



SingHealth Centralised Institutional Review Board (CIRB)

e-CIRB User Guidebook: Department and Institution Representative Endorsement

TABLE OF CONTENTS

1. GENERAL INFORMATION	3
1.1 System Requirements	4
1.2 Contact Us	4
2. GETTING STARTED	5
2.1 Department Representative/Institution Representative and their Role	5
2.2 Understanding the User Interface	7
2.2.1 iSHaRe Icons	7
2.2.2 Dashboard	7
2.2.3 My Tasks.....	8
2.2.4 Institution Studies	9
2.3 Endorsement Process	10
2.3.1 Department Representative Endorsement Process	11
2.3.1.1 Accessing a CIRB application	11
2.3.1.2 Endorsing a CIRB application	14
2.3.1.3 Rejecting a CIRB application	16
2.3.1.4 Query and reply the Principal Investigator	18
2.3.1.5 Re-endorsing a CIRB application	22
2.3.2 Institution Representative Endorsement Process	23
2.3.2.1 Accessing a CIRB application	23
2.3.2.2 Endorsing a CIRB application	25
2.3.2.3 Rejecting a CIRB application	28
2.3.2.4 Query and reply the Principal Investigator	30
2.3.2.5 Re-endorsing a CIRB application	33
2.4 Routing Process for Endorsement	34

1. GENERAL INFORMATION

Integrated System in Healthcare for Research (iSHaRe) is a web-based platform accessible by both internal and external users. It can be used to apply for ethics approval for research studies involving human subjects and submit forms for continuing review of the approved studies. With effective from 15 September 2014, all new CIRB applications have to be submitted via iSHaRe e-CIRB for review and approval.

For a CIRB application to reach CIRB for review, it has to be endorsed by both the Department Representative and Institution Representative after the Principal Investigator has performed his/her declaration.

This User-Guidebook is aimed to provide the information necessary for users (i.e. Department Representative and Institution Representative) to effectively use the e-CIRB module to endorse the CIRB applications. This guidebook includes a walkthrough of the basic system navigation and step-by-step procedures for the endorsement process.

1.1 System Requirements

iSHaRe can be accessed using the following internet browsers:

- Internet Explorer 9 - 11
- Google Chrome
- Mozilla Firefox

The minimal system requirement is:

- Microsoft Window 7 and above



iSHaRe does not support Window XP system and Internet Explorer 8.

1.2 Contact Us

If you have any queries, please contact irb@singhealth.com.sg.

2. GETTING STARTED

This section provides a general overview of the user interface and also step-by-step procedures to guide users in the endorsement of a CIRB application.

2.1 Department Representative/Institution Representative and their Role

Department Representative

As a Department Representative, one would need to support and endorse the study via iSHaRe e-CIRB. If the study involves multi sites, the Site-Principal Investigator's Department Representative would need to endorse the study as well. The Department Representative is to ensure that the proposed study is keeping with standards set by his/her department. Only when the endorsement by the Department Representative is completed, will the CIRB application be forwarded to the appropriate Institution Representative for review and endorsement.

In iSHaRe e-CIRB, there are 3 groups of users who can perform the DR endorsement.

1. Department Representative: The Department Representative is usually the Head of Department or equivalent of the Principal Investigator's and Site-Principle Investigator's department. Where appropriate, the Head/Director of Division who oversees several departments may endorse in lieu of the Head of Department.
2. Conflict of Interest Department Representative: When the Department Representative is involved in a study, her/she will not be allowed to endorse his/her own CIRB application. A Conflict of Interest Department Representative will need to be appointed and he/she is usually the Department Representative's reporting officer or equivalent.
3. Back-up Department Representative: When the Department Representative is on leave, the Back-up Department Representative can be appointed to endorse the pending CIRB application(s) on behalf of the Department Representative. There can be up to 3 back-ups appointed.

Institution Representative

As an Institution Representative, one would need to support and endorse the study via iSHaRe e-CIRB before the study can be submitted to CIRB for review. If the study involves multi sites, the Site-Principal Investigator's Institution Representative would need to endorse the study as well. The Institution Representative is to ensure that the proposed study is keeping with standards set by his/her Institution. Only when the endorsement by the Institution Representative is completed, will the CIRB application be forwarded to CIRB for review.

