

NHG ROAM

Research Online Administration & Management

How to complete Section B of the online DSRB Application Form in ROAM

Version 1, 3 August 2011

How to complete Section B of the online DSRB Application Form in ROAM

(Version 1, 3 August 2011)

Section B (Study Team & Submission Domain) of the online DSRB Application Form tells the DSRB who are involved in the Study, their respective study roles and the locations where the Study will be conducted.

This section is important because it states who is responsible for the conduct of the Study and affects the DSRB's approval for the locations where the study can be conducted.

List of Institutions under the purview of NHG Domain Specific Review Boards (DSRB)

National Healthcare Group (NHG) member Institutions

- Tan Tock Seng Hospital
- Institute of Mental Health
- National Skin Centre
- NHG Polyclinics
- Johns Hopkins Singapore International Medical Centre
- NHG 1-Health
- NHG College
- NHG Diagnostics
- NHG Eye Institute
- NHG Pharmacy
- Energy
- Primary Care Academy
- Singapore Footcare Centre

Partner Institutions

Institutions & Organizations who have chosen to place their research ethics governance under the purview of the NHG Domain Specific Review Boards (DSRBs). Correct as of 3 August 2011.

- Alexandra Hospital (JurongHealth)
- Dover Park Hospice
- Health Sciences Authority
- Khoo Teck Puat Hospital (Alexandra Health)
- Lilly-NUS Centre for Clinical Pharmacology Pte Ltd
- National University Health System
- St Luke's Hospital

The Overall Principal Investigator, Site PI and Study Sites

Each Study Site which is under the purview of the DSRB must have one Site PI. For Studies which have only one Study Site, the Site PI is also the Overall Principal Investigator. (Fig. 1)

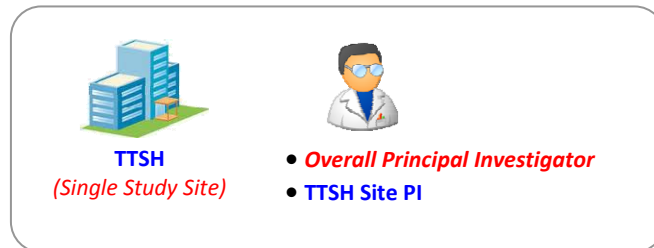


Fig. 1: Single Site Study

For a Study with multiple Study Sites which are under the purview of the DSRB, the Overall Principal Investigator must be chosen from among the Site PI's.

The following example shows a Study with 3 Study Sites – TTSH, NUHS and KTPH. (Fig. 2) Each Study Site must have one Site PI from that Institution. In this example, the TTSH Site PI is also appointed as the Overall Principal Investigator.

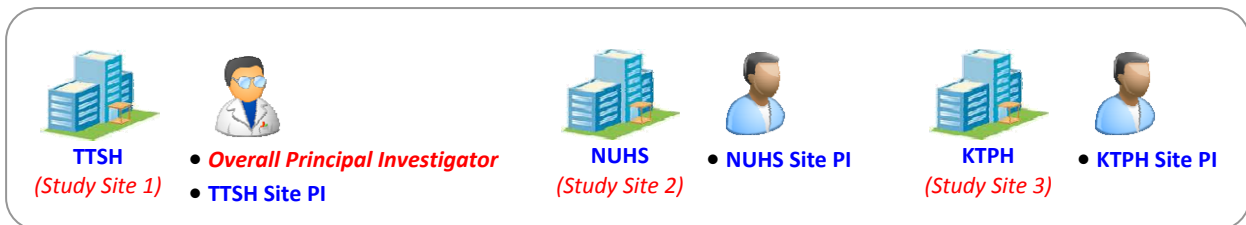


Fig.2: Multi-center Study

The Overall Principal Investigator has the responsibility of communicating with the DSRB for the overall conduct of the Study in all the Sites. The Overall Principal Investigator is also the only person who can submit any of the forms to the DSRB.

Changing the name of the Overall Principal Investigator in the DSRB Application Form

When a user creates a new draft DSRB Application Form, the ROAM system will default them as the Overall Principal Investigator and include the user's Institution as the default Study Site.

In this example, Kian Wah, from NHG HQ, is the person who has created a new draft DSRB Application Form. (Fig. 3)

Ethics Main Application Form

Section B - Study Team & Submission Domain

B1 Study Sites & Study Team Members

All investigators who have a responsibility for the consent process and/or direct data collection for this study should be listed below. Study Team Members with registered user account with us will be notified of their participation in this study when the Application is submitted. For a Multi-centre study, please appoint a Site PI for each site (Mandatory). The Principal Investigator will be the Site PI for their own Institution, and will also be the primary contact person for the DSRB.

