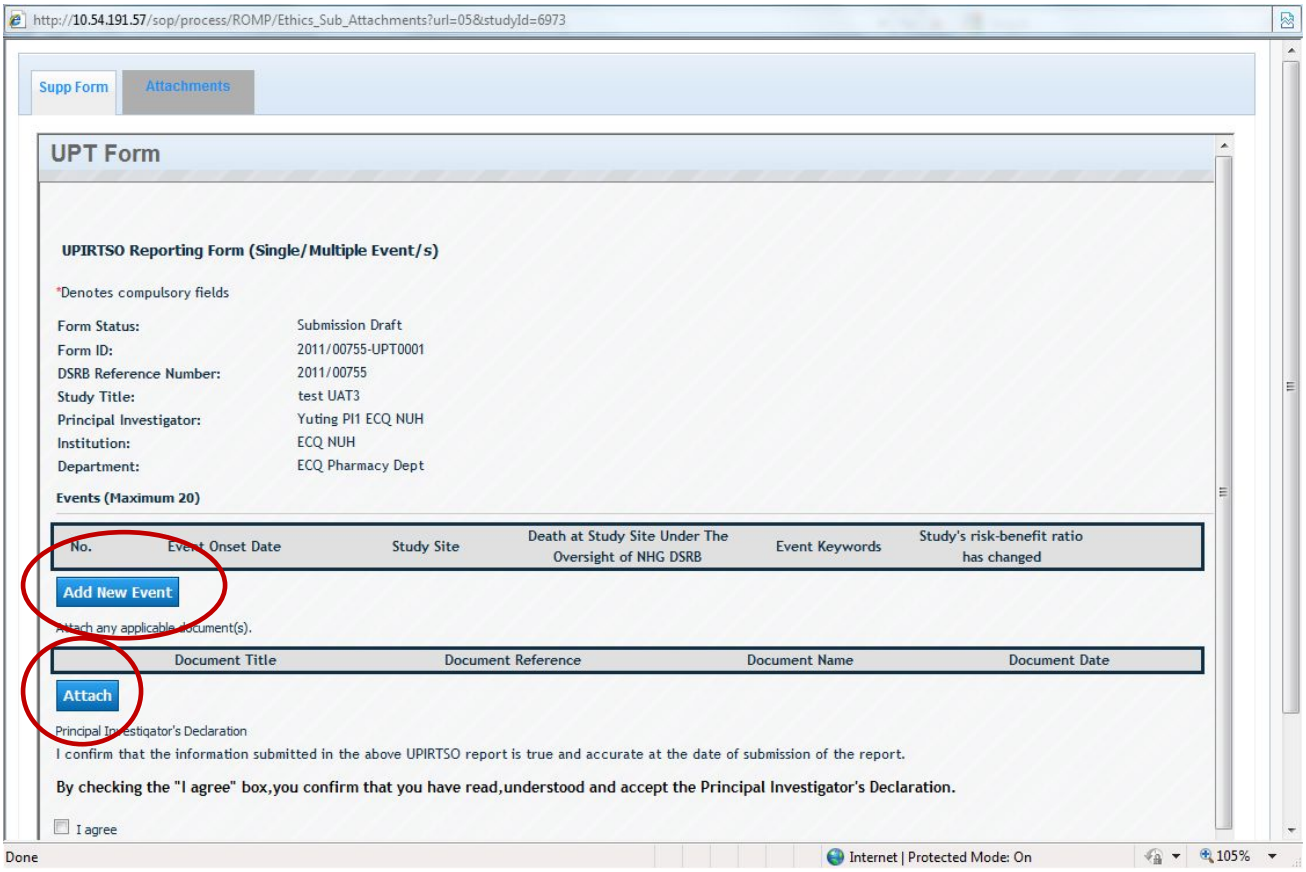


Figure 102 UPIRTSO Form

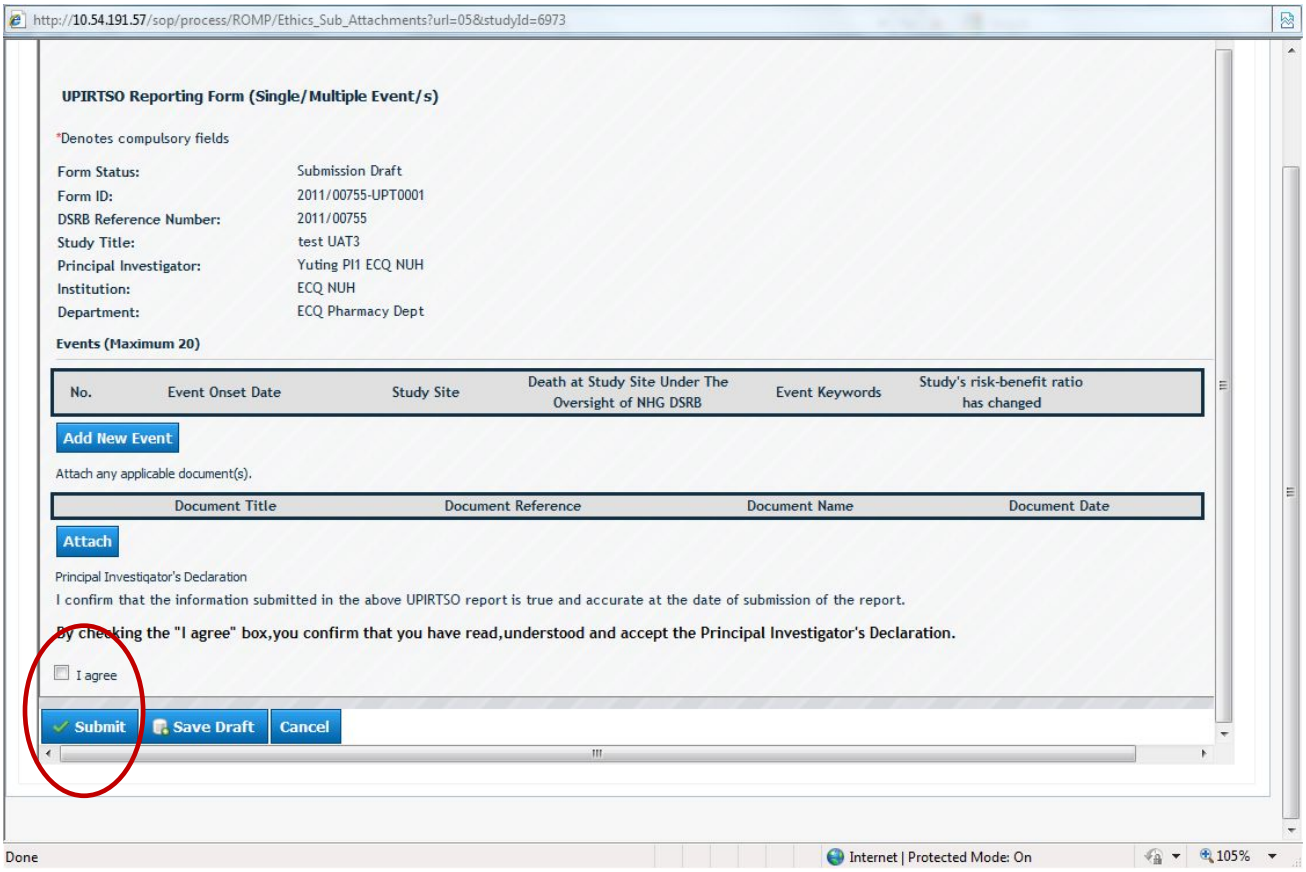


Figure 103 UPIRTSO Form II

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.

