

# NHG ROAM

*Research Online Administration & Management*

## ROAM Introductory Session

[www.research.nhg.com.sg](http://www.research.nhg.com.sg)

# Training Agenda

## What we will be covering...

- ROAM Accounts & the ROAM Workspace
- Drafting the DSRB Application Form
- Understanding the Submission Process
- Responding to Queries
- Creating Supplementary Report Forms  
(eg Study Amendment Form, Status Report Form)
- Common Issues & Best Practices
- Q & A



# 1. Connecting to the ROAM system



# Introducing NHG ROAM

- The NHG Domain Specific Review Boards (DSRB) uses the Research Online Administration & Management (ROAM) platform to process applications for ethics approval.
- NHG-ROAM is available to you as long as you have an Internet connection and a compatible Web-Browser such as Mozilla Firefox or Google Chrome.



[www.research.nhg.com.sg](http://www.research.nhg.com.sg)



# ROAM Requirements

- Internet connection
- Compatible Browser
  - **Firefox and Chrome** (all versions) are the recommended Browsers.



- Internet Explorer, Safari (eg iPads) → **NOT RECOMMENDED** due to compatibility issues



**IMPORTANT:** Please do not use incompatible browsers as it can **corrupt or delete** your DSRB Application and data.

# 2. Creating Your ROAM Accounts



# What you will need for creating a new Account

- **Softcopy of Resume / CV**

Used by the DSRB to assess the person's qualifications, experience and ability to conduct the proposed study.

- **Minimum Training Certifications**

All key investigators, such as the **overall Principal Investigator, Site Principal Investigators**, and **Co-Investigators** are required to have completed basic research ethics training.

*“The intent of having minimum training requirements is for the research community to appreciate and apply the underlying ethical principles to their day-to-day research practice.”*

More information on Minimum Training requirements are available at [www.research.nhg.com.sg](http://www.research.nhg.com.sg) under **“Conducting Research”**.

# What you will need for creating a new Account

## FOR Staff of NHG Institutions and NUH

(TTSH, NSC, IMH, NHG Polyclinics, NHQ Diagnostics, NHG HQ, NUH, KTPH, WHC)

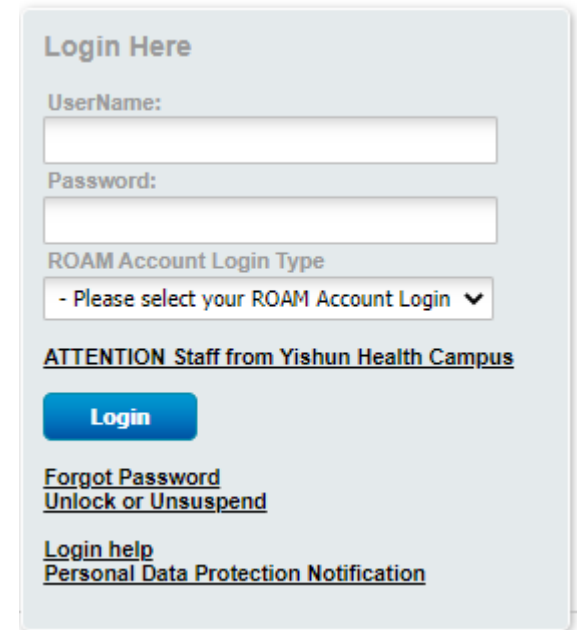
- Please register a ROAM profile via the “Create NHG ROAM Account” process at the ROAM Login Page.
- You can use your NHG / NUHS Active Directory ID (ADID) to login directly to the ROAM system.
- Your ROAM account login would use your ADID login as follows:

(ROAM) UserID:	Your ADID Username
(RAOM) Password:	Use your latest ADID password. <b>(Note: When you update your ADID password, you must use that updated password for your ROAM login as well)</b>
Domain:	Select option “NHG / NUHS”

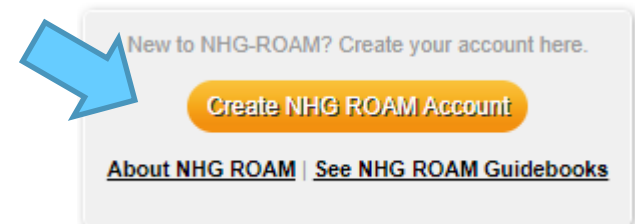
- If you have issues with your NHG ADID, you will need to contact the **ITD Helpdesk** at **1800 483 4357** for assistance

# Creating your ROAM Account

- 1) Go to [www.research.nhg.com.sg](http://www.research.nhg.com.sg)
- 2) Click on “**Login**” found on top-right corner of the page.
- 3) Click on “**Create NHG ROAM Account**”. Follow on-screen instructions.
- 4) You will need:
  - **Valid ADID**
  - **Work email**

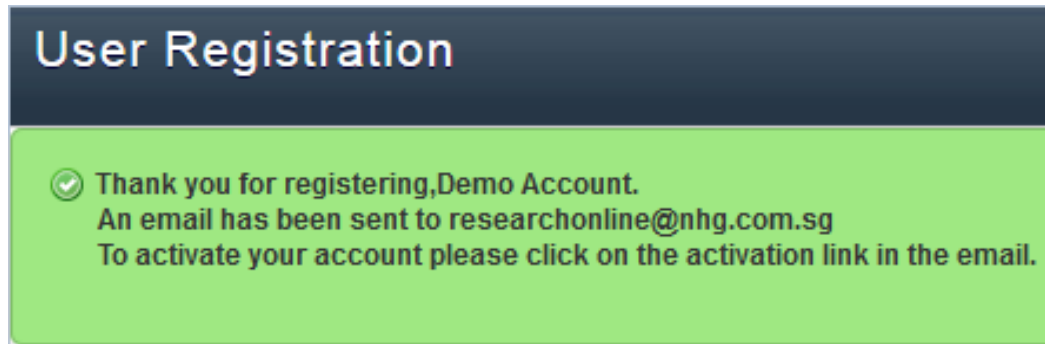


The screenshot shows a login form titled "Login Here". It includes fields for "UserName:" and "Password:". Below these is a dropdown menu for "ROAM Account Login Type" with the option "- Please select your ROAM Account Login". A blue "Login" button is present. Below the button are links for "Forgot Password", "Unlock or Unsuspend", "Login help", and "Personal Data Protection Notification". A note reads "ATTENTION Staff from Yishun Health Campus".



# Creating your ROAM Account

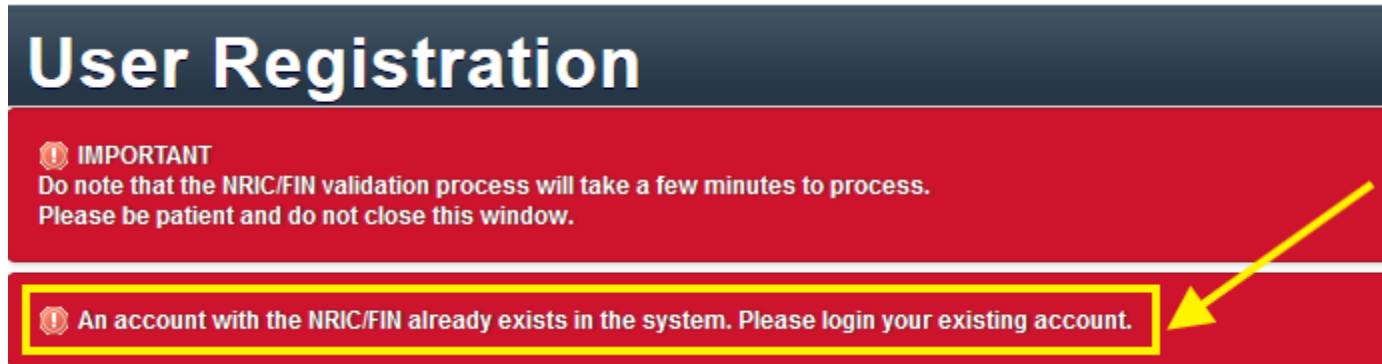
- 5) When your registration has been successfully submitted, the system will inform you that an **Account Activation Email** has been sent to you.