In iSHaRe e-CIRB, there are 3 groups of users who can perform the IR endorsement.

1. Institution Representative: The Institution Representative is usually the Institution's Director of Research (or equivalent) or Chairman of Medical Board. The Institution Representative is determined by each Institution and he/she is given the authority to determine if the proposed research activity is keeping with the Institution's research objectives, reputation and standards.
2. Conflict of Interest Institution Representative: When the Institution Representative is involved in a study, he/she will not be allowed to endorse his/her own CIRB application. A Conflict of Interest Institution Representative will need to be appointed and he/she is usually the Institution Representative's reporting officer or equivalent.
3. Back-up Institution Representative: When the Institution Representative is on leave, the Back-up Institution Representative can be appointed to endorse the pending CIRB application(s) on behalf of the Institution Representative. There can be up to 3 back-ups appointed.



The Conflict of Interest Department Representative and/or Institution Representative will have to be selected from the endorser list. See: [User-Guidebook \(New Application\)](#) on how to add the Conflict of Interest Department Representative and/or Institution Representative. If there is no Conflict of Interest Department Representative and/or Institution Representative to select, please contact CIRB.



CIRB application pending endorsement will be routed to the Back-up Department Representative and/or Institution Representative or the next back-up in line if not endorsed. See: [2.4 Routing Process for Endorsement](#) on how a CIRB application will be routed.



The list of Department Representatives and Institution Representatives are provided to CIRB by the Research Development Office of each institution. If there is any change to the appointments, please contact CIRB for re-assignment of Department Representative and/or Institution Representative. Please ensure that the Department Representative and/or Institution Representative have/has an iSHaRe account and provide the following information for the assignment.

- a. Name
- b. Institution
- c. Department
- d. Designation
- e. Email Address
- g. Name of the institution and/or department to perform endorsement for

2.2 Understanding the User Interface

Understanding the user interface will allow users to navigate through iSHaRe effortlessly.

2.2.1 iSHaRe Icons

The following are the icons users commonly encounter when endorsing a CIRB application and their respective functions.



General Comment



View Endorsers and
Endorsement Status



Print



DR Endorsement



IR Endorsement

2.2.2 Dashboard

The “Dashboard” is the navigation hub of iSHaRe.

As shown in the image below is the “Dashboard” page if a user is both a Department Representative and Institution Representative. Different group of users may have a different view upon log-in. The access right is determined by one’s role in iSHaRe e-CIRB. An appointed Department Representative and Institution Representative will only have the “DR Endorsement” and “IR Endorsement” tile respectively on their “Dashboard” page.

The screenshot shows the iSHaRe dashboard interface. At the top, there is a navigation bar with tabs: Dashboard, My Tasks, Notifications, Study Listing, Form Listing, Institution Studies (highlighted with a red box), Resources, and News. Below the navigation bar, the dashboard content is organized into sections. On the left, there is a 'Forms Creation' section with links for CIRB and IACUC. In the center, there is a 'Notifications' section showing 3586 / 3588 notifications and a 'My Tasks' section with three tiles: 'My Study Tasks' (0), 'DR Endorsement' (0), and 'IR Endorsement' (8). The 'DR Endorsement' and 'IR Endorsement' tiles are highlighted with red boxes. On the right, there is a 'News' section with a 'See All' link and a list of news items, including one dated 12-Jun-2016 about CIRB forms.



“Institution Studies” tab is available for both the Department Representative and Institution Representative. Though a common feature, there are differences too. The details will be explained in a later section. See: [2.2.4 Institution Studies](#).

2.2.3 My Tasks

The “My Tasks” page is where users can view the items that are pending their action.

As shown in the image below, users can access the “My Tasks” page by clicking on the “DR Endorsement” or “IR Endorsement” tile. The figure in the tile provides an overview and reflects the number of pending task(s) to be done.

The screenshot shows the iSHaRe dashboard. The user is logged in as 'Mr Department Representative & Institution Representative'. The 'My Tasks' section is highlighted, showing three task categories: 'My Study Tasks' (0), 'DR Endorsement' (0), and 'IR Endorsement' (8). A notification banner indicates 3586 unread notifications. A news item dated 12-Jun-2016 is also visible.