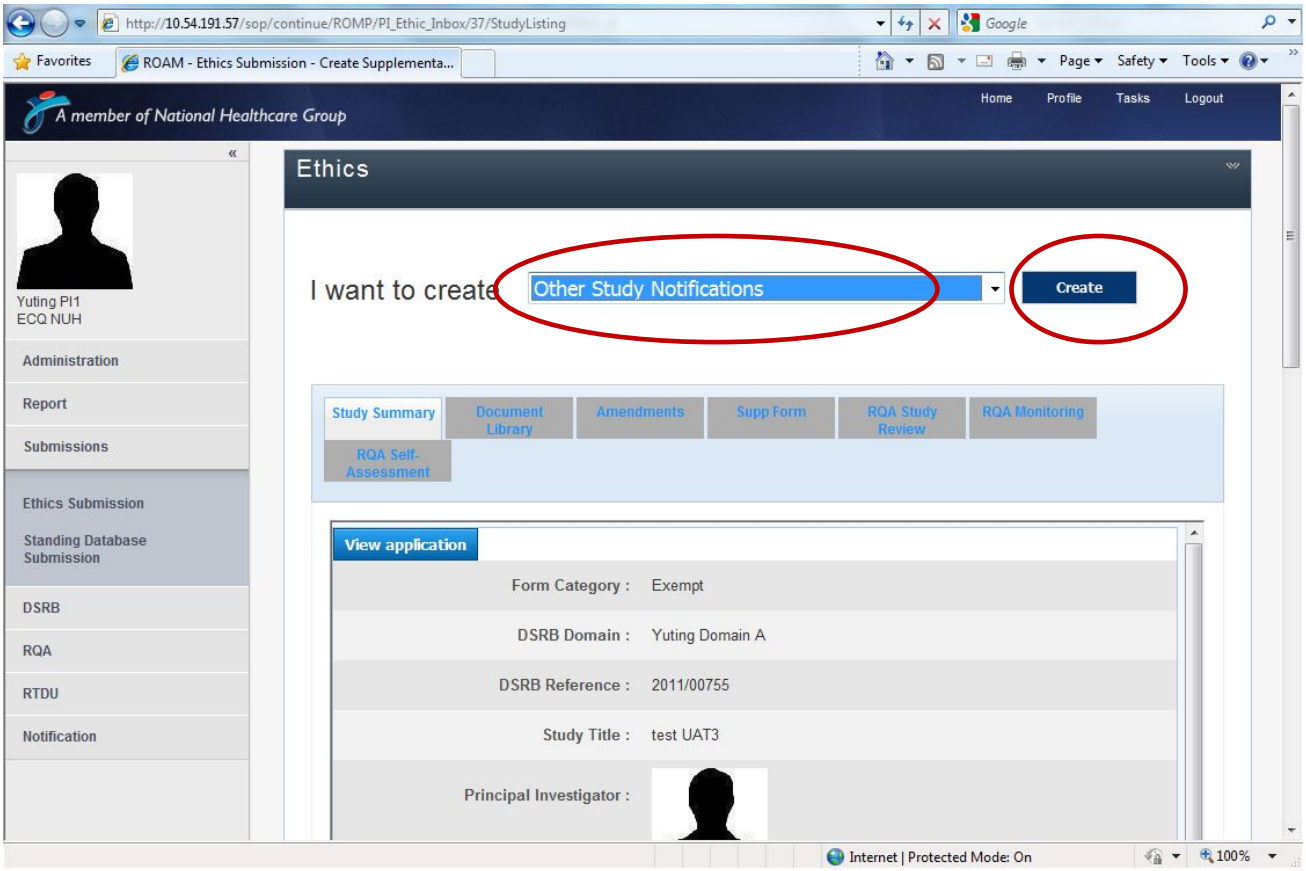


Figure 104 Creating Other Study Notifications

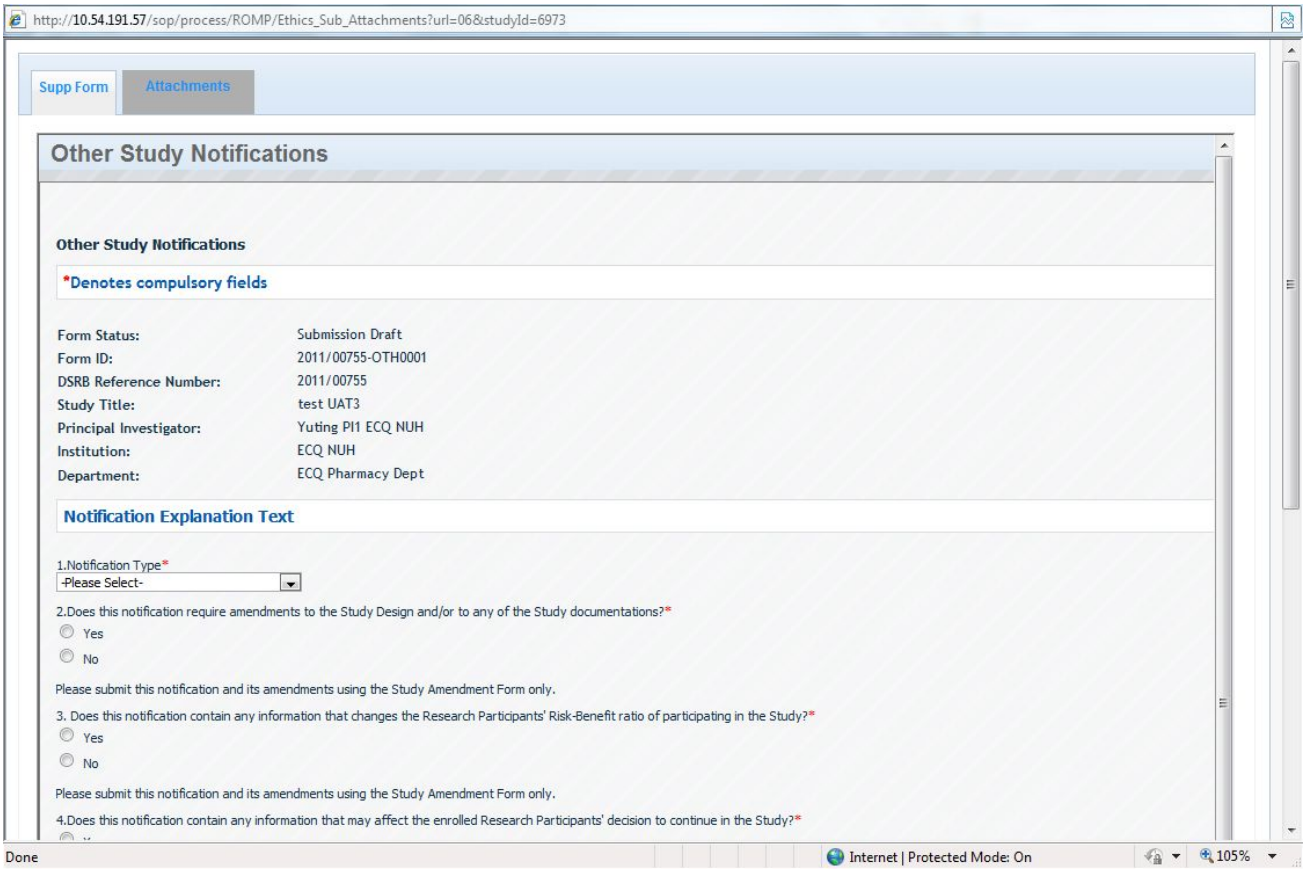