- 6) Do **check your Spam folder** for the Activation Email in case it may have been filtered there.
- 7) You must **click on the link** in the email **to activate your account** for use.

# Creating your ROAM Account

However, if you get this error message instead..



**User Registration**

**IMPORTANT**  
Do note that the NRIC/FIN validation process will take a few minutes to process.  
Please be patient and do not close this window.

An account with the NRIC/FIN already exists in the system. Please login your existing account.

- 1) For **Staff of NHG Institutions & NUH**: You should be using your NHG/NUH Active Directory ID (ADID) to login to the ROAM system.
- 2) For **Ex-Staff of NHG Institutions**: You will need to create a new ROAM account with information that is appropriate to your current employment status.
- 3) For **Non-Staff**: You already have an existing ROAM account. You cannot create another ROAM account.



# To Login to ROAM

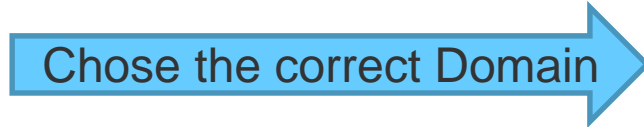
Go to [www.research.nhg.com.sg](http://www.research.nhg.com.sg).

Click on the Login button found on the top-right of the page.

There are **TWO** types of Login Accounts.

- (1) For **NHG & NUH Staff** – Active Directory Account Login (Domain: “**NHG/NUHS**”)
- (2) For **Non-NHG Staff** – Non-ADID Account Login (Domain: “**Guest Login**”)

Chose the correct Domain



### Login Here

UserName:

Password:

ROAM Account Login Type  
- Please select your ROAM Account Login ▼

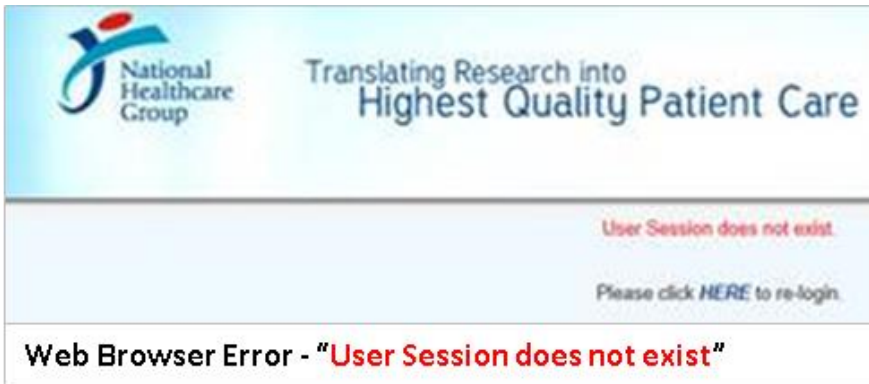
**ATTENTION Staff from Yishun Health Campus**

[Login](#)

[Forgot Password](#)  
[Unlock or Unsuspend](#)

[Login help](#)  
[Personal Data Protection Notification](#)

# Login Problem – ‘User Session Does not Exist’



This error is caused by the default settings of the Internet Explorer Browser.

- *There is nothing wrong with your login information or your ROAM account.*
- We do recommend that you use other web browsers like **Mozilla Firefox** or **Google Chrome** when using the ROAM system.
- If you are unable to install new programs on your computer, you can consider using a **portable version of Firefox** which does not require installation and works directly from any USB thumb-drive. (Google "Portable Firefox")

# Completing your Account Profile

- On **your first login**, you will be prompted to complete your Account Profile.
- Can be accessed via top menu -> Profile

## Update User Profile

Account Info Personal Info Contact Info

This Section shows your ROAM Account login information. > [Help](#)

ROAM Account Login Type: \* NHG Active-Directory Login

Login Username: \* [REDACTED]

From  to

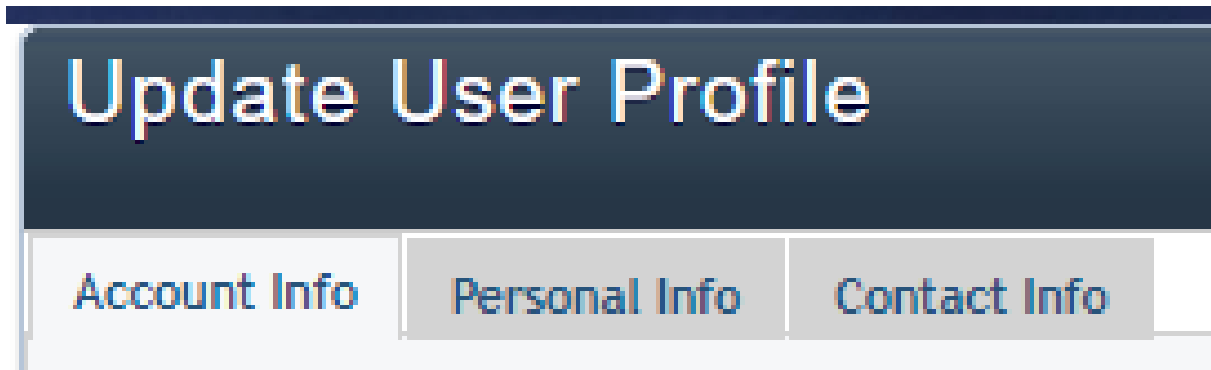
Out Of Office Period: The Out-of-Office feature will be activated between the period as indicated. When the Out-of-Office feature is active, all endorsement requests to you (only where applicable) as the Department and/or Institution Representative will be automatically diverted to the next eligible Representative.

Next Tab

# Completing your Account Profile

The Account Profile is made up of 5 tabs.

- 1) Account Info
- 2) Personal Info (*Most Important*)
- 3) Contact Info



# Completing your Account Profile

1. Complete the compulsory questions as indicated with a **red asterisk \***, beginning with the **[Account Info]** Tab.
2. After filling out each tab, click on the **{Next Tab}** button *until you reach the last tab* with the **{Save All Tabs}** button.
3. **\*\***When all Tabs are finished, click on the **{Save All Tabs}** button to save your information. **Unless you do this, none of the information will be saved.**
4. When the changes to your Profile are saved, you will be shown the message **“Your Profile has been updated successfully”**.

