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# NHG ROAM

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**Research Online Administration & Management**

## **User's Guide to Generating Reports in ROAM**

**(Release date: 07 July 2014)**

**A. New Function in ROAM for Users to Generate Reports**

**B. Types of ROAM Reports**

**C. Steps to Generate a New Report**

*(Version 1.0)*

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## **A. New Function in ROAM for Users to Generate Reports**

The new “Generate Reports” function is now available in ROAM and will enable users to generate basic reports of their studies and submissions to DSRB.

Users can locate this new function under “Reports” on the left side panel after he/she logs in to ROAM.

## **B. Types of ROAM Reports**

Users will be able to generate reports of the studies that they have been granted access to. Please refer to the description in the table below for more information on the access rights.

<b>User Roles</b>	<b>Access to Studies</b>
Study Team Members (e.g. Principal Investigators, Site Principal Investigators, Co-Investigators, Collaborators) & Study Administrators	Studies submitted by Principal Investigators where user is a Study Team Member or Study Administrator (i.e. access to studies listed under “My Studies” tab)
Department Representative (DR) & Department Staff	Studies submitted by staff from his/her department (i.e. access to studies listed under “My Department” tab)
Institutional Representative (IR) & Institutional Staff	Studies submitted by staff from his/her institution (i.e. access to studies listed under “My Institution” tab)

Users will be able to generate 7 types of ROAM reports as shown below. The reports can be accessed and downloaded as an Excel or Portable Document Format (PDF) document.

- RPT01 List of New Applications Approved by DSRB
- RPT02 List of Study Amendments Approved by DSRB
- RPT03 List of UPIRTSO Reports Submitted to DSRB
- RPT05 List of Study Status Report Approved by DSRB
- RPT06 List of Non Compliance / Deviation Reports Submitted to DSRB
- RPT08 List of All Expiring Studies before This Date
- RPT09 List of Other Notifications Reports Submitted to DSRB

Please refer to Appendix A for a description of each report and the data output that can be expected in the generated report.

### **C. Steps to Generate a New Report**

1. Click on “Report” on the left side panel to open the link to the “Reports” function.

The screenshot displays the 'Generate Report' interface. On the left, a sidebar menu includes 'Submissions', 'Research Training', 'Notification', 'Report', and 'Reports', with 'Reports' highlighted in a red box. The main content area is titled 'Generate Report' and features the following elements:

- Report:** A dropdown menu set to 'RPT01 - LIST OF NEW APPLICATIONS APPROVED BY DSRB'.
- Filter Criteria:**
  - Studies:** A dropdown menu set to 'My Studies'.
  - Domain:** Two dropdown menus, the first set to 'All Domain' and the second to '--All Sub Domain--'.
  - Review Category:** A dropdown menu set to '-ALL-'.
  - Approved Since:** Two date pickers labeled 'From:' and 'To:'.
- Generate Report:** A blue button at the bottom of the form.

2. Click on the dropdown list under “Report” to view the list of reports and select the report which you would like to generate.

The screenshot shows the 'Generate Report' interface. The 'Report' dropdown menu is open, displaying a list of report options: RPT01 - LIST OF NEW APPLICATIONS APPROVED BY DSRB, RPT02 - STUDY AMENDMENTS APPROVED BY DSRB, RPT03 - LIST OF UPIRISO REPORTS SUBMITTED TO DSRB, RPT05 - LIST OF STUDY STATUS REPORTS APPROVED BY DSRB, RPT06 - LIST OF NON COMPLIANCE / DEVIATION REPORTS SUBMITTED TO DSRB, RPT08 - LIST OF ALL EXPIRING STUDIES BEFORE THIS DATE, and RPT09 - LIST OF OTHER NOTIFICATIONS REPORTS SUBMITTED TO DSRB. The 'Report' field is currently set to RPT01. Other fields include 'Studies', 'Domain', 'Review Category' (set to -ALL-), and 'Approved Since' (From and To date pickers). A 'Generate Report' button is at the bottom.

3. The system will display the different filtering functions (e.g. Review Category, Approval Period etc.) according to the type of report. Select the appropriate filtering criteria to generate the desired report.

The screenshot shows the 'Generate Report' interface with the 'Filter Criteria' section expanded. The 'Report' dropdown is set to RPT01. The 'Filter Criteria' section includes: 'My Studies' dropdown, 'DSRB Domain B' and 'DSRB Sub Domain B1' dropdowns, 'Review Category' dropdown (set to -ALL-), and 'Approved Since' date pickers (From: 01-Jul-2013, To: 01-Jul-2014). A 'Generate Report' button is at the bottom.

