

NHG ROAM

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
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(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.

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

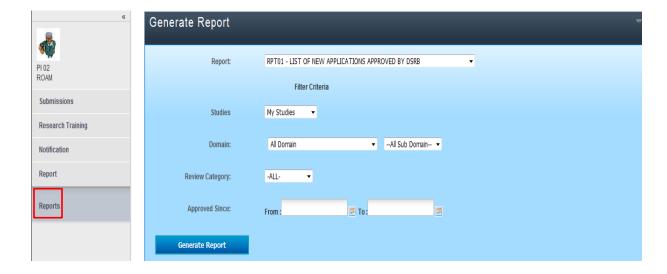
Users will be able to generate 7 types of ROAM reports as shown below. The reports can be accessed and downloaded as an Excel or Portable Document Format (PDF) document.

- 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

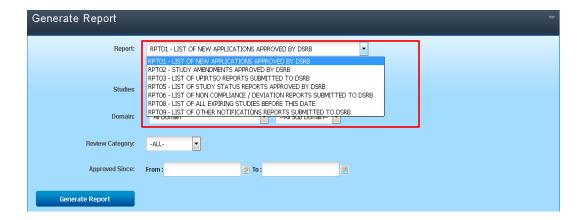
Please refer to Appendix A for a description of each report and the data output that can be expected in the generated report.

C. Steps to Generate a New Report

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



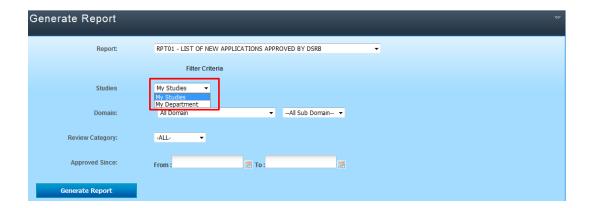
2. Click on the dropdown list under "Report" to view the list of reports and select the report which you would like to generate.



The 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.



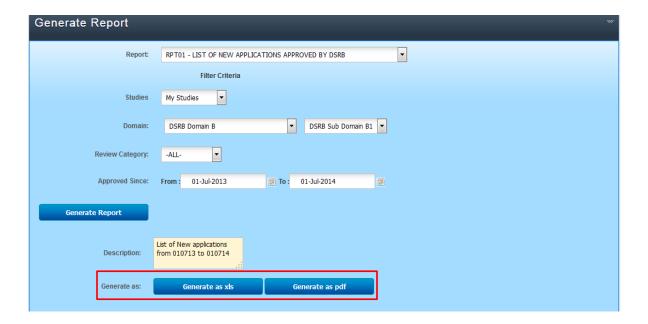
4. If you have more than one user role (e.g. PI and DR), select the appropriate filtering criteria (e.g. My Studies / My Department) to generate the desired report.



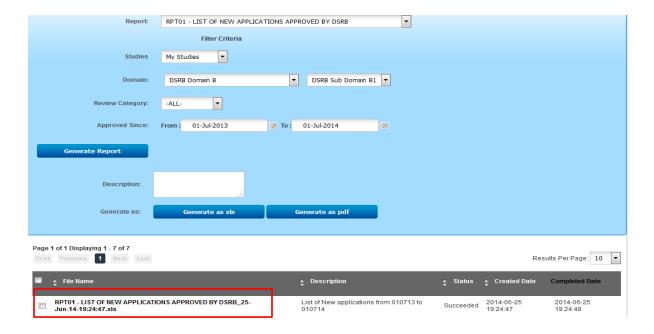
5. Click on the "Generate Report" button and you can add a description of the report to be generated.



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



7. 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.



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.

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.

Data Columns	Labels
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.

Data Columns	Labels
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	Review category of the study amendment
Category	(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.).

Data Columns	Labels
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	UPIRTSO Report Section E5: Describe the
form	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.

Data Columns	Labels
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)

	- Ongoing (Last participant, last visit, Only
	Data analysis ongoing)
	- Completed
	- Withdrawn
	- Terminated
	- Suspended
	- Not yet initiated
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.).

Data Columns	Labels
DSRB Reference	DSRB Reference Number (e.g. 20XX/12345)
Non-Compliance / Deviation	Non Compliance / Study Deviation Report
Event Date	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 of the non compliance /
Review Category	study deviation (e.g. Full Board, Expedited)
Non Compliance / Deviation	Review outcome status
Review Outcome	

Outcome Date	Date the non compliance / study deviation
	received an outcome

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	Other Study Notification Form Q4: Does this
Continue	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