Figure 105 Other Study Notifications Form

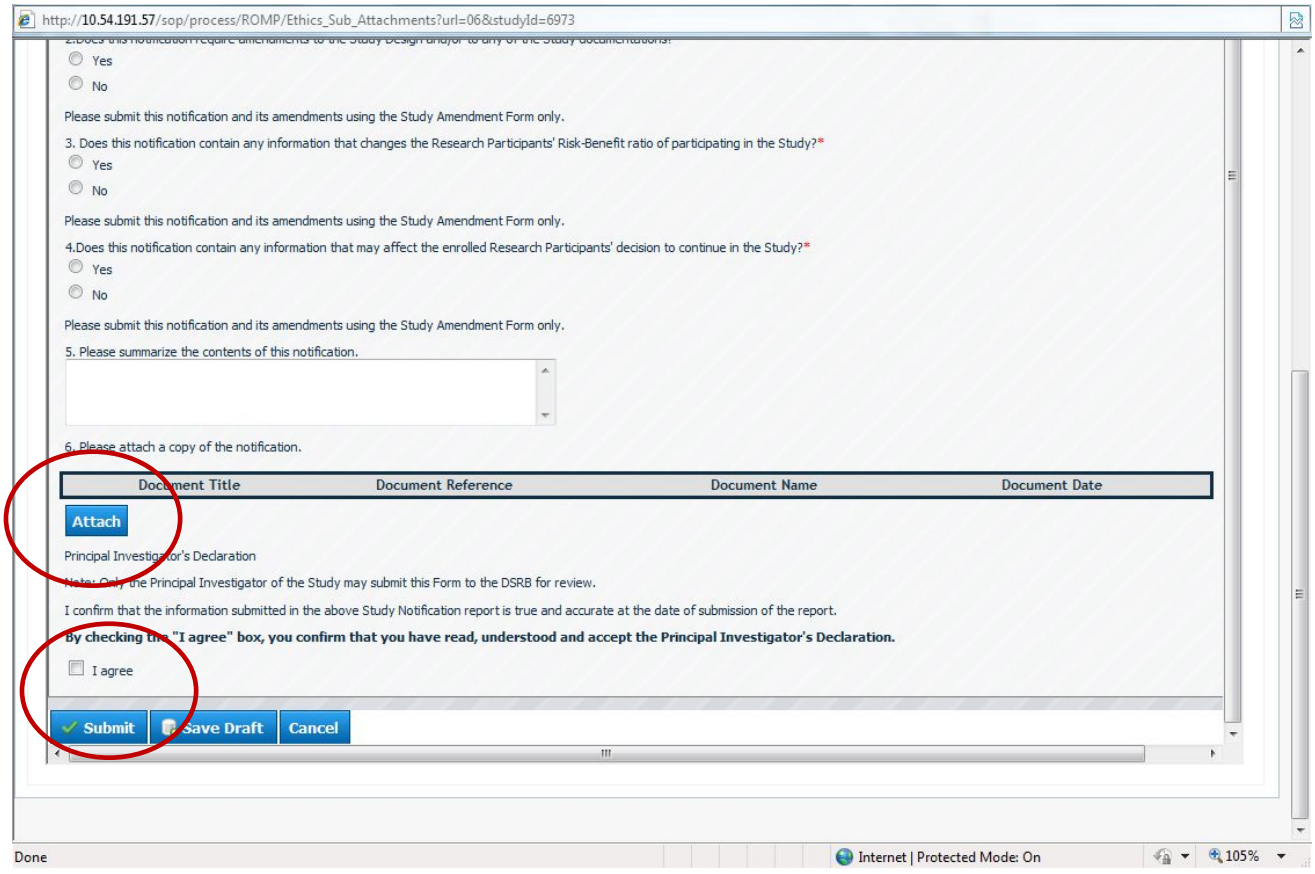


Figure 106 Other Study Notifications Form II

5 EVENTS

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