The screenshot shows the 'Update User Profile' interface with the 'Account Info' tab selected. The form contains the following fields and sections:

- Account Info** (selected), Personal Info, Contact Info
- Section header: "This Section shows your ROAM Account login information. > [Help](#)"
- ROAM Account Login Type: NHG Active-Directory Login
- Login Username: \* [Redacted]
- Out Of Office Period: From [ ] to [ ]
- Out Of Office Period description: "The Out-of-Office feature will be activated between the period as indicated. When the Out-of-Office feature is active, all endorsement requests to you (only where applicable) as the Department and/or Institution Representative will be automatically diverted to the next eligible Representative."
- Next Tab** button (highlighted with a blue arrow)

The screenshot shows the 'Update User Profile' interface with the 'Contact Info' tab selected. The form contains the following fields and sections:

- Account Info**, Personal Info, **Contact Info** (selected)
- Section header: "This Section contains your Contact Information. > [Help](#)"
- Email** section: Registered Email Address: \* [ ]
- Contact Information** section: Telephone (Work): \* [ ]
- Telephone (Work) description: "This will be used for the DSRB to contact you when necessary."
- Mobile Number: \* [ ]
- Mobile Number description: "This will be used for 2-Factor Authentication(2FA) with your ROAM Account login."
- Previous Tab** button
- Save All Tabs** button (highlighted with a blue arrow)



# ROAM Account Profile

- The **ROAM Account Profile must be completed BEFORE** the Account becomes validated and can be used for making submissions to the DSRB.
- An **incomplete or outdated** ROAM Account Profile **will cause problems** with the submission process and **delay** any submissions made in the system.
- Other ROAM users will also **be unable search/locate you** in the ROAM system or to add you as part of their Study Team.
- Being able to login to your ROAM account **DOES NOT MEAN** the Account Profile is successfully completed.

# Creating Additional Appointments

- If you hold other concurrent Appointments at other Institutions, you may list them under the {Additional Appointment} section.

**Primary Appointment**

**Important:** Selecting the "Others" option for your Organization will not route your DSRB Applications correctly. If you are a Staff member, do not select "Others".

Organization/Cluster (Primary) \* Agency for Science, Technology and Research (A\*STAR) ▼

Institution (Primary) \* Singapore Institute of Clinical Sciences (SICS) ▼

Department (Primary) \* Cell and Molecular Biology (CMB) ▼

Appointment (Primary) \* Adjunct Research Fellow ▼

Do you hold any other concurrent appointments?  Yes  No ←

**Additional Appointment**

Organization/Cluster (Additional)	Institution (Additional)	Department (Additional)	Appointment (Additional)	
NHG	NHG HQ	Research & Development Office	Coordinator	<input type="button" value="Del"/>
National University of Singapore	NUS - School of Computing	Department of Information Systems	Coordinator	<input type="button" value="Del"/>
-Please Select- ▼	-Please Select- ▼	-Please Select- ▼	-Please Select- ▼	<input type="button" value="Add"/>

←

←



# Some available options for Appointments

Organization	Institution	Department
Agency for Science, Technology and Research (A*STAR)	<ul style="list-style-type: none"> <li>Singapore Institute of Clinical Sciences</li> </ul>	<ul style="list-style-type: none"> <li>Cell and Molecular Biology (CMB)</li> <li>Clinical Nutrition Research Centre (CNRC)</li> <li>Human Development (HD)</li> <li>Neurodevelopment Center (NDC)</li> <li>Systems Biology (SB)</li> </ul>
National University Health Systems (NUHS)	<ul style="list-style-type: none"> <li>National University Hospital (NUH)</li> <li>Saw Swee Hock School of Public Health</li> <li>Yong Loo Lin School of Medicine</li> </ul>	<p><i>* The full list of available Departments for each Institution will be shown to the user when the Organization and Institution options have been selected by the user.</i></p>
National University of Singapore (NUS)	<ul style="list-style-type: none"> <li>NUS Business School</li> <li>Faculty of Arts and Social Sciences</li> <li>Faculty of Engineering</li> <li>Faculty of Law</li> <li>Faculty of Science</li> <li>School of Computing</li> <li>School of Design and Environment</li> </ul>	



**DO NOT USE** these choices in your Appointment selection. (These are 'legacy data' options.)

- Not Applicable (Non-NHG)
- Others (Non-NHG)
- ROAM-ORG

# Choosing between multiple Appointments

- When you start a new DSRB Application Form, the system will **by default**, use **your Primary Appointment** in the Form.
- However, the System allows you **to change and select the Appointment** for which you are using for your DSRB Application.

Name: demo account  
Institution: All  
Department: All  
Email Address:

Search Clear

Page 1 of 1 Displaying 1 - 3 of 3  
First Previous 1 Next Last

Name	Institution	Department	Email	
Demo Account	Singapore Institute of Clinical Sciences (SICS)	Cell and Molecular Biology (CMB)	researchonline@nhg.com.sg	Select
Demo Account	NHG HQ	Research & Development Office	researchonline@nhg.com.sg	Select
Demo Account	NUS - School of Computing	Department of Information Systems	researchonline@nhg.com.sg	Select

Close

All three Appointments are available for selection.

# Appointments – How it affects your submissions

The **Appointment** that is used in the DSRB Application Form, will **determine** which **Department** and **Institution Representative** will be assigned to endorse the Application.

Default Selection for new Forms as PI.

## Primary Appointment



SICS Appointment



Dept Rep



Inst Rep

## Additional Appointment



NUH Appointment



Dept Rep



Inst Rep

## Additional Appointment



NUS Appointment



Dept Rep



Inst Rep



DSRB Ethics Review Board



Tom has 3 concurrent appointments with different Institutions.

He can choose to use a different appointment for his Application where applicable.



# [Personal Info] → Primary Appointments

- Each Account **must have** a Primary Appointment.
- **By default**, the system will **use the Primary Appointment** in a new DSRB Application but this can be changed in the Form.
- The chosen Appointment **determines how** submissions are automatically **routed** for oversight **endorsements** by the respective **Department Representative** (DR) and **Institution Representative** (IR).
- **DO NOT USE** these choices in your Appointment selection.
  - Not Applicable (Non-NHG)
  - Others (Non-NHG)
  - ROAM-ORG
- Once the DSRB Application Form has been submitted, it will **not be possible to change** the Appointment of the PI / Site PI.



## [Personal Info] → Primary Appointments

- Once the DSRB Application Form has been submitted, it will **not be possible to change** the Appointment of the PI / Site PI.
- An **Outdated/Incorrect** Primary Appointment will cause delays to your submission as the assigned DR/IR **will reject** your application as they **do not recognize you** as part of their Staff.
- Once an Application **is Rejected**, it will **NOT be reviewed** by the DSRB. There is no recourse.
- The PI will have to **re-submit a new Application**.

# 3. Navigating the ROAM Workspace



# ROAM – My Workspace

ROAM organizes all your activities into 3 main sections.

**Home**

**My Workspace**

**Announcements: Latest news**

- \* 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 Requirements for Studies Involving Prospective Collection of Biological Sample(s) and Re-Consenting Subjects for Ongoing Studies \* [+]Show Details
- \* DSRB Announcement: New Minimum Training Requirements for Principal Investigators [+]Show Details
- \*\*NEW\*\* DSRB Announcement: Revised Proper Conduct of Research SOPs (Updated 15 Dec 2015) [+]Show Details
- \*\*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

**Notifications: Updates about your Submissions**

**TASKS: Action Items that the PI must do, such as responding to Queries from the DR/IR or DSRB.**



# ROAM – Tasks

- For Researchers, a **Task** is usually a **Query from the DR / IR or DSRB**.
- The entire Study Team & Administrators will receive Email notifications and see this in their Accounts.
- Any member of the Study Team may view, amend, save and post responses to the Query via the Task section.
- However, **ONLY** the **overall Principal Investigator** may **re-submit** the responses and amendments back to the querying party for review.



