

# **NHG ROAM** Research Online Administration & Management

# How to respond to a 'Query' task in the ROAM system Guidebook

Version 1, dated 13 May 2016



### (1) What is a "Query"?

During the Endorsement Process by the Department Representatives (DR), Institution Representatives (IR) and Ethics Review Process by the DSRB, there may be some questions or clarifications required from the Overall Principal Investigator (PI).

In the ROAM system, these questions are termed as a "Query". Fig. 1 below shows the various stages where a Query can occur.

Queries can be raised for all submissions and reports made to the DSRB, including Study Status Reports, Non-Compliance Reports, Study Amendments and UPIRTSO reports.

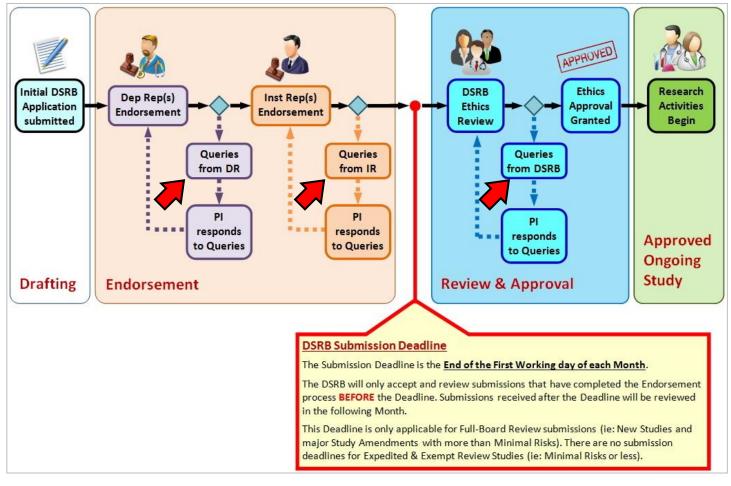


Fig 1: The red arrows indicate where a 'Query' can happen.

#### (2) What is a 'Task'?

In the ROAM system, a 'Task' refers to an Action that is required from the Overall PI, such as responding to a Query raised by the DR / IR or DSRB.

For example, a Query raised by the DR, IR or DSRB will be listed under the { Tasks } section (See Fig. 2).

# (3) Where can I find these 'Tasks' in the ROAM system?

There are two ways in which you can access your Tasks in the ROAM system after you login. (See Fig. 2)

- (1) Go to the **Top-Right corner** of the page and click on **{ Tasks }** link.
- (2) On your Workspace, scroll down to the { Tasks } section.

Thational Healthcare		gout				
*	Home					
Demo Account	My Workspace					
Submissions	1 Announcements	~				
Ethics Submission Standing Database Submission Research Training Notification	* ROAM Announcement: New Function for Users to Generate Reports is Now Available on ROAM [+]Show Details *** First time using ROAM? Not sure what to do? [+]Show Details *** [IMPORTANT] - Do not open multiple browser windows/studies concurrently [+]Show Details * DSRB Announcement: Online Registration of Standing Databases/Tissue Banks for Research [+]Show Details * DSRB Announcement: Updates to Use of Short Consent Form for Non-English Speaking Subjects [+]Show Details * DSRB Announcement: Changes to the Informed Consent Form Ror Non-English Speaking Subjects [+]Show Details * DSRB Announcement: Changes to the Informed Consent Form Ror Non-English Speaking Subjects [+]Show Details * DSRB Announcement: New Minimum Training Requirements for Principal Investigators [+]Show Details * DSRB Announcement: Revised Proper Conduct of Research SOPs (Updated 15 Dec 2015) [+]Show Details					
Report	**NEW** DSRB Announcement: Revised DSRB Review Fees [+]Show Details * DSRB Announcement: Mutual Recognition of Research Ethics Review between SingHealth-CIRB and NHG-DSRB * [+]Show Details					
~	A Notifications	~				
	Tasks	~				
	PI					
	You have <u>1 Submission</u> Pending Reviewer Assignment (DSRB Queried)					

Fig 2: The two ways in which you can quickly access your Tasks.

