



NHG ROAM

Research Online Administration & Management

User's Guide to ROAM Enhancements

(Release date: 16 April 2014)

- A. Improved Function to Withdraw New Study Applications**
- B. New Function to Withdraw New Study Amendments and Supplementary Forms**
- C. New Prompt in the Study Status Report for Completed Studies**
- D. New Notification of Study Suspension, Termination or Re-instatement by DSRB (via ROAM)**

(Version 1.0)

NHG Research
Translating Research into Highest Quality Patient Care
www.research.nhg.com.sg

A. Withdrawal of New Study Applications

Previously, Principal Investigators could not initiate a withdrawal request for a new study application via the “Withdraw Study” button after DSRB has set the Review Category for the study. Now, a new feature has been added into ROAM that enables the Principal Investigator to **initiate a withdrawal request** for a new study application **at any of the review stages after the DSRB has received the application until the study is approved**. The DSRB will also be able to receive the notification of the withdrawal request immediately and process it quicker.

If the Submission Status of the study has been updated to “Submission Approved”, then the Principal Investigator **will not** be able to withdraw the study. The Principal Investigator would have to submit a Study Status Report to close the study application. The Submission Status is reflected in the same row as the study details under the “My Studies” tab. The Principal Investigator will also not be able to withdraw the study if it is not approved.

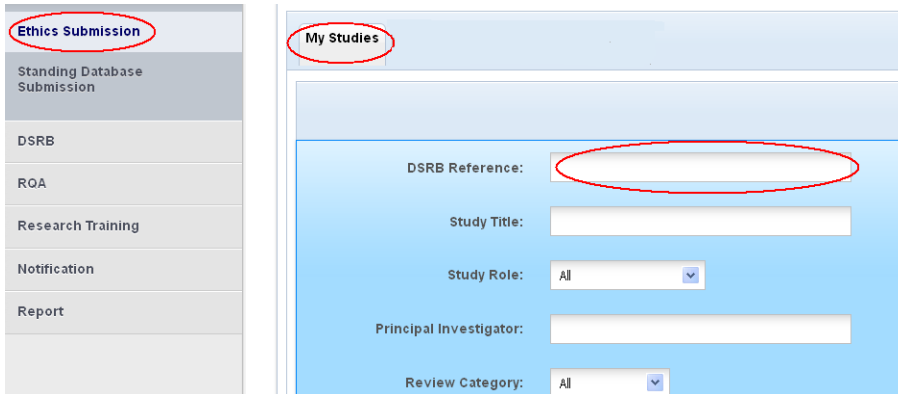
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No.	DSRB Reference	Study Title	Study Role	Principal Investigator	Review Category	Submission Status	Study Status	Study Approval Date	Study Expiry Date
1	d		PI		-	Submission Draft	Not yet initiated	-	-
2	2007/00				Expedited	Submission Approved	Expired		

Steps to Withdraw a New Study Application

1. Click on the “Ethics Submission” tab to locate the “My Studies” tab. Under the “My Studies” tab, search for the study by using the search function.

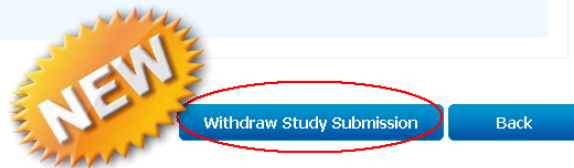


- Once the study has been found, click on the icon located at the right side of the study details to go to the “Study Summary” page.



- Scroll down the “Study Summary” page and click on the “Withdraw Study Submission” button to withdraw the study application.

HSA Clinical Trial Certificate(CTC) :	a) Is the HSA Clinical Trial Certificate required for this Study?	To be determined
	b) Has a valid CTC been submitted for each of the NHG Study Sites?	To be determined
Abstract:	xxx	
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



- Under the “Choose” option, select the correct study reference number in the drop-down list and state the reason for study withdrawal in the “Reason” textbox. Next, click the “Withdraw” button to send the withdrawal request to DSRB.

Choose:* 2014/001

Reason:*

Withdraw Study Submission Back

Withdraw Cancel

- A pop-up window will appear to confirm the sending of withdrawal request. Click “OK” to send the withdrawal request to DSRB.

Are you sure you want to withdraw this submission?

OK Cancel

- An acknowledgement message will appear to indicate that the withdrawal request has been sent successfully to DSRB. An auto-generated email will be sent to the Principal Investigator and all study team members to inform them of the withdrawal.