# Ethics Submission – Submit New Study

- [Submissions] → [Ethics Submissions] → [My Studies]
- All your DSRB Applications are kept under [My Studies].
- You can also create new Applications via the **Submit New Study** button.

The screenshot displays the 'Ethics Submission' web interface. On the left is a vertical navigation menu with the following items: Demo Account, Submissions, Ethics Submission, Standing Database Submission, Research Training, Notification, and Report. A yellow arrow points to the 'Submissions' menu item. The main content area has a dark header with the text 'Ethics Submission'. In the top right corner of this area is a blue button labeled 'Submit New Study', with a yellow arrow pointing to it. Below the header is a light blue bar with a tab labeled 'My Studies'. Underneath this is a large empty light blue box. A pagination bar shows 'Page 1 of 1 Displaying 1 - 1 of 1' and navigation buttons: First, Previous, 1, Next, Last. To the right of these buttons is a 'Results Per Page' dropdown menu set to 10. Below the pagination is 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 table contains one row with the following data: 1, [DRAFT], Demo Non-Exempt Form, PI, Demo Account, -, Submission Draft, Not yet initiated, -, -. A yellow arrow points to the first row of the table. At the bottom right of the table area is a blue button labeled 'Delete Submission'. Below the table is another pagination bar identical to the one above, showing 'Page 1 of 1 Displaying 1 - 1 of 1' and navigation buttons, with a 'Results Per Page' dropdown set to 10.

# Study Summary Page (DSRB Approval Letters)

- [My Studies] → [Click on 'View Study' Icon]

## Ethics Submission

Submit New Study

My Domain

My Studies


My Institution

My Reviews

Page 2 of 4 Displaying 11 - 20 of 40

First Previous 1 2 3 4 Next Last

Results Per Page: 10

No.	DSRB Reference	Study Title	Study Role	Principal Investigator	Review Category	Submission Status	Study Status	Study Approval Date	Study Expiry Date	
11			Co-Investigator		Expedited	Submission Approved	Expired	09-Oct-2008	08-Oct-2009	

'View Study' Icon



# Study Summary Page (DSRB Approval Letters)

- [My Studies] → [Click on 'View Study' Icon] → ["Study Summary" page]

Ethics

I want to create

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

**View application**

Form Category : Non Exempt

DSRB Domain : DSRB Domain A

DSRB Reference : [Redacted]

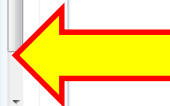
Study Title : [Redacted]

Principal Investigator : [Redacted]

PI's Institution / Department : [Redacted]

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?

Official DSRB Letters : [200910\\_Renewal\\_A-08-565.pdf](#) [051109\\_Renewal\\_A-08-565.pdf](#) [220409-Approval-A-08-565.pdf](#) [220210\\_Amendment A-08-565.pdf](#) [2008/00565-SRF0002\\_15-08-2011](#) [2008/00565-SRF0003\\_13-08-2012](#) [2008/00565-SRF0004\\_25-07-2013](#) [2008/00565-SRF0005\\_09-07-2014](#) [2008/00565-SRF0006\\_14-07-2015](#) [2008/00565-Expiry\\_08-07-2015](#)



**DSRB Approval Letters**

# 4. Drafting your DSRB Application Form



# Drafting your DSRB Application Form

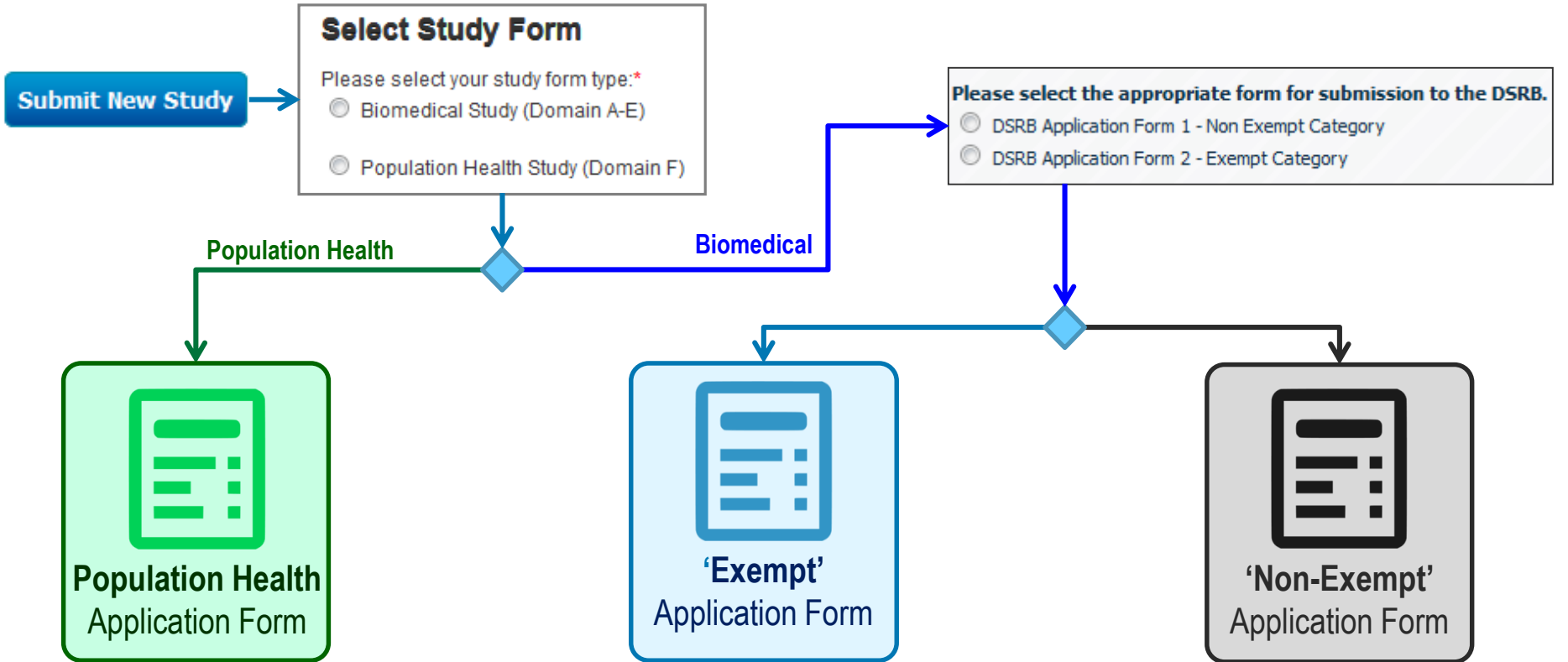
- **Anyone\*** can create a new Draft DSRB Application Form.
- By default, the Application Form creator will be automatically assigned as the **Overall Principal Investigator** (and using their Primary Appointment).
- However, the Overall PI and their Appointment can be changed.
- **Only** the **Overall PI** can **'Submit'** the Application Form.

\* **'Anyone'** refers to any NHG or Partner Institution Staff whose account has been given Authoring Rights.

An Account may not been automatically given Authoring Rights due to the email domain used.