4. If you have more than one user role (e.g. PI and DR), select the appropriate filtering criteria (e.g. My Studies / My Department) to generate the desired report.

The screenshot shows the 'Generate Report' interface with the 'Filter Criteria' section expanded. The 'Report' dropdown is set to RPT01. The 'Filter Criteria' section includes: 'My Studies' dropdown (highlighted), 'My Studies' and 'My Department' options, 'Domain' dropdown (set to All Domain), and 'Review Category' dropdown (set to -ALL-). The 'Approved Since' date pickers are empty. A 'Generate Report' button is at the bottom.

5. Click on the “Generate Report” button and you can add a description of the report to be generated.

The screenshot shows the 'Generate Report' interface. At the top, there is a 'Report:' dropdown menu set to 'RPT01 - LIST OF NEW APPLICATIONS APPROVED BY DSRB'. Below this is the 'Filter Criteria' section, which includes: 'Studies' dropdown set to 'My Studies'; 'Domain:' dropdown set to 'DSRB Domain B' and 'DSRB Sub Domain B1'; 'Review Category:' dropdown set to '-ALL-'; and 'Approved Since:' with 'From:' and 'To:' date pickers set to '01-Jul-2013' and '01-Jul-2014' respectively. A red box highlights the 'Generate Report' button and the 'Description:' text area, which contains the text 'List of New applications from 010713 to 010714'. Below the description are two buttons: 'Generate as xls' and 'Generate as pdf'.

6. Click on the appropriate button to generate the report as Excel (xls) or PDF (pdf) format.

This screenshot is identical to the previous one, showing the 'Generate Report' interface with the same filter criteria and description. However, a red box highlights the 'Generate as xls' and 'Generate as pdf' buttons, indicating the next step in the process.

- Once the report has been generated successfully, a new row will be displayed as a new result at the bottom of the page. Click on the link to download and view the report.

Report: RPT01 - LIST OF NEW APPLICATIONS APPROVED BY DSRB

Filter Criteria

Studies: My Studies

Domain: DSRB Domain B DSRB Sub Domain B1

Review Category: -ALL-

Approved Since: From: 01-Jul-2013 To: 01-Jul-2014

**Generate Report**

Description:

Generate as: **Generate as xls** **Generate as pdf**

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File Name	Description	Status	Created Date	Completed Date
RPT01 - LIST OF NEW APPLICATIONS APPROVED BY DSRB_25-Jun-14-19:24:47.xls	List of New applications from 010713 to 010714	Succeeded	2014-06-25 19:24:47	2014-06-25 19:24:48

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

**DSRB Secretariat:**

Tel: (+65) 6471 3266

**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](mailto:researchonline@nhg.com.sg).

## **Appendix A. Description of ROAM Reports**

This section contains the description of the reports and the data output to be generated for each report.

i. RPT01 List of New Applications Approved by DSRB

This report lists all initial submissions approved within a chosen time period.

<b>Data Columns</b>	<b>Labels</b>
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Review Category	Review category of the study (e.g. Full Board, Expedited, Exempt)
Submission Date	Date the study was submitted by the PI
Study Title	Title of the study
Main PI, Main PI Institution	Name of the Overall PI, Institution of the Overall PI
Recruitment Target of each site	Recruitment target of each study site
Approval Start Date	Start date of the ethics approval
Approval Expiry Date	Expiry date of the ethics approval

ii. RPT02 List of Study Amendments Approved by DSRB

This report lists all study amendments approved within a chosen time period.

<b>Data Columns</b>	<b>Labels</b>
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Review Category	Review category of the study (e.g. Full Board, Expedited, Exempt)
Study Amendment Review Category	Review category of the study amendment (e.g. Full Board, Expedited, Exempt)
Submission Date	Date the study amendment was submitted by the PI
Study Title	Title of the study
PI, PI Institution	Name of the PI, Institution of the PI
Approval Date	Date the study amendment was approved

iii. RPT03 List of UPIRTSO Reports Submitted to DSRB

This report lists all UPIRTSO reports submitted within a chosen time period regardless of submission status (e.g. Noted, Pending Review Outcome etc.).