Ethics Acknowledgement

✔ Your withdrawal has been submitted successfully for the Ethics Application (Ref: 2014/).

A task has been sent to

7. Follow Step 1 to check that the study withdrawal request has been submitted. The Submission Status should now reflect “Withdrawal request pending DSRB acknowledgement”.

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No.	DSRB Reference	Study Title	Study Role	Principal Investigator	Review Category	Submission Status	Study Status	Study Approval Date	Study Expiry Date
1	2014/00	New Study Application	PI	-	-	Withdrawal request pending DSRB acknowledgement	Not yet initiated	-	-

8. Once DSRB accepts the withdrawal request, an auto-generated email will be sent to the Principal Investigator and all study team members to inform them of the withdrawal. Follow Step 1 to check that the study application has been withdrawn. The Submission Status and Study Status should now reflect “Withdrawn”.

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No.	DSRB Reference	Study Title	Study Role	Principal Investigator	Review Category	Submission Status	Study Status	Study Approval Date	Study Expiry Date
1	2014/00	New Study Application	PI	-	-	Withdrawn	Withdrawn	-	-

B. Withdrawal of Study Amendments and Supplementary Forms

Previously, Principal Investigators could not withdraw any study amendment or supplementary forms in ROAM. Furthermore, ROAM did not have a “Withdraw” option for DSRB to process the incorrect submissions appropriately. Now, a new feature is available to Principal Investigators to initiate withdrawal requests for new study amendments and supplementary forms which includes the following:

- Study Status Report + Self-Assessment Checklist
- Non-Compliance / Study Deviation Report
- UPIRTSO Reports
- Other Study Notifications

The Principal Investigator can **submit a withdrawal request** for a new study amendment or any supplementary forms **at any of the review stages after the DSRB has received the application until the study amendment or supplementary form is approved or acknowledged**. The DSRB will receive the notification of the withdrawal request immediately.

If the study amendment or supplement form has been approved or acknowledged, the Principal Investigator **will not** be able to withdraw the study amendment or supplementary form. The Principal Investigator would have to submit a new Study Amendment to supersede the previous amendment, or submit an Other Study Notification form to inform DSRB of the incorrect submission. The Principal Investigator will also not be able to withdraw the study amendment or supplementary form if it is not approved.

Example:

As the Submission Status of the Other Study Notification Form **has not been updated to “Submission Approved”**, it is possible for the Principal Investigator to submit a withdrawal request.

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Form ID	Supplementary Form Type	Submission Date	Approval Date	Submission Status	Review Category
20140X-OTH0001	Other Study Notification	04-Apr-2014	-	Pending Category Assignment	-

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Steps to Withdraw New Study Amendments and Supplementary Forms

1. Click on the “Ethics Submission” tab to locate the “My Studies” tab. Under the “My Studies” tab, search for the study by using the search function.

The screenshot shows a web interface with a sidebar on the left containing several tabs: 'Ethics Submission' (circled in red), 'Standing Database Submission', 'DSRB', 'ROA', 'Research Training', 'Notification', and 'Report'. The main content area has a 'My Studies' tab (also circled in red) which is active. Below this tab, there are search filters: 'DSRB Reference:' with an empty text input field (circled in red), 'Study Title:' with an empty text input field, 'Study Role:' with a dropdown menu set to 'All', 'Principal Investigator:' with an empty text input field, and 'Review Category:' with a dropdown menu set to 'All'.

2. Once study has been found, click on the icon located at the right side of the study details to go to the “Study Summary” page.

The screenshot shows a table with the following columns: No., DSRB Reference, Study Title, Study Role, Principal Investigator, Review Category, Submission Status, Study Status, Study Approval Date, and Study Expiry Date. The first row contains the following data: 1, 2014/00, New Study Application, PI, -, -, -, -, -. A red circle highlights a small icon in the rightmost column of the first row. Below the table, there is a 'Delete Submission' button. The page number is 'Page 1 of 1 Displaying 1 - 1 of 1' and 'Results Per Page: 10'.

3. Click on the “Amendments” or “Supp Form” tab to check the Submission Status and Reference Number of the form (e.g. 20XX/00001-AMD0001 or 20XX/00001-OTH00001 etc.).

The screenshot shows a 'Study Summary' page with several tabs: 'Study Summary', 'Document Library', 'Amendments' (circled in red), 'Supp Form' (circled in red), 'ROA Study Review', and 'ROA Monitoring'. Below the tabs, there is a 'View application' button. The page displays the following details: 'Form Category : Exempt', 'DSRB Domain : DSRB Domain', 'DSRB Reference : 2014/00', and 'Study Title : New Study Application'.

