

# NHG ROAM

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*Research Online Administration & Management*

## **Institution 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 Institution Representative

The Study must be supported by the Principal Investigator's and Site PI's Department Representatives as well as the Institution Representatives of any other NHG or Partner Institutions which may be involved in the Study (ie: multi-centre studies in NHG). The Institution Representative's endorsement is necessary before the research activity can be conducted in their institution.

**Note:** *The Institution Representative's role is not to evaluate the scientific or ethical merits of the proposed research study (although they may offer their comments) which will be considered by the DSRB or grant approving body (if applicable).*

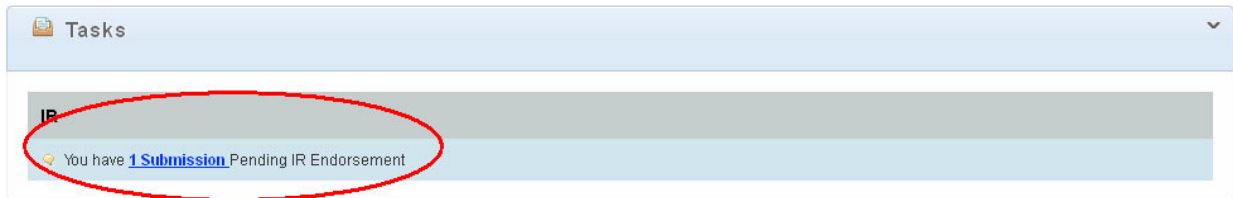
## Who is the Institution Representative?

The Institution Representative has been determined by each Institution as the authority that considers that the proposed research activity is in keeping with the institution's research objectives, image and standards.

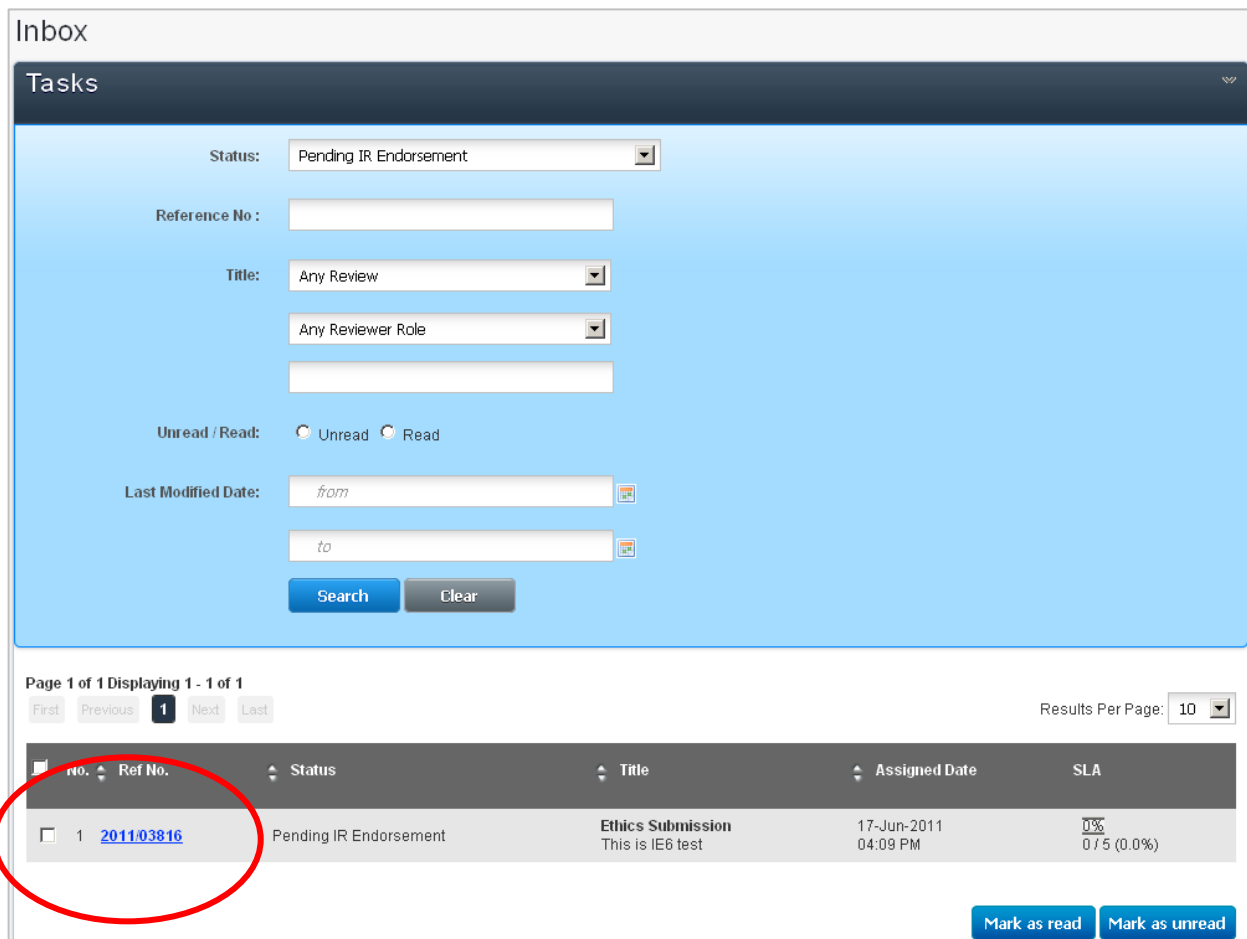
The Institution Representative can be your institution's Director of Research (or equivalent), the Chairman of a specially appointed committee for this purpose, or the Chairman Medical Board (CMB) of your institution.