# Choice of DSRB Application Forms



## Research Types

- 1) Education Research
- 2) Health Services and Outcomes Research
- 3) Prevention & Health Promotion Programme
- 4) Epidemiological Research
- 5) Social and Behavioral Research
- 6) Community-based Participatory Research

## Research Types

- 1) Normal Educational Practices and Settings
- 2) Anonymous Educational Tests, Surveys, Interviews or Observations
- 3) Identifiable Subjects in Special Circumstances
- 4) Collection of Existing Data
- 5) Public Benefit or Service Programs
- 6) Taste and Food Evaluation and Acceptance Studies

- PI should use the Non-Exempt Form if their research activity does not qualify under the Exempt Category.
- Submissions using the Biomed Non-Exempt Form will be reviewed via the Full Board or Expedited route.



If you are not sure which Application Form to use, please refer to the **Investigator's Manual (Pg 32)** or contact the DSRB ([ohrpp@nhg.com.sg](mailto:ohrpp@nhg.com.sg)) for clarification.



# Choice of DSRB Application Forms

- Decide carefully which **DSRB Application Form** is appropriate for your submission.
- If you use the **Wrong Form** for submission, you will need to **Start Over** again (including obtaining the DR / IR endorsements) with the right Form.
- There is **no function to change or switch the Form type**.



If you are not sure which Application Form to use, please refer to the **Investigator's Manual (Pg 32)** or contact the DSRB ([ohrpp@nhg.com.sg](mailto:ohrpp@nhg.com.sg)) for clarification.

# Tips for Drafting your DSRB Application Form

- Download the “**Online DSRB Application Form Guidebook**” for the list of Questions and **draft your Application content** in a Word document first.
- When ready, you can ‘Copy/Paste’ your content/answers from your Word document draft. This prevents data loss should something go wrong. The text fields in the form only accept **Plain Text**.
- Remember to assign a **Version Number & Date** to all your Attachments /Documents.
- Check your entire Application (including your Attachments) before clicking Submit. **There is no “Cancel Submit” or “Recall” function.**
- **Only the Overall PI can submit the Application.** This is equivalent to the Study PI signing their signature on a paper-form.





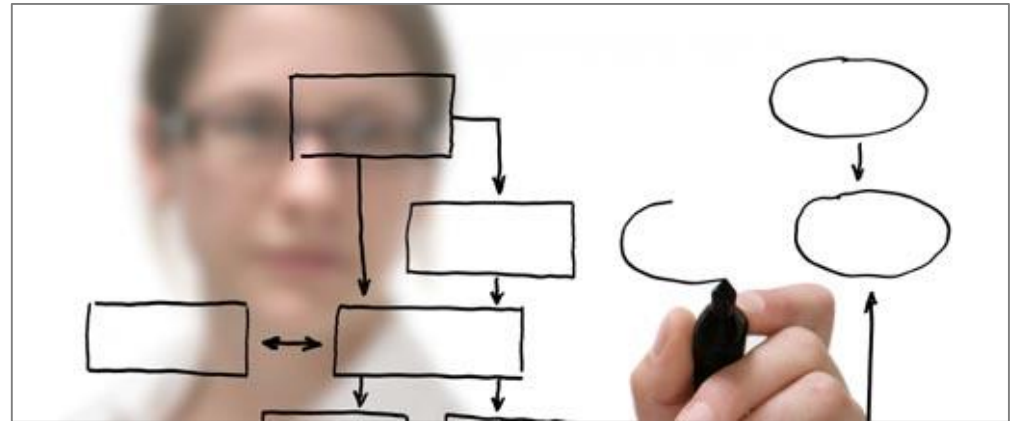
# AVOID AT ALL COSTS

There are some things that you must never do. These can irreversibly corrupt your Application Form and cause permanent data loss to your submission.

- **DO NOT** open **Multiple Browser windows** with **Different Studies** at any time.
- **DO NOT** **edit** the same Application Form **concurrently**.
- **DO NOT** leave your computer / idle the Form for more than **5 minutes**. The website can time-out / disconnect if you take too long between **Saves or Action**. Editing text **does not** count as an **Action**.
- **DO NOT** Login **concurrently** with **different logins** on the **same computer**.
- Be careful when deleting Drafts (ie: multiple roles, multiple listings). **Once deleted, it cannot be retrieved.**
- **DO NOT** use any **special symbols** or **bullet-points** in the Forms. **Use Plain Text only.**



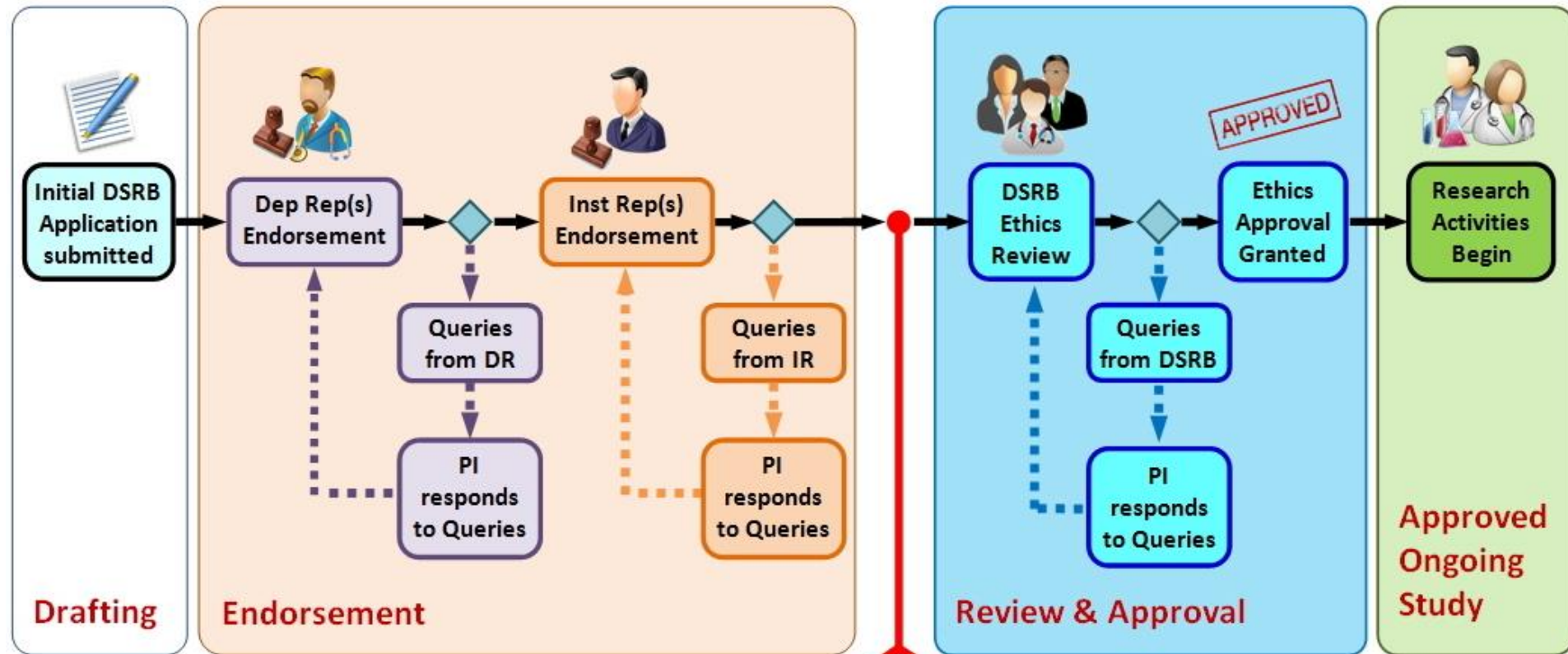
# 5. The Submission Process



# Submission of the DSRB Application Form

- Submission is a 3-step process.
  - **Step 1:** Submission of Application Form by Overall PI.
  - **Step 2:** Department Representative (DR) reviews and endorses application form.
  - **Step 3:** Institution Representative (IR) reviews and endorses application form.
  - After which the System forwards the Application Form to the DSRB when the DR & IR Endorsement process is completed.
- The Application must be endorsed online by all relevant 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.
- The DSRB will only accept and review Applications which have completed the Endorsement Process **BEFORE** the monthly Deadline (applicable only for Full-Board review Studies).