4. Once the Submission Status and Reference Number of the form to be withdrawn has been verified, return to the “Study Summary” page, scroll down the page, and click on the “Withdraw Study Submission” button to withdraw the form.

HSA Clinical Trial Certificate(CTC) :	a) Is the HSA Clinical Trial Certificate required for this Study?	To be determined
	b) Has a valid CTC been submitted for each of the NHG Study Sites?	To be determined
Abstract:	xxx	
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



[Withdraw Study Submission](#) [Back](#)

5. Under the “Choose” option, select the correct form’s Reference Number in the drop-down list and state the reason for form withdrawal in the “Reason” textbox. Next, click the “Withdraw” button to send withdrawal request to DSRB.

[Withdraw Study Submission](#) [Back](#)

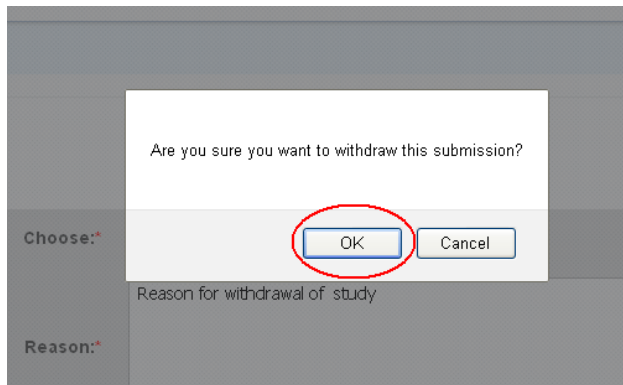
NEW Choose:

2014/00	--AMD0001	▼
2014/00	--AMD0001	
2014/00.	OTH0001	

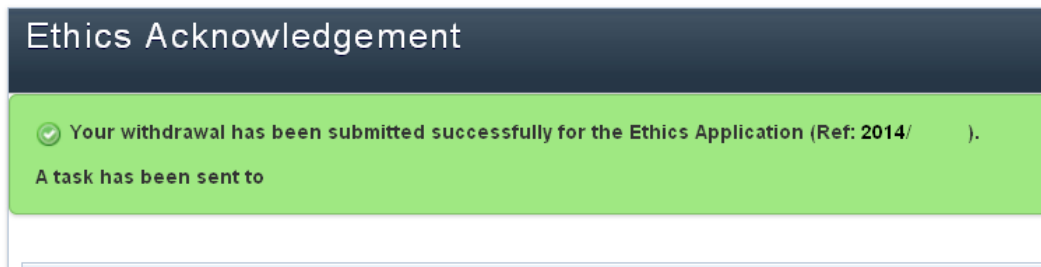
Reason:*

[Withdraw](#) [Cancel](#)

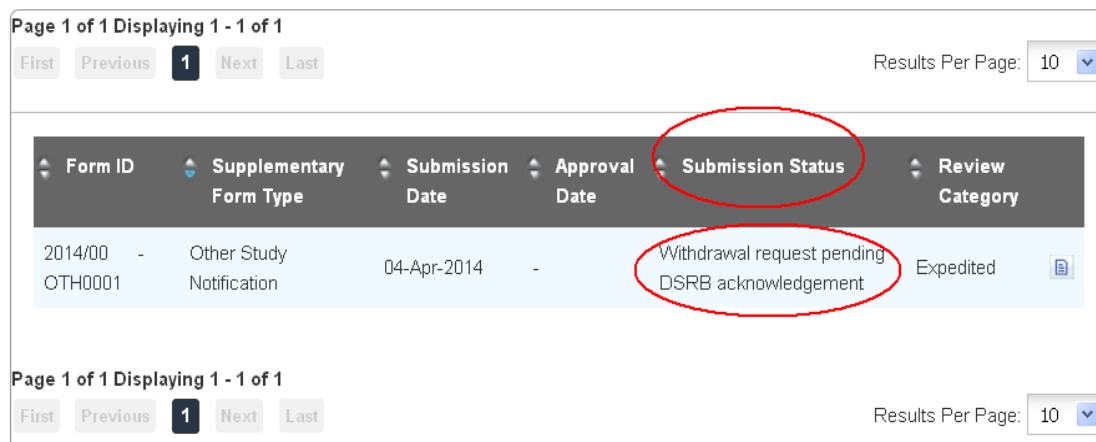
- A pop-up window will appear to confirm sending of withdrawal request. Click “OK” to send the withdrawal request to DSRB.