#### (4) Who can respond to the Query tasks?

During the Endorsement Process, the DR and/or IR may query or seek clarifications from the PI about their Application. Likewise during the DSRB Review process, the DSRB may post queries for the PI to clarify as well.

These queries are sent through the ROAM system and become 'Tasks' for the Overall PI to complete.

Email notifications are also sent to the Overall PI and to the Study Team & Administrators to alert them of the 'Task'.



There are three possible Actions when there is a Query task.

Possible ACTIONS	Who can do the Action	
(1) Post a Response to the Query.	<ul> <li>Overall PI</li> <li>Study Team members</li> </ul>	
(2) View, Edit and Save changes to the Application Form and/or to the Attachments.	Study Administrators	
(3) Re-Submit the Query Response back to the Querying party for review.	Overall PI	



- The DSRB / DR / IR will NOT be able to view any of the responses to their Query UNTIL the Overall PI has clicked on the [ Re-submit Form for Review ] button.
- Posting a new comment, and/or saving a change to the Form DOES NOT RE-SUBMIT the Form for review.
- ONLY THE OVERALL STUDY PI can re-submit the Query Response back to the Querying party for review.

# (5) How do I respond to a Query task?

#### STEP (1): Go to the {Task} Section

After you login to the ROAM system, to the **Top-Right corner** of the page and click on **{ Tasks }** link.

roup	Home	Profile	Tasks	Logout
Home				
My Workspace				
1 Announcements				~

#### STEP (2): Locate the Query in the {Task} Table

Once the **{ Task }** page is loaded, scroll down past the blue search box. You should see the Study listed in the Table. Click on the Study Reference number (eg: 2015/12345-AMD001) in the Table.

📕 No. 🛊 Ref No.	✿ Status	🔹 Title
1 2011/00357	Pending Reviewer Assignment (DSRB Queried)	<b>Ethics Submission</b> The Knowledge, Attitude
$\checkmark$		

The system will now load up an editable version of the Form for you to make changes as may be required by the Query. To view and edit the Form, click on the blue [ View Submission (2011/00357) ] button.



#### **STEP (3):** Posting a Text response to the Query

To post a comment in response to the Query, type in your response in the textbox and click on the blue [ Add Comment ] button.

Any member of the Study Team & Administrators may post a Response. **However, posting a new comment to the Form DOES NOT RE-SUBMIT the Form back for review**.

•	Be mindful of what you post. Any comments that are posted cannot be edited or removed.

		View Submission (2011/00357) Re-submit Form for Review	
Reply Query	/:	*	
	ote that DR/IR/DS ts the form for revi	RB will not be able to read the comments posted until the Principal Investigator w	
Title: Prelimary Revi	iew (1)		
Jiahui (Jeannie) Tay(DSRBStaff)	<ol> <li>(1) Please reply directly</li> <li>(2) Amend the relevant s</li> <li>(3) Resubmit the application</li> <li>(4) Do note that the ROA</li> </ol>	rm has been unlocked for you to make the necessary amendments (in response to the concerns raised in an Preliminary Revi point by point) to the email, ections of the online application form and tion after addressing the requested clarifications. A Application Form may consist of additional fields not present in the previous application form. Please ensure that all fields are eview of this study once all necessary information is received.	
	Write a comment:		
			Add Comment



- The DSRB / DR / IR will NOT be able to view any of the responses to their Query UNTIL the Overall PI has clicked on the [ Re-submit Form for Review ] button.
- ONLY THE OVERALL STUDY PI can re-submit the Query Response back to the Querying party for review.

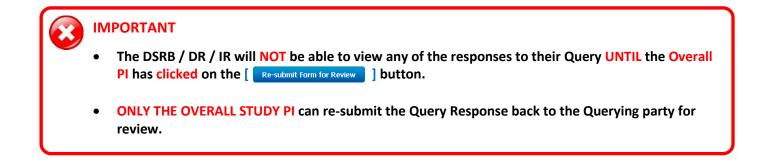
### **STEP (4):** Editing the Form and its attachments

To open the editable version of the Form, click on the blue **{ View Submission }** button.



The system will now load up an editable version of the Form for you to make amendments as may be required by the Query. The process of editing, saving and uploading attachments is the same as how you would draft a new Form.