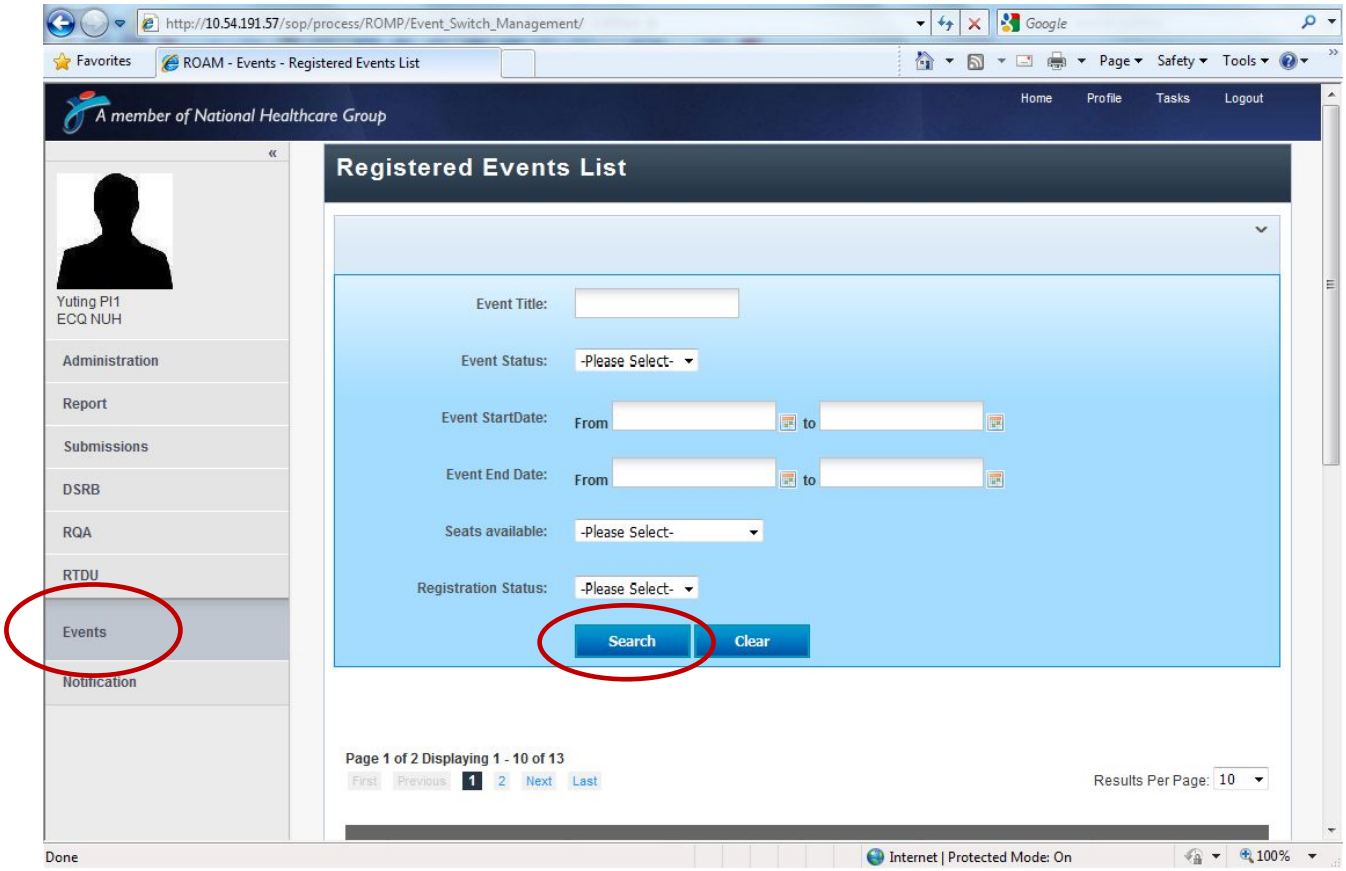


Figure 107 Events main screen

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.