# Overview of the Submission process to DSRB



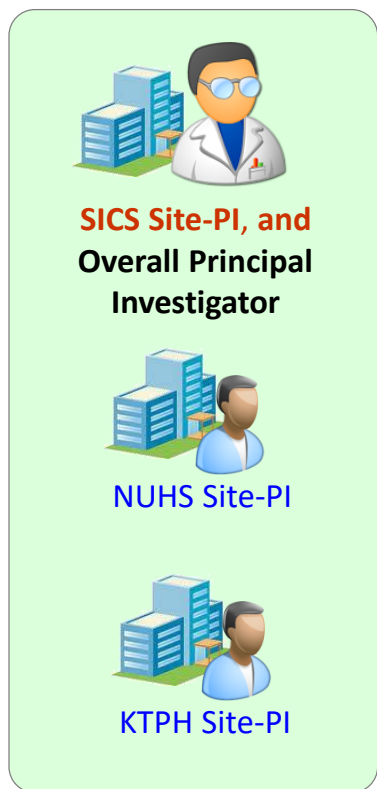
## DSRB Submission Deadline

The Submission Deadline is the **End of the First Working day of each Month**.

The DSRB will only accept and review submissions that have completed the Endorsement process **BEFORE** the Deadline. Submissions received after the Deadline will be reviewed in the following Month.

This Deadline is only applicable for Full-Board Review submissions (ie: New Studies and major Study Amendments with more than Minimal Risks). There are no submission deadlines for Expedited & Exempt Review Studies (ie: Minimal Risks or less).

# Endorsement Process for Multi-site Studies



Submission of Application  
by the  
**Overall Principal Investigator**



DSRB receives Study Application for Review

Concurrent Endorsement Process \*

\* The Application Form is sent to DSRB **ONLY** when **ALL** Endorsement decisions are made.



# Possible Endorsement Outcomes

These are the possible Endorsement Decisions by your respective Department Representative (DR) or Institution Representative (IR).



## Endorse Application

The DR / IR supports the Application “as-is” and it moves on to the next stage.



## Query PI

The DR / IR has queries for the Overall PI. The Overall PI must respond to the queries, and make any changes if required.



## Reject Application

The DR / IR rejects the Application. The Study will not be allowed to proceed for that particular Study Site.

**If the Application is a single Site Study, the entire Application is rejected and no further review will take place.**

The decision to reject an Application is **final and irreversible**.



# 6. Responding to Queries



# Task: Responding to Queries

- During the Endorsement process, the DR or IR may query or seek clarifications from the PI about their Application.
- Likewise during the DSRB Review process, there would be queries posed to the PI as well.
- These queries are sent through the ROAM system and become **'TASKS'** for the PI to complete. Email notifications are sent to the entire Study Team.
- When there is a Query, there are three possible Actions.
  - (1) Post a Response to the Query.**
  - (2) Make changes to the Application Form and/or Attachments.**
  - (3) Re-Submit the Responses back for review (ONLY for Overall PI)**
- Any member of the Study Team, including Study Administrators may do Actions **(1)** and **(2)**.
- **Only the Overall Principal Investigator may do Action (3)** *(Resubmitting for review.)*

# Task: Responding to Queries


- You can find all your Tasks in the [[Tasks](#)] section.
- You must go through the [[Tasks](#)] section in order to be able to respond to the Query.

The screenshot displays the National Healthcare Group (NHG) website interface. The top navigation bar includes links for Home, Profile, **Tasks**, and Logout. A red arrow points to the 'Tasks' link. The main content area is titled 'Home' and 'My Workspace'. It features three expandable sections: 'Announcements', 'Notifications', and 'Tasks'. The 'Tasks' section is highlighted with a red arrow. Below the 'Tasks' section, a notification box indicates: 'PI You have [1 Submission](#) Pending Reviewer Assignment (DSRB Queried)'. The left sidebar contains a user profile for 'Demo Account' and a list of menu items: Submissions, Ethics Submission, Standing Database Submission, Research Training, Notification, and Report.

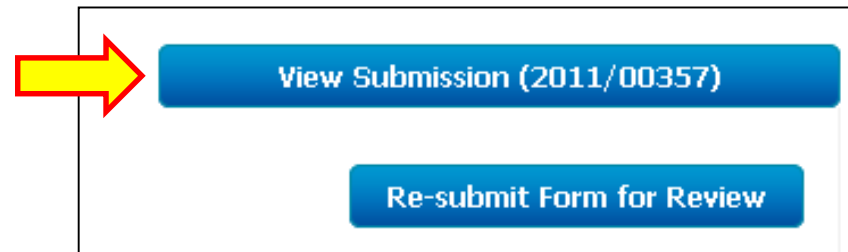
# Task: Responding to Queries – Step 1

## (1) LOCATE THE TASK 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.

<input type="checkbox"/>	No.	Ref No.	Status	Title
	<input type="checkbox"/>	<a href="#">2011/00357</a>	Pending Reviewer Assignment (DSRB Queried)	<b>Ethics Submission</b> The Knowledge, Attitude

- The system will now load up an editable version of the Application Form for you to make amendments as required by the Query.
- To view / edit the Application Form, click on the blue [View Submission] button.



# Task: Responding to Queries – Step 2


## (2) TO POST A RESPONSE TO THE QUERY

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

View Submission (2011/00357)

Re-submit Form for Review

Reply Query: ▾

 Please note that DR/IR/DSRB will not be able to read the comments posted until the Principal Investigator re-submits the form for review

Title: Preliminary Review (1)


The online application form has been unlocked for you to make the necessary amendments (in response to the concerns raised in an Preliminary Review email that was sent to you on 22 June 2011)

**Jiahui (Jeannie) Tay**(DSRBStaff)

(1) Please reply directly (point by point) to the email,  
(2) Amend the relevant sections of the online application form and  
(3) Resubmit the application after addressing the requested clarifications.  
(4) Do note that the ROAM Application Form may consist of additional fields not present in the previous application form. Please ensure that all fields are completed before resubmitting your study for re

DSRB will continue the review of this study once all necessary information is received.

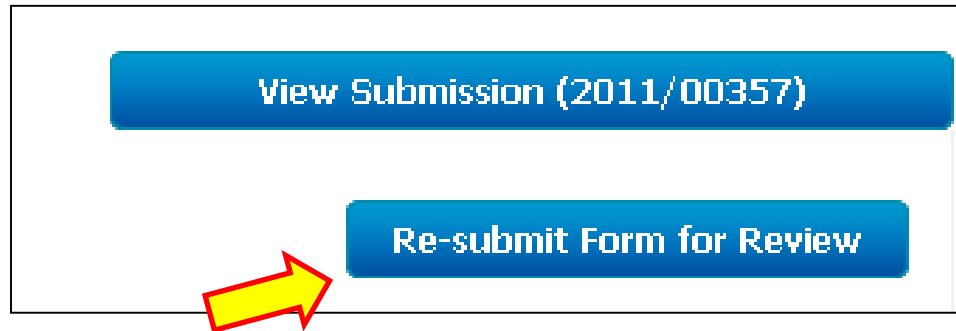
Write a comment:



# Task: Responding to Queries – Step 3

## (3) TO RE-SUBMIT THE RESPONSES / APPLICATION FORM FOR REVIEW

- To re-submit your changes and comments for review, the **Overall Principal Investigator** must click on the blue [**Re-Submit Application**] button.