Any member of the Study Team & Administrators may edit and save changes to the Form. However, saving the changes made to the Form **DOES NOT RE-SUBMIT** the Form for review.



#### **STEP (5):** Re-submitting the Query response back for Review

After all the relevant comments have been posted and amendments to the Form made, the Overall PI must click on the blue [ Re-submit Form for Review ] button to re-submit the query response for review by the querying party.





# • ONLY THE OVERALL STUDY PI can re-submit the Query Response back to the Querying party for review.

- We recommend that the Overall PI carefully check through the responses and any relevant changes to the Form for accuracy and completeness **BEFORE** clicking on the [ Re-submit Form for Review ] button.
  - Once the re-submit button is clicked, the system will lock the Form and send the Form back to the querying party.
  - No further changes can be made. The submission cannot be recalled.

#### (6) Frequently Asked Questions

#### (a) Can we recall the Form submission? We forgot to make some changes.

No. The Form **cannot** be recalled once the Overall PI has re-submitted for review.

What the Overall PI will have to do is to separately contact the Querying party (ie: DR, IR or DSRB) to query the Form again so that the Form is unlocked and sent back to the Overall PI and Study Team.

Hence, we advise users to check their Forms for accuracy and completeness before re-submitting the Form.

#### (b) A comment that was posted has some errors or mistakes. Can we edit or delete that comment?

No. Once the comments have been posted, it cannot be edited or removed.

What can be done is for the Overall PI or Study Team to post a new comment to state that the particular comment is to be disregarded, or has been superseded by a later comment.

Hence, we advise users to check their responses carefully before posting a comment.

Some Studies will discuss and collate their responses to the Query offline, before the Overall PI posts the responses and re-submits the Form back to the Querying party.

#### (7) ROAM User Guidebooks and DSRB Reference materials

If you are new to research and/or using the ROAM system, we *strongly recommend* that you download and read the following guides *before* attempting any new applications in the ROAM system, as the learning curve to use the system is quite steep, to prevent any problems/delays in their submissions.

- DSRB: NHG Investigators' Manual
- NHG ROAM: Researchers' Guidebook
- NHG ROAM: Online DSRB Application Form Guidebook
- NHG ROAM: Completing Section B (PI & Study Team) of the DSRB Application Form
- Conducting Research: The regulatory requirements and policies that you need to know (Website)

These guidebooks and more are <u>available for download here</u>. NHG Research website → Resources → ROAM Guidebooks [<u>https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/roam+guidebooks</u>]

#### (8) Troubleshooting

#### (a) For DSRB Ethics review and approval related queries

For queries relating to the DSRB ethics review and approval, please contact the DSRB:

- OHRPP@nhg.com.sg
- (+65) 6471 3266 (Office hours only). (Download the DSRB Secretariat Contact List here)

Please provide the DSRB Study Reference number and Study Title where applicable.

#### (b) For Technical issues with the ROAM system

If you are experiencing difficulties with the ROAM system, please send an email to **researchonline@nhg.com.sg** with the following information.

- The Study Title and the DSRB Reference number (where applicable).
- Screen-captures of the exact Error Message / Problem
- Brief description of the Problem faced

*Eg:* What you are trying to do when the error occurred? What is the error message? Was there anything unusual that happened?

Name and Version of the Web Browser\* being used to access the ROAM system.
 \*Note:

- Not all web browsers are compatible for use with the ROAM system. Some problems are caused by incompatible browsers, and can be resolved by using a compatible browser.
- We recommend using <u>Mozilla Firefox</u> or <u>Google Chrome</u> when using the ROAM system.
- If you are unable to install new programs on your computer, you can consider using a <u>portable version of Firefox</u> which does not require installation and works directly from any USB thumb-drive. (Google 'Portable Firefox' for more information.)

For most situations, the problem can be resolved within 2 working days. However, the turnaround time will depend on the complexity of the problem as well as our workload. Hence, it would be very helpful if you can provide as much information as possible about the problem so that we can efficiently pin-point and troubleshoot the problem for you.

NHG Research • www.research.nhg.com.sg •