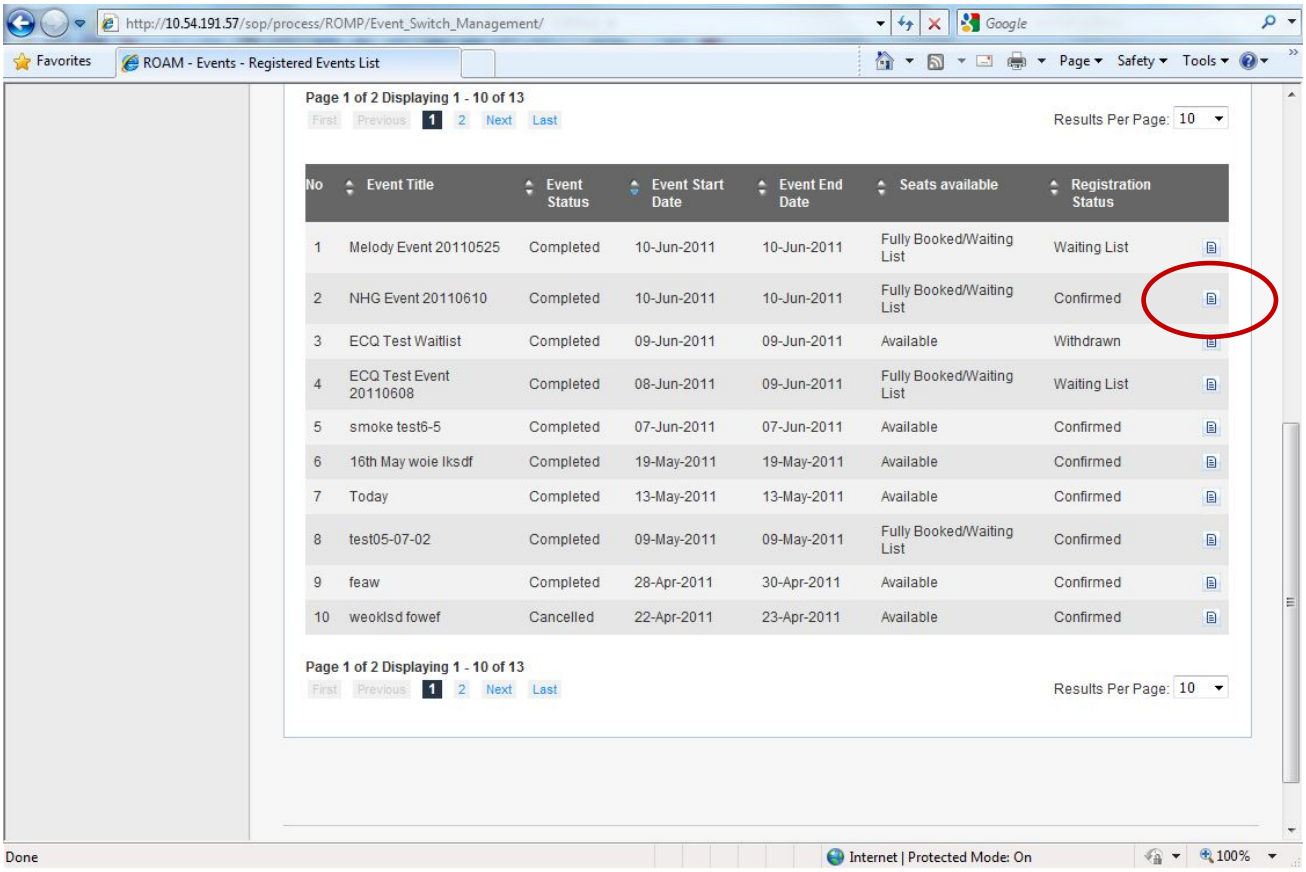


Figure 108 Events main screen II

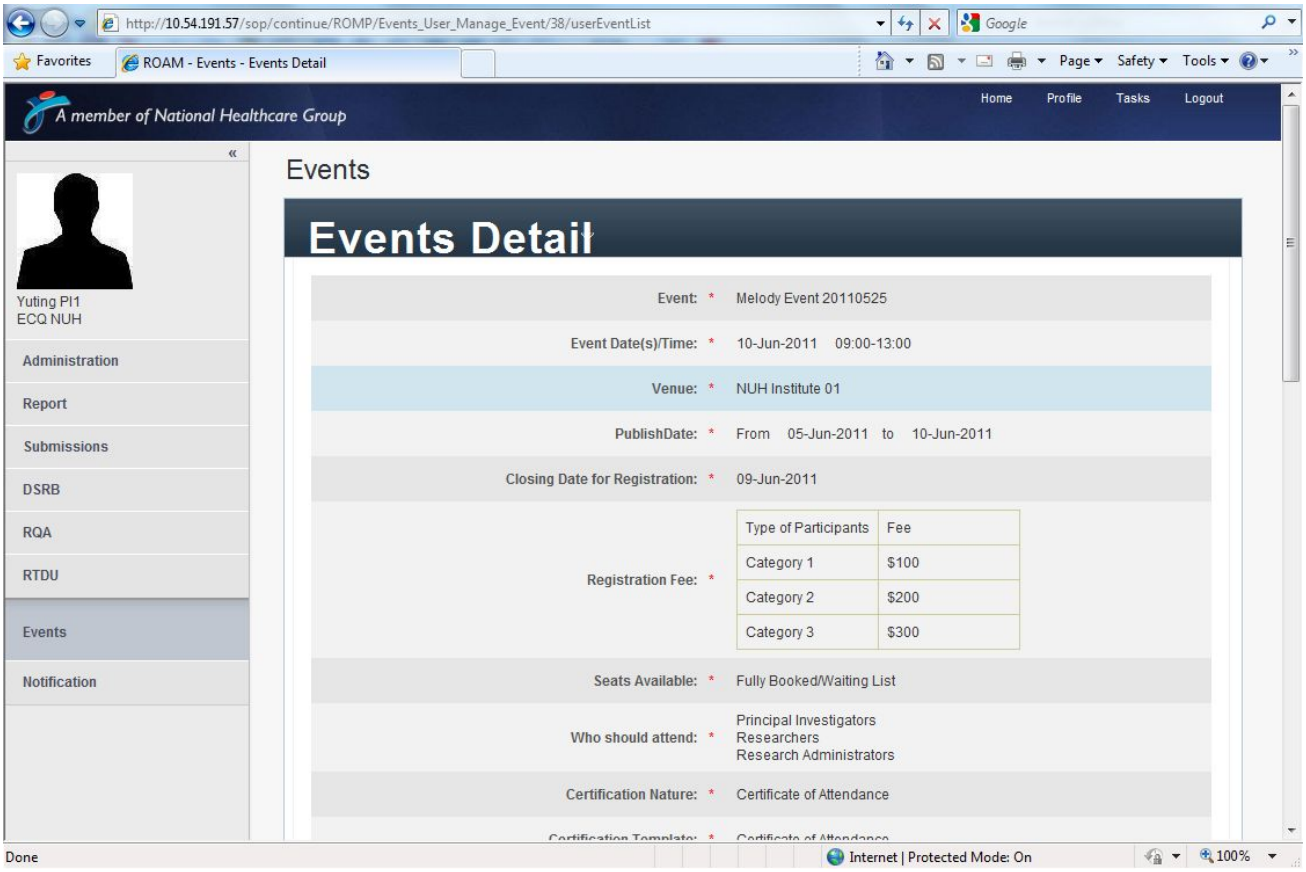