- Once clicked, the system will then send back your response to the querying party. No further changes can be made.



- The DSRB / Dept Rep / Inst Rep **WILL NOT** be able to see your comments posted **UNTIL** the Overall Principal Investigator has **RE-SUBMITTED** the Form for review.
- Posting a new comment, and/or saving a change to the Form **DOES NOT** re-submit the Form for review.
- Only the current Overall Principal Investigator may re-submit the Form for Review.

# 7. Creating Supplementary Report Forms

- Study Amendment Form
- Study Status Report Form
- Other Reporting Forms



# Creating “Supp” Forms

- Supplementary Report Forms or “Supp Forms” are the additional Report Forms that you will need to use for reporting certain information and/or events to the DSRB.
- Supp Forms include:
  - **Study Amendment Form**
  - **Study Status Report Form**
  - **Non-Compliance / Study Deviation Report Form**
  - **UPIRTSO Report**
  - **Other Study Notifications**
- These Forms are only available when the Study has been approved.



The screenshot shows a web interface with a navigation menu at the top. The menu items are: Study Summary, Document Library, Amendments, Supp Form, RQA Study Review, RQA Monitoring, and RQA Self-Assessment. A yellow arrow with a red outline points to the 'Supp Form' button. Below the navigation menu, there is a section titled 'Supplementary Forms' and a field labeled 'DSRB Reference:' followed by a blurred input area.



# To create “Supp Forms”

[My Studies] → [View Study Icon] → “Study Summary” page

The screenshot shows the 'Ethics' system interface. At the top, there is a dark header with the word 'Ethics' and a dropdown arrow. Below the header, the main content area is divided into several sections. On the left, there is a section titled 'I want to create' with a dropdown menu. A yellow arrow points to the dropdown menu, which is open and shows the following options: 'New Amendment' (highlighted in blue), 'Study Status Report + Self Assessment Checklist', 'Non Compliance/Study Deviation Report', 'UPIRTSO Report', and 'Other Study Notifications'. To the right of the dropdown menu is a blue 'Create' button, with another yellow arrow pointing to it. Below the 'I want to create' section, there is a horizontal navigation bar with several tabs: 'Study Summary' (active), 'Docum Librat', 'A Monitoring', and 'RQA Self-Assessment'. Below the navigation bar, there is a 'View application' button. Below the button, there is a table with the following information:

Form Category :	Non Exempt
DSRB Domain :	-
DSRB Reference :	2011/01753
Study Title :	Performance Test: 4 Aug 2011 (Level 3, NUH, Main Building)

# 7a. Creating Study Amendments

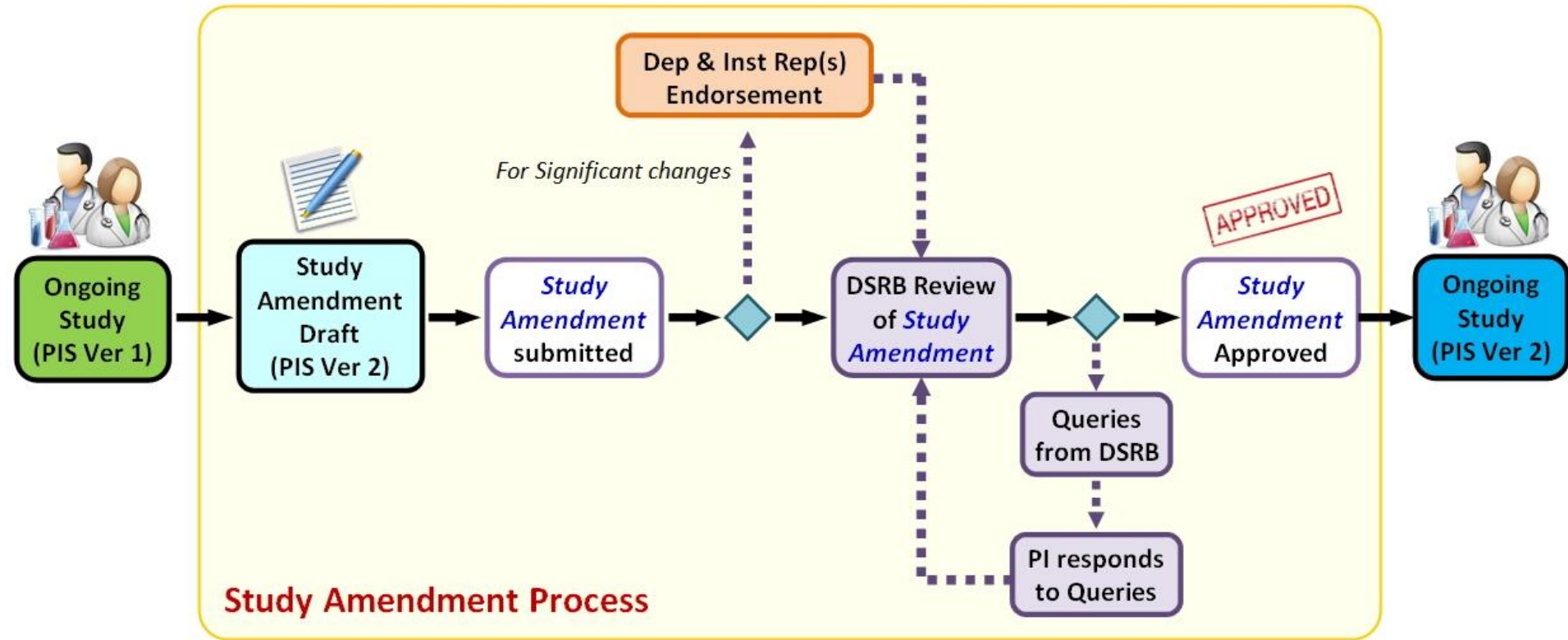




# Study Amendment Forms

- Each study can only have **ONE draft Study Amendment Form** at any time.
- There is also **no “Undo” function** when you edit the Amendment Form.
- You can only create another draft Study Amendment Form when the existing Study Amendment submission has been approved/rejected, or if the draft is deleted.
- So plan your Amendments carefully.