(i) 'Overall Principal Investigator': Mr Kian Wah, Yeo (Mr)

(ii) Study Sites under the oversight of NHG DSRB (eg: NHG's Institutions, St Luke's Hospital, HSA, Dover Park Hospice, etc)

Add Team Member Delete Site

| Main Site | Study Site | Name | Study Role | Institution | Department | Min Training |
|-----------|------------|--------------------|------------|-------------|-------------------------------|--------------|
| | NHG HQ | Kian Wah, Yeo (Mr) | PI | NHG HQ | Research & Development Office | Completed |

Fig. 3

By default, the system has made Kian Wah the Overall Principal Investigator (question B1(i)), as well as being the Site PI for the Study Site - NHG HQ (question B1(ii)).

To change the name of the Site PI, click on the 'man' icon found at the end of the table. This will open a new panel as shown in Figure 4.

Important

If there is only 1 study Site in the table, do not delete it. This will cause problems with the Form.



Important

If there is only 1 study Site in the table, do not delete it. This will cause problems with the Form.

Click on 'Add Site PI'. (Fig. 4)

Study Site: NHG HQ

| Study Role | Site PI's Name | Institution | Department | Minimum Training |
|------------|--------------------|-------------|-------------------------------|------------------|
| Site PI | Kian Wah, Yeo (Mr) | NHG HQ | Research & Development Office | Completed |

Add Site PI

Please List All Study Team Members Participating in this Study Site here:-

(a) Study Team Members with registered user accounts (eg: NHG Personnel):

Note: Please note that you can only add existing registered users to the Study Team list here. You may search for existing users by clicking in the search icon. Users listed here will be notified of their participation in this study. All **NHG personnel** will need to register for a user account before they can be part of the Study Team.

Add Study Team Member

Name * Study Role * Institution * Department * Minimum Training *

(b) Study team members from External institutions without user accounts:

Note: Please note that users listed here will NOT be notified of their participation in this study.

Add Study Team Member

Name * Study Role * Institution * Department *

Save **Cancel**

Fig. 4

This will bring up a search panel so you can search for the name of the actual person who is to be the Site PI. (Fig. 5)

Name: kee peck

Institution: All

Department: All

Email Address:

Search **Clear**

Page 1 of 1 Displaying 1 - 1 of 1 Results Per Page: 10

First Previous 1 Next Last

| Name | Institution | Department | Email |
|--------------|-------------|-------------------------------|-------------------------|
| KEE PECK TAN | NHG HQ | Research & Development Office | kee_peck_tan@nhg.com.sg |

Select

Close

Fig. 5

Once you have found the person you are looking for, click on 'Select'. The panel will automatically change back to the previous window and update its information. (Fig. 5) In our example, we are making Kee Peck the new Site PI.

Now, the new Site PI for NHG HQ is Kee Peck. (Fig. 6) Click on 'Save' when you are done. The panel will close and the new information updated to the Application Form.

Study Site: NHG HQ

| Study Role | Site PI's Name | Institution | Department | Minimum Training |
|------------|----------------|-------------|-------------------------------|------------------|
| Site PI | KEE PECK TAN | NHG HQ | Research & Development Office | Not completed |

Add Site PI

Please List All Study Team Members Participating in this Study Site here:-

(a) Study Team Members with registered user accounts (eg: NHG Personnel):

Note: Please note that you can only add existing registered users to the Study Team list here. You may search for existing users by clicking in the search icon. Users listed here will be notified of their participation in this study. All NHG personnel will need to register for a user account before they can be part of the Study Team.

Add Study Team Member

| Name | Study Role | Institution | Department | Minimum Training |
|------|------------|-------------|------------|------------------|
|------|------------|-------------|------------|------------------|

(b) Study team members from External Institutions without user accounts:

Note: Please note that users listed here will NOT be notified of their participation in this study.

Add Study Team Member

| Name | Study Role | Institution | Department |
|------|------------|-------------|------------|
|------|------------|-------------|------------|

Save **Cancel**

Fig. 6



Important

If you are to be a Study Administrator or to be part of the Study Team, remember to add yourself in either Section A or Section B.

If you forget to do so, you will not be able to access the draft Application Form once you have logged out. Otherwise, you will need to contact the new Site PI to add you back to the Application Form.

The table in Section B1(ii) is now updated. (Fig. 7) Kee Peck is now the Site PI for NHG HQ, as well as being the Overall Principal Investigator for the Study.

Adding a New Study Site

To add a new Study Site, click on the 'Add Study Site' button. (Fig. 7) A window as shown in Figure 8 will appear.

Ethics Main Application Form

Section B - Study Team & Submission Domain

B1 Study Sites & Study Team Members

All investigators who have a responsibility for the consent process and/or direct data collection for this study should be listed below. Study Team Members with registered user account with us will be notified of their participation in this study when the Application is submitted. For a Multi-centre study, please appoint a Site PI for each site (mandatory). The Principal Investigator will be the Site PI for their own Institution, and will also be the primary contact person for the DSRB.