Figure 109 Specific event Form

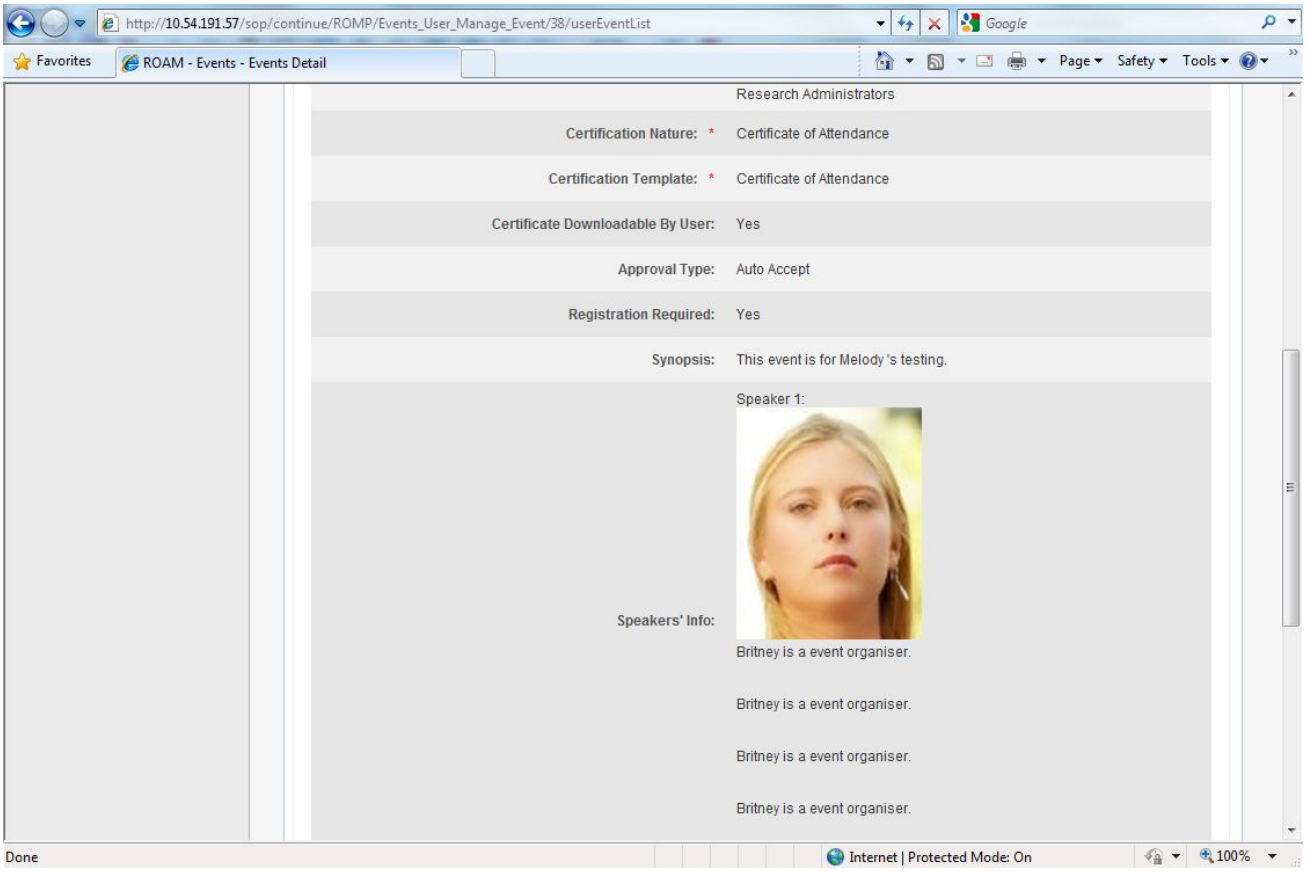