## Where to see your Endorsement Tasks

After logging into the NHG ROAM portal, Institution 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”, Institution Representatives will be able to jump straight to a table showing the Tasks that they are interested in.



The screenshot shows the 'Inbox' section with a 'Tasks' filter. Below the filter, there is a table of tasks. The first row is circled in red. The table has the following columns: 'no.', 'Ref No.', 'Status', 'Title', 'Assigned Date', and 'SLA'.

no.	Ref No.	Status	Title	Assigned Date	SLA
1	<a href="#">2011.03816</a>	Pending IR Endorsement	<b>Ethics Submission</b> This is IE6 test	17-Jun-2011 04:09 PM	0% 0 / 5 (0.0%)

At the bottom right of the table, there are two buttons: 'Mark as read' and 'Mark as unread'.

By clicking on the Reference number of the Study, the Institution 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 Institution Representatives can chose to view the Study information or to select an endorsement option.

**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 \(2011/02621\)](#)

The Institution Representative has been determined by the institution as the authority that declares whether the research is in keeping with the institution's research objectives, reputation and standards. The role of the Institution Representative is not to evaluate the scientific or ethical aspects of your study although he/she may offer his/her comments.

Action:  Endorse Application  Reject Application  Query PI

Please enter your comments here(if any):

By checking this box, I acknowledge that this research is in keeping with standards set by my Institution.

[Submit](#)

## Viewing the Study submission

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

**Ethics Submission Endorsement**

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

[Hide]

**Ethics Submission Endorsement**

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Action:  Endorse Application  Reject Application  Query PI

These Tabs provide a summary of the information pertaining to the Study submission. (See diagram below)

**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.

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

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

## The Endorsement options

There are 3 endorsement options for the Institution Representative.

- Endorse Application
- Reject Application
- Query PI

## Endorse Application

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

[View Submission \(2011/03184\)](#)

The Institution Representative has been determined by the institution as the authority that declares whether the research is in keeping with the institution's research objectives, reputation and standards. The role of the Institution Representative is not to evaluate the scientific or ethical aspects of your study although he/she may offer his/her comments.

Action:  Endorse Application  Reject Application  Query PI

Please enter your comments here (if any):

Test for IR Approval

By checking this box, I acknowledge that this research is in keeping with standards set by my Institution.

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

**Ethics Acknowledgement**

✔ You have endorsed the Ethics Application (Ref: [201103184](#)).

A task has been sent to Yuting DSRB Asst Coord ECQ TTSH(DSRBStaff) , Yuting DSRB Coord ECQ TTSH(DSRBStaff).

Process Tracking

Ethics Application

Ethics Endorsement

Ethics Review

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graph LR; A((new application)) --> B((DR endorsement)); B --> C((IR endorsement)); C --> D((DSRB Review)); D --> E((DSRB domain member review));
```

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

## Reject Application

This option indicates that the Institution 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. For Multi-centre studies, the Institutions which have rejected the study will not be included in the DSRB review. For single-centre studies, the Study will not continue to be reviewed by the DSRB.

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: 2011-02621).  
A notification has been sent to Yuting Study Admin ECO NUH(PI), Yuting P11 ECO NUH(PI), Yuting CO-1 ECO NUH(PI), Yuting P12 ECO TTSH(PI), Yuting P15 ECO Pharmacy(PI).

Process Tracking

Ethics Application Ethics Endorsement Ethics Review

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

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

## Query PI

This option allows the Institution 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 Institution 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: 2011-02621).  
A task has been sent to Yuting Study Admin ECO NUH(PI) , Yuting PI1 ECO NUH(PI) , Yuting CO-I ECO NUH(PI) , Yuting PI2 ECO TTSH(PI) , Yuting PI5 ECO Pharmacy(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](#)  
[Post another message](#)  
[Click here to see the full endorsement information](#)