# Overview of Study Amendment submission



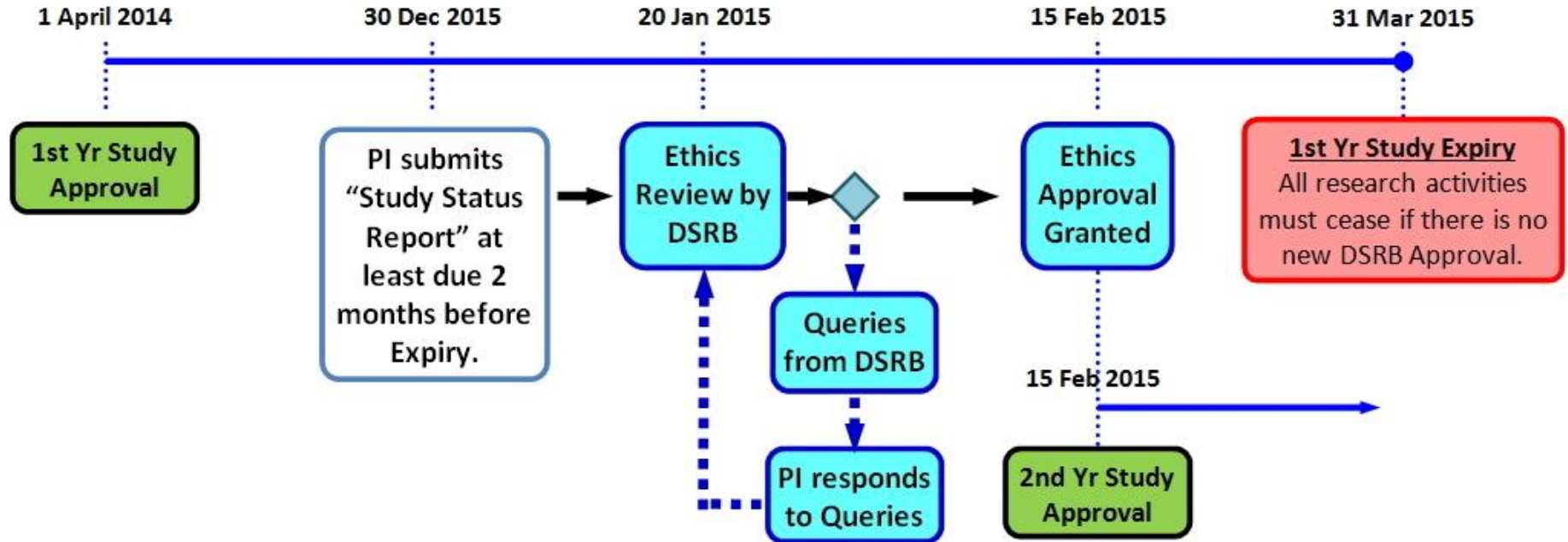
- **Amendments cannot be implemented until DSRB has given its Approval.**
- Submission Deadlines apply for Study Amendments which require Full-Board Review.
- This process is typical for all other submissions (eg: UPIRTSO, Study Deviation Report etc) to the DSRB.

# 7b. Study Status Reports

- **Renewing your Ethics Approval**
- **Closing off a Study**



# Overview of Ethics Approval Renewal

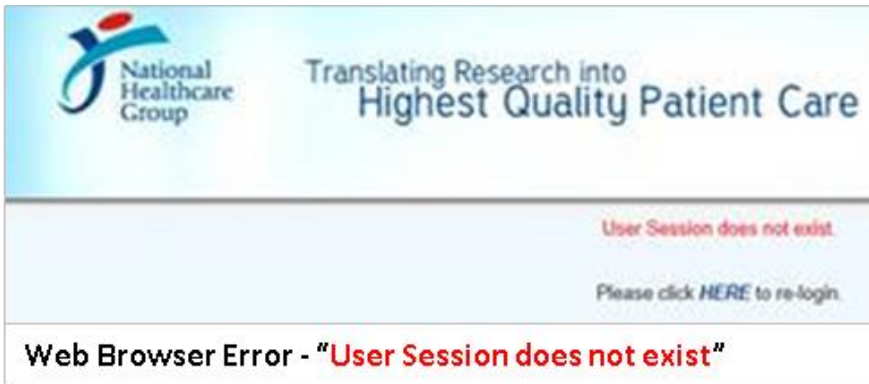


- The Study's DSRB Ethics Approval is usually for **1 calendar year**.
- The PI is required to submit a Study Status Report **at least 2 months** prior to the expiry date.
- **Only one** draft Study Status Report form is allowed at any one time.
- If a Status Report is not received and reviewed by the Expiry date, the Ethics Approval for the Study will lapse, and **ALL** research activities **must cease**.

# 8. Common Issues



# Login Problem – ‘User Session Does not Exist’



This error is caused by the default settings of the Internet Explorer Browser.

- *There is nothing wrong with your login information or your ROAM account.*
- We do recommend that you use other web browsers like **Mozilla Firefox** or **Google Chrome** when using the ROAM system.
- If you are unable to install new programs on your computer, you can consider using a **portable version of Firefox** which does not require installation and works directly from any USB thumb-drive. (Google "Portable Firefox")



# Other Issues

- **“I can’t find the ‘Submit New Study’ button.”**
- **“I can’t find my colleague to add to the Application Form.”**
- **“I accidentally deleted my draft Application Form. Can I get it back?”**
- **Related :** *“Why is the same Study listed twice (or more) on my Study List?”*
- **I’ve submitted my Application but now I need to make some more changes or add new information. What can I do?”**
- **“Our Study’s Ethics Approval is expiring BUT the original PI has left the Institution, and we can’t submit the Status Report Form!”**

# 9. Best Practices



# Best Practices

- Use either Firefox or Google Chrome to access the ROAM system.
- Use the Question Lists and prepare your Application offline in a Word document.
- Ensure that the file names of your attachments are **SHORT**.
- Ensure that the file size of each attachment is no larger than **10MB**.
- Save your work regularly.
- Read the User Guides on “how to do it”. (eg: Editing Section B)
- Use the provided document templates (eg: Consent Form).
- Check your entire Application (including your Attachments) for errors before clicking Submit.
- Prepare your submissions early.





# AVOID AT ALL COSTS

There are some things that you must never do. These can irreversibly corrupt your Application Form and cause permanent data loss to your submission.

- **DO NOT** open **Multiple Browser windows** with **Different Studies** at any time.
- **DO NOT** **edit** the same Application Form **concurrently**.
- **DO NOT** leave your computer / idle the Form for more than **5 minutes**. The website can time-out / disconnect if you take too long between **Saves or Action**. Editing text **does not** count as an **Action**.
- **DO NOT** Login **concurrently** with **different logins** on the **same computer**.
- Be careful when deleting Drafts (ie: multiple roles, multiple listings). **Once deleted, it cannot be retrieved.**
- **DO NOT** use any **special symbols** or **bullet-points** in the Forms. **Use Plain Text only.**



# Resources

New users are **STRONGLY ENCOURAGED** to read the following guides **BEFORE** attempting to draft any new applications in the ROAM system to prevent any problems/delays in their submissions.



## Guidebooks for ROAM Beginners

- NHG Investigators' Manual - All that an Investigator Needs to Know
- ROAM Researchers Guidebook
- Online DSRB Application Form Guidebook (Question List)
- Completing Section B (PI & Study Team) of the DSRB Application Form

[www.research.nhg.com.sg](http://www.research.nhg.com.sg)

[NHG Research Website](#) → [Resources](#) → [ROAM Guidebooks](#)



# Any Questions?



# Thank you for your time!

## Questions related to DSRB Ethics review and approval

- [OHRPP@nhg.com.sg](mailto:OHRPP@nhg.com.sg)
- **6471 3266** (Office hours only)

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

## Technical difficulties related to the ROAM System

- [researchonline@nhg.com.sg](mailto:researchonline@nhg.com.sg)

Please provide your **Full name** and a **brief description** of the problem together with **screen-capture** where possible. And where applicable, please provide the **Study Reference number** and **Study Title**. The more information you provide, the better we can troubleshoot and resolve the problem.