- An acknowledgement message will appear to indicate that the withdrawal request has been sent successfully to DSRB. An auto-generated email will be sent to the Principal Investigator and all study team members to inform them of the withdrawal.



- Follow Steps 1 to 3 to check that the study amendment and/or supplementary form(s) withdrawal request have been submitted. The Submission Status should now reflect “Withdrawal request pending DSRB acknowledgement”.



9. Once DSRB accepts the withdrawal request, an auto-generated email will be sent to the Principal Investigator and all study team members to inform them of the withdrawal. Follow Steps 1 to 3 to check that the study amendment and/or supplementary form(s) have been withdrawn. The Submission Status should now reflect “DSRB Staff/Chair Approved Withdrawal”.

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Form ID	Supplementary Form Type	Submission Date	Approval Date	Submission Status	Review Category
2014/00147-OTH0001	Other Study Notification	04-Apr-2014	-	DSRB Staff Approve Withdrawal	Expedited

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C. Updates to the Study Status Report for Completed Studies

The following criteria should be met before a study can be reported as “Completed”:

- The research is permanently closed to the enrollment of new participants.
- All participants have completed all research-related interventions
- Collection and analysis of individually identifiable data has been complete
- Completion date (DD/MM/YYYY)

Previously, the DSRB would have to query the Principal Investigators after receiving the Study Status Reports to determine if the criteria have been met. Now, a new feature is available to Principal Investigators when they are submitting the Study Status Reports for completed studies.

If the Principal Investigator selects “Completed” under Section A, Status of Study, the criteria will appear as a reminder. The 3 criterions should be checked and the completion date must be completed (as indicated below) so that the Study Status Report can be submitted.

Section A: Status of Study


Study Status*


<input type="radio"/> Ongoing	<input type="radio"/> Ongoing (Enrolment closed, Participants on follow-up only)
<input type="radio"/> Ongoing (Last Participant, Last Visit Over, Only Data Analysis Ongoing)	<input checked="" type="radio"/> Completed
<input type="radio"/> Terminated	<input type="radio"/> Suspended
<input type="radio"/> Not yet initiated	

If the study is 'Completed', please ensure that ALL of the following criteria are fulfilled, by checking the boxes.*

- The research is permanently closed to the enrollment of new participants.
- All participants have completed all research-related interventions.
- Collection and analysis of individually identifiable data has been completed.

Completion date: *



If there is an unchecked criterion and/or the completion date has not been completed, an error message will prompt the Principal Investigator when the Study Status Report is submitted.

D. Notification of Study Suspension, Termination or Re-instatement by DSRB

A new feature is available in ROAM to notify Principal Investigators and all study team members if a study has been suspended, terminated or re-instated by DSRB.

Once the DSRB has determined to suspend, terminate or re-instate the study, an auto-generated email will be sent to the Principal Investigator and all study team members to inform them of the Suspension, Termination or Re-instatement. The Study Status will reflect “Suspended”, “Terminated” or “Reinstated” accordingly.

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No.	DSRB Reference	Institution	Department	Study Title	Principal Investigator	Review Category	Submission Status
1	2014/00			New Study Application		Exempted	Submission Approved

Under the “Study Summary” page, the study suspension, termination or re-instatement will also be reflected in the “Suspension/Termination History” details.


Study Status : Suspended

Reasons : xx

Study Status Last Modified Date : 04-Apr-2014

Study Approval Period :

Suspension/Termination History : 1) DSRB Staff Suspended this study on 04-Apr-2014



Scroll down to the “Official DSRB Letters” to view the letter and more details about the suspension, termination or re-instatement initiated by DSRB.

US FDA IND or IDE :

Is this a US FDA IND/IDE study or data is intended to be reported to the
FDA in support of a IND/IDE application?

Official DSRB Letters :

[2014/00147 04-04-2014](#)

[2014/00148 04-04-2014](#)

[2014/00149 04-04-2014](#)



For more information or help, please contact your friendly DSRB secretariat or ROAM administrators.

DSRB Secretariat: Tel: (+65) 6471 3266

You may also download the [DSRB Contact List here](#).

ROAM Helpdesk: For any queries relating to the NHG ROAM system, please send an email containing your Full Name, NRIC/FIN, Institution & Department and contact number to researchonline@nhg.com.sg