(i) Overall Principal Investigator: KEE PECK TAN

(ii) Study Sites under the oversight of NHG DSRB (eg: NHG's Institutions, St Luke's Hospital, HSA, Dover Park Hospice, etc)

Add Team Member **Delete Site**

| Main Site | Study Site | Name | Study Role | Institution | Department | Min Training |
|-----------|------------|--------------|------------|-------------|-------------------------------|--------------|
| | NHG HQ | KEE PECK TAN | Site PI | NHG HQ | Research & Development Office | Completed |

Add Study Site

Fig. 7

First, you must select the Study Site that you wish to add from the dropdown list. (Fig. 8)

Study Site: -Please Select-

| Study Role | Site PI's Name | Institution | Department | Minimum Training |
|------------|----------------|-------------|------------|------------------|
| Site PI | - | - | - | - |

Add Site PI

Please List All Study Team Members Participating in this Study Site here:-

(a) Study Team Members with registered user accounts (eg: NHG Personnel):

Note: Please note that you can only add existing registered users to the Study Team list here. You may search for existing users by clicking in the search icon. Users listed here will be notified of their participation in this study. All **NHG personnel** will need to register for a user account before they can be part of the Study Team.

Add Study Team Member

| Name * | Study Role * | Institution * | Department * | Minimum Training * |
|--------|--------------|---------------|--------------|--------------------|
| | | | | |

(b) Study team members from **External Institutions** without user accounts:

Note: Please note that users listed here will **NOT** be notified of their participation in this study.

Add Study Team Member

| Name * | Study Role * | Institution * | Department * |
|--------|--------------|---------------|--------------|
| | | | |

Save Cancel

Fig.8

Next, click on the 'Add Site PI' button to add the Site PI. Finally, add any other Study Team members for the Study Site using the "Add Study Team Member" button. Once the information is correct, click on the 'Save' button. This panel will close and return to the Application Form.

Section B - Study Team & Submission Domain

B1 Study Sites & Study Team Members

All investigators who have a responsibility for the consent process and/or direct data collection for this study should be listed below. Study Team Members with registered user account with us will be notified of their participation in this study when the Application is submitted. For a Multi-centre study, please appoint a Site PI for each site (Mandatory). The Principal Investigator will be the Site PI for their own Institution, and will also be the primary contact person for the DSRB.

(i) Overall Principal Investigator: KEE PECK TAN

(ii) Study Sites under the oversight of NHG DSRB (eg: NHG's Institutions, St Luke's Hospital, HSA, Dover Park Hospice, etc)

Add Team Member Delete Site

| Main Site | Study Site | Name | Study Role | Institution | Department | Min Training |
|----------------------------------|--|---|------------|------------------------|-------------------------------|---------------|
| <input checked="" type="radio"/> | NHG HQ | KEE PECK TAN | PI | NHG HQ | Research & Development Office | Not completed |
| <input type="radio"/> | Tan Tock Seng Hospital | Felicia P11 NUH | Site PI | Tan Tock Seng Hospital | Orthopaedic Surgery | - |

Add Study Site

Fig. 9

We have thus added 'Tan Tock Seng Hospital' as the other Study Site. (Fig. 9) This is now a two center Study, with Kee Peck and Felicia as the respective Site PI's. In addition, Kee Peck is the Overall Principal Investigator for the Study.

Changing the Overall Principal Investigator

To change the Overall Principal Investigator, use the radio button under the 'Main Site' column to indicate who the Overall Principal Investigator will be. (Fig. 10)

Section B - Study Team & Submission Domain

B1 Study Sites & Study Team Members

All investigators who have a responsibility for the consent process and/or direct data collection for this study should be listed below. Study Team Members with registered user account with us will be notified of their participation in this study when the Application is submitted. For a Multi-centre study, please appoint a Site PI for each site (Mandatory). The Principal Investigator will be the Site PI for their own Institution, and will also be the primary contact person for the DSRB.

(i) 'Overall Principal Investigator': Felicia P11 NUH

(ii) Study Sites under the oversight of NHG DSRB (eg: NHG's institutions, St Luke's Hospital, HSA, Dover Park Hospice, etc)

Add Team Member Delete Site

| Main Site | Study Site | Name | Study Role | Institution | Department | Min Training |
|----------------------------------|------------------------|-----------------|------------|------------------------|-------------------------------|---------------|
| <input type="radio"/> | NHG HQ | KEE PECK TAN | PI | NHG HQ | Research & Development Office | Not completed |
| <input checked="" type="radio"/> | Tan Tock Seng Hospital | Felicia P11 NUH | Site PI | Tan Tock Seng Hospital | Orthopaedic Surgery | - |

Add Study Site

Fig. 10

toggling the radio button will instantly update B1(i), where the name of the Overall PI is shown. In this example, we have changed the Overall Principal Investigator from Kee Peck to Felicia

Important Notes

While any member of the Study Team or Study Administrator can initiate and edit a draft Application Form, only the Overall Principal Investigator can submit the Form to the DSRB. This act is equivalent to the Overall PI signing on a physical form.

Access to any Study is based on the name-list found in Section A (Study Administrators) and Section B (Study Team Members). If any person has left the Study, we strongly encourage the Overall Principal Investigator to update these sections of Application Form through a Study Amendment Form.