

# NHG ROAM

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*Research Online Administration & Management*

## **Department Representative Endorsement Guidebook**

*Version 1*

## Overview of the Department & Institution Representative

The DSRB Application must be supported and endorsed online by all respective Department and Institution Representative(s) where the Study is being conducted.

Only when the DSRB Application has been endorsed by all parties, will the DSRB receive and review the Application.

## Role of Department Representative

The DSRB Application must be supported and endorsed online by the Principal Investigator and Site PI's Department Representative (for multi-centre studies) before the Application is forwarded to the appropriate Institution Representative for review and endorsement.

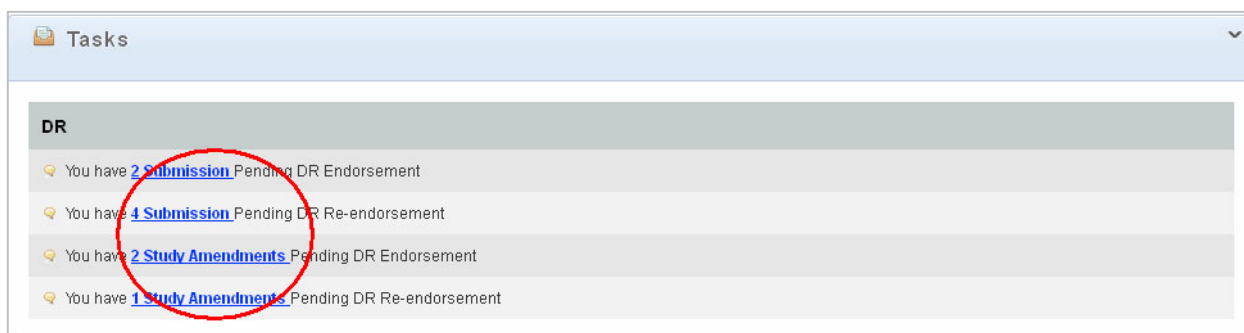
## Who is the Department Representative?

In general, the Department Representative would be the "Head of Department" (HOD), Chief, Department Research Head or equivalent of the Principal Investigator and Site PI's Department.

Where appropriate, the Head/Chief of a Division (e.g. Division of Medicine) that oversees several departments may comment in lieu of the "HOD". Should the Head or Chief be the PI or be part of the Study Team, then their reporting officer should be the Department Representative.

## Where to see your Endorsement Tasks

After logging into the NHG ROAM portal, Department Representatives will see their endorsement Tasks on the homepage. Upon completing the Task, this list will be automatically updated and completed Tasks will be removed.



By clicking on the "blue hyperlinked text", Department Representatives will be able to jump straight to a table showing the Tasks that they are interested in.

**Inbox**

**Tasks**

Status: Pending DR Endorsement

Reference No:

Title: Any Review

Any Reviewer Role

Unread / Read:  Unread  Read

Last Modified Date: from  to

Page 1 of 1 Displaying 1 - 2 of 2

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

No.	Ref No.	Status	Title	Assigned Date	SLA
<input type="checkbox"/> 1	<a href="#">2011.03850</a>	Pending DR Endorsement	<b>Ethics Submission</b> cae test firefox 1	19-Jun-2011 11:10 AM	0% 0 / 5 (0.0%)
<input type="checkbox"/> 2	<a href="#">2011.03849</a>	Pending DR Endorsement	<b>Ethics Submission</b> cae test chrome 1	19-Jun-2011 11:10 AM	0% 0 / 5 (0.0%)

By clicking on the Reference number of the Study, the Department Representatives can access the Study submission package from the Principal Investigator, as well as see the endorsement options available to them.

This is where the Department Representatives can chose to view the Study information or to select an endorsement option.

### Ethics Submission Endorsement

**Ethics Application** | **Ethics Endorsement** | **Ethics Review**

[Hide]

#### Ethics Submission Endorsement

[View Submission \(2011/03816\)](#)

Action:  Endorse Application  Reject Application  Query PI

**1. Significance:**  
Does the study address an important problem? Will the study affect concepts and methods that drive the field? \*

Yes  No

**2. Approach:**  
Is the conceptual framework adequately developed? Are the design, methods and analyses adequately developed and appropriate? \*

Yes  No

**3. Innovation:**  
Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods? \*

Yes  No

**4. Principal Investigator:**  
Is the Principal Investigator appropriately trained to conduct this study? Does the Principal Investigator have evidence of commitment (e.g. previous track record)? \*

Yes  No

**5. Environment:**  
Is the Principal Investigator's environment suited to conduct the study? Is there an adequate patient pool and are there adequate resources? \*

Yes  No

**6. Budget:**  
Are the projected costs appropriate (i.e. accurate)? Is the overall budget reasonable for the significance of the study? \*

Yes  No

**7. Time:**  
Does the Principal Investigator have adequate resources and time to conduct and complete the study? \*

Yes  No

Please enter your comments here(if any):

By checking this box, I acknowledge that this research is in keeping with standards set by the Principal Investigator's Department

[Submit](#)

## Viewing the Study submission

Department Representatives can view the Study submission package by clicking the 'View Submission' button.

**Ethics Submission Endorsement**

**Ethics Application** | **Ethics Endorsement** | **Ethics Review**

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

[Hide]

**Ethics Submission Endorsement**

**View Submission (2011/03850)**

**Action:**  Endorse Application  Reject Application  Query PI

**1. Significance:**  
Does the study address an important problem? Will the study affect concepts and methods that drive the field? \*

Yes  No

**2. Approach:**  
Is the conceptual framework adequately developed? Are the design, methods and analyses adequately developed and appropriate? \*

Yes  No

These Tabs provide a summary of the information pertaining to the Study submission.