<b>Data Columns</b>	<b>Labels</b>
Event Onset Date	Event Onset Date
Patient ID UPIRTSO form	UPIRTSO Report Section B1: Participant Identifier
Location	UPIRTSO Report Section A7: Study Site
Problem Summary UPIRTSO form	UPIRTSO Report Section E5: Describe the outcome of the problem, including details of what was taken to resolve the problem, and if there was any resulting impact on the participant or others.
Study Arm	UPIRTSO Report Section B5: Which study arm is the participant in?
Sponsor	UPIRTSO Report Section D2: Opinion of the Sponsor
NHG PI	UPIRTSO Report Section D1: Opinion of the NHG PI
Investigational Product	UPIRTSO Report Section C: Does this problem involve an investigational Product (drug/device/biological/other agent)?
Change	UPIRTSO Report Section F4: Do you recommend changes to protocol and/or informed consent document?

iv. RPT05 List of Study Status Report Approved by DSRB

This report lists all study status report forms approved within a chosen time period.

<b>Data Columns</b>	<b>Labels</b>
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Study Title	Title of the study
Study Status	The current status of the study: - Ongoing - Ongoing (Enrolment closed, Participants on follow-up only)



	<ul style="list-style-type: none"> <li>- Ongoing (Last participant, last visit, Only Data analysis ongoing)</li> <li>- Completed</li> <li>- Withdrawn</li> <li>- Terminated</li> <li>- Suspended</li> <li>- Not yet initiated</li> </ul>
Study Review Category	Review category of the study (e.g. Full Board, Expedited, Exempt)
Main PI, Main PI Institution	Name of the Overall PI, Institution of the Overall PI
Recruitment Target of each site	Recruitment target of each site
Approval Date	Date the study status report form was approved
Report Details	The site status and recruitment information for all study sites

v. RPT06 List of Non Compliance / Deviation Reports Submitted to DSRB

This report lists all non-compliance / study deviation reports submitted within a chosen time period regardless of submission status (e.g. Noted, Pending Review Outcome etc.).

<b>Data Columns</b>	<b>Labels</b>
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Non-Compliance / Deviation Event Date	Non Compliance / Study Deviation Report Q1: Date of Non-Compliance / Deviation Event
Brief Description of NC event	Non Compliance / Study Deviation Report Q2: Please describe in detail the nature of the Protocol Deviation including the date of occurrence
Date report received by	Date when Non Compliance Report / Study Deviation Report was submitted by the PI
Non Compliance / Deviation Review Category	Review category of the non compliance / study deviation (e.g. Full Board, Expedited)
Non Compliance / Deviation Review Outcome	Review outcome status

Outcome Date	Date the non compliance / study deviation received an outcome
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vi. RPT08 List of All Expiring Studies before This Date

This report lists all studies which have an approval period that is expiring within a chosen time period.

Data Columns	Labels
Domain	DSRB Domain that reviewed the study
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Study Title	Title of the study
PI	Name of the PI
Review Category	Review category of the study status report form (e.g. Full Board, Expedited, Exempt)
Approval Start Date	Start date of the ethics approval
Approval Expiry Date	Expiry date of the ethics approval
Study Status	Current status of the study
SRF Submitted	Current status of the study status report form

vii. RPT09 List of Other Notifications Reports Submitted to DSRB

This report lists all other study notifications submitted within a chosen time period regardless of submission status (e.g. Noted, Pending Review Outcome etc.).

Data Columns	Labels
Domain	DSRB Domain that reviewed the study
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Study Title	Title of the study
PI	Name of the PI
Submission Date	Date when Other Study Notification Form was submitted by the PI
Notification Type	Other Study Notification Form Q1: Type of other study notification (e.g. DSMB Reports, Interim Data Analysis, Letter from Study Sponsors etc.)
Require Amendments	Other Study Notification Form Q2: Does this notification require amendments to the Study

	Design and/or to any of the Study documentations?
Change Risk-Benefit Ratio	Other Study Notification Form Q3: Does this notification contain any information that changes the Research Participants' Risk-Benefit ratio of participating in the Study?
Change Participant's Decision to Continue	Other Study Notification Form Q4: Does this notification contain any information that may affect the enrolled Research Participants' decision to continue in the Study?
Summary of Notification	A summarised contents of the notification
Review Category	Review category of the study notification (e.g. Full Board, Expedited)
Review Outcome	Review outcome status
Outcome Date	Date the study notification received an outcome