Figure 110 Event form II

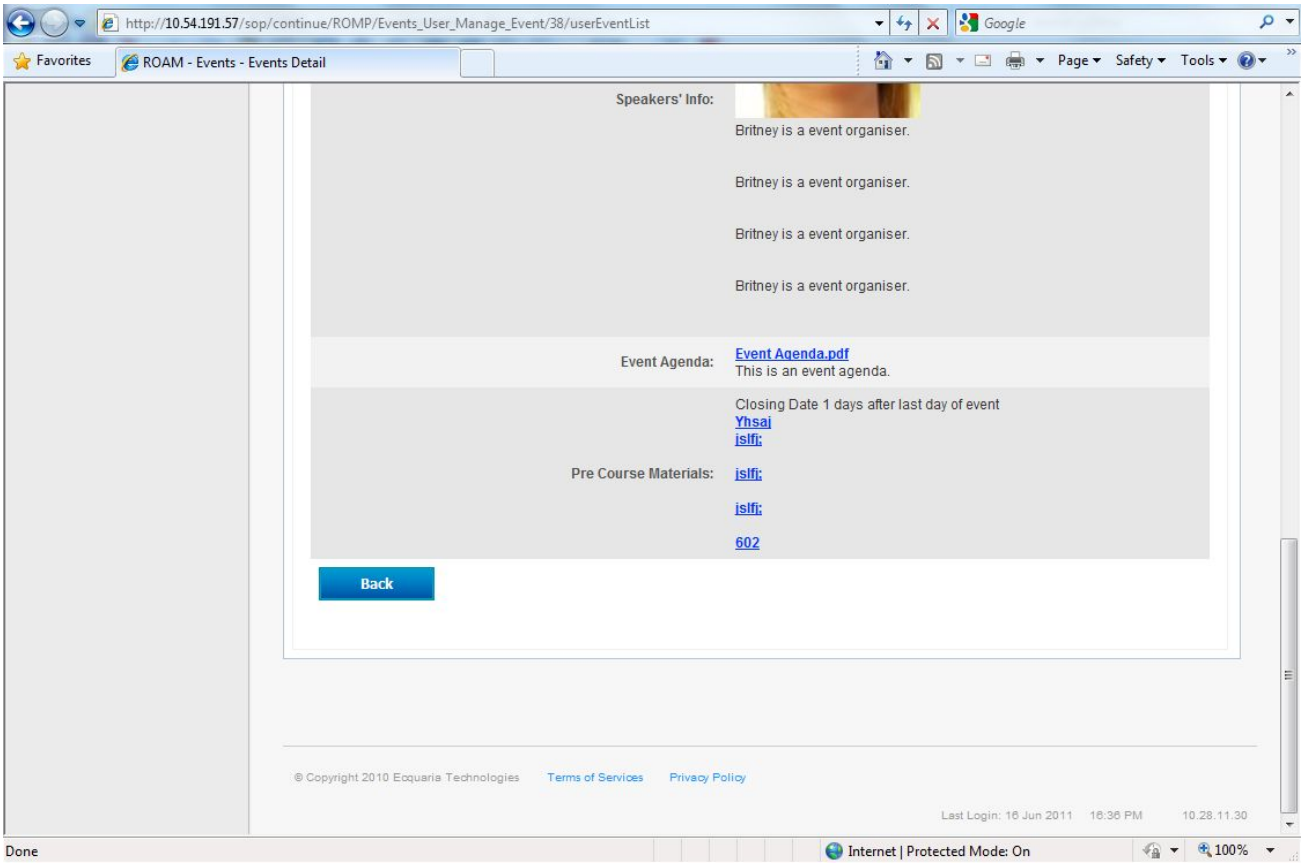


Figure 111 Event form III

End of Document