**Study Summary** – This tab shows a quick summary of the Study submission.

**Document Library** – This tab shows all the attachments submitted by the Principal Investigator for review.

**Amendments** – This tab shows the amendment history of the Study.

**Supp Form** - This tab shows all the various Supplementary Reports submitted throughout the life of the Study.

**RQA Study Reviews, RQA Monitoring, RQA Self-Assessment** – These tabs shows all the activities related to the Quality Assurance audits for the Study.

[Submit](#)

Study Summary Document Library Amendments Supp Form RQA Study Review RQA Monitoring RQA Self-Assessment

Form Category :	Non Exempt	
DSRB Domain :	Hands-On Training Domain	
DSRB Reference :	2011/03850	
Study Title :	cae test firefox 1	
Principal Investigator :	 Yuting PI1 ECQ NUH	
PI's Institution / Department :	ECQ NUH / ECQ Pharmacy Dept	
PI's Email :	abcytgpi1@hotmail.sg	
PI's Contact Number :	83456789	
Study Administrators :		
Study Sites :	ECQ NUH	Status: Not yet initiated
Study Review Category :		
Study Status :	Not yet initiated	
Study Status Last Modified Date :	19-Jun-2011	
Study Approval Period :		
Application Form Version No :	0	
HSA Clinical Trial Certificate(CTC) :	a) Is the HSA Clinical Trial Certificate required for this Study?	Tbd
	b) Has a valid CTC been submitted for each of the NHG Study Sites?	Tbd
Abstract:	NA	
US FDA IND or IDE :	Is this a US FDA IND/IDE study or data is intended to be reported to FDA in support of a IND/IDE application?	No

## The Endorsement options

There are 3 endorsement options for the Department Representative.

## Endorse Application

This option indicates the support of the Department Representative for the conduct of the Study. To endorse, the Department Representative must complete the assessment form and click submit.

### Ethics Submission Endorsement

[View Submission \(2011/03816\)](#)

Action:  Endorse Application  Reject Application  Query PI

**1. Significance:**  
Does the study address an important problem? Will the study affect concepts and methods that drive the field? \*

Yes  No

**2. Approach:**  
Is the conceptual framework adequately developed? Are the design, methods and analyses adequately developed and appropriate? \*

Yes  No

**3. Innovation:**  
Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods? \*

Yes  No

**4. Principal Investigator:**  
Is the Principal Investigator appropriately trained to conduct this study? Does the Principal Investigator have evidence of commitment (e.g. previous track record)? \*

Yes  No

**5. Environment:**  
Is the Principal Investigator's environment suited to conduct the study? Is there an adequate patient pool and are there adequate resources? \*

Yes  No

**6. Budget:**  
Are the projected costs appropriate (i.e. accurate)? Is the overall budget reasonable for the significance of the study? \*

Yes  No

**7. Time:**  
Does the Principal Investigator have adequate resources and time to conduct and complete the study? \*

Yes  No

Please enter your comments here (if any):

By checking this box, I acknowledge that this research is in keeping with standards set by the Principal Investigator's Department

[Submit](#)

This is the notification screen when the Application has been successfully endorsed.

### Ethics Acknowledgement

✔ You have endorsed the Ethics Application (Ref: 2011/03816).  
A task has been sent to Yuting IR1 ECO NUH(IR).

#### Process Tracking

**Ethics Application**

new application

**Ethics Endorsement**

DR endorsement IR endorsement

**Ethics Review**

DSRB Review DSRB domain member review

[Back to Task List](#)  
[Click here to see the full endorsement information](#)

## Reject Application

This option indicates that the Department Representative does not support the conduct of the Study. A reason must be provided for the rejection.

**Warning:** Once the Application has been rejected, the decision cannot be reversed. The Principal Investigator will have to re-submit a fresh Application.

Ethics Submission Endorsement

View Submission (2011/02621)

Action:  Endorse Application  Reject Application  Query PI

Reason For Rejection: Reject for testing

Submit

This is the notification screen when the Application has been rejected. A notification will also be sent to the Study Team.

Ethics Acknowledgement

✔ You have rejected the Ethics Application (Ref: 2011-03165).  
A notification has been sent to Yuting Study Admin ECO NUH(PI), Yuting PI1 ECO NUH(PI), Yuting PI2 ECO TTSH(PI), Yuting CO-1 ECO NUH(PI).

Process Tracking

Ethics Application Ethics Endorsement Ethics Review

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

[Back to Task List](#)  
[Click here to see the full endorsement information](#)



## Query PI

This option allows the Department Representative to ask the Principal Investigator to clarify or make changes to the Application.

When the Query is submitted, the Study Team is notified. When there is a response from the Principal Investigator, this will be reflected to the Department Representative as a new endorsement task.

### Ethics Submission Endorsement

[View Submission \(2011/02621\)](#)

Action:  Endorse Application  Reject Application  Query PI

Comments Title: \*

Comments: \*






[Post New Query](#)

This is the notification screen when the Query has been submitted. A notification will also be sent to the Study Team.

### Ethics Acknowledgement

✔ Your query has been submitted successfully for the Ethics Application (Ref: 2011.03816).  
A task has been sent to Yuting PI1 ECO NUH(PI).

#### Process Tracking

Ethics Application	Ethics Endorsement	Ethics Review
 new application	 DR endorsement	 IR endorsement
	 DSRB Review	 DSRB domain member review

[Back to Task List](#)  
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[Click here to see the full endorsement information](#)