While in the “My Tasks” page, users can click on the various tabs to navigate to the different sections to view their pending task(s). Clicking on the blue hyperlink text will bring users to the “Study Workspace” page where they can perform their task(s).

The screenshot shows the 'My Tasks' page with a table of pending tasks. The table has columns for S/No., Notification Date, Task Required, Form Type, iSHaRe Ref. No., CIRB Ref No., Protocol Title, Protocol No., and PI Name. A red box highlights the 'Task Required' column, and red arrows point to the 'iSHaRe Ref. No.' and 'Protocol Title' columns.

S/No.	Notification Date	Task Required	Form Type	iSHaRe Ref. No.	CIRB Ref No.	Protocol Title	Protocol No.	PI Name
1	12-Dec-2016 17:16:52	Pending Endorsement	CIRB Exemption Application Form	201612-00027	-	Testing Application (12/12/2012)	-	Dr Principal Investigator

The screenshot shows the 'My Tasks' page with a table of pending tasks. The table has columns for S/No., Notification Date, Task Required, Form Type, iSHaRe Ref. No., CIRB Ref No., Protocol Title, Protocol No., and PI Name. A red box highlights the 'Task Required' column, and red arrows point to the 'iSHaRe Ref. No.' and 'Protocol Title' columns.

S/No.	Notification Date	Task Required	Form Type	iSHaRe Ref. No.	CIRB Ref No.	Protocol Title	Protocol No.	PI Name
1	12-Dec-2016 17:16:52	Pending Endorsement	CIRB Exemption Application Form	201612-00027	-	Testing Application (12/12/2012)	-	Dr Principal Investigator

⚠ Once a task is completed, it will be removed from the “My Tasks” page. To access the study, users can do so via the hyperlink in the system and email notification or search for the study in the “Institution Studies” page.

2.2.4 Institution Studies

The “Institution Studies” page is where users can view all the CIRB applications belonging to his/her department(s) or within his/her institution. This access is determined as according to one’s assigned role in iSHaRe e-CIRB. As a Department Representative, the user will be able to see all the CIRB applications within his/her department(s). Whereas, as an Institution Representative, the user will be able to see all the CIRB applications that are within his/her institution.

The studies in this listing includes any studies as long as it is conducted in the institution i.e. when there is a Principal Investigator/ Site-Principal Investigator from the institution or when the institution is used as a study site.

The page is segmented into study and form level. Users can click on either the “CIRB Studies” or “CIRB Forms” tabs to get to the different listings.

“CIRB Studies” Listing

This listing provides the high level study details. Users can click on the blue hyperlink text which will direct them to the “Study Workspace” page. Clicking on the “Forms” hyperlink will direct one to the “CIRB Forms” listing page filtered to the form(s) from the particular study.

The screenshot displays the iSHaRe e-CIRB interface. At the top, there is a navigation bar with tabs for Dashboard, My Tasks, Notifications, Study Listing, Form Listing, Institution Studies (selected), Resources, and News. Below the navigation bar, there are tabs for CIRB Studies (selected) and CIRB Forms. The main content area contains search filters for iSHaRe Ref. No., CIRB Ref. No., and Protocol Title. There are also checkboxes for Study Status (All, Draft, Pending CIRB Review, Approved, Not Approved, Review Not Required, Completed, Terminated, Withdrawn, Terminated (Expired), Expired). The Institution filter is set to Singapore General Hospital (SGH). Below the filters are Search and Reset buttons. A table shows a total of 1505 records. The table has columns for S.No., iSHaRe Ref. No., CIRB Ref. No., Protocol Title, Protocol No., PI Name, Study Role, Study Status, Initial Outcome Date, Valid Till Date, and Link. Two records are shown, both with 'Forms' links highlighted in red boxes. Red arrows point to the 'CIRB Ref. No.' and 'Protocol Title' columns.

S.No.	iSHaRe Ref. No.	CIRB Ref. No.	Protocol Title	Protocol No.	PI Name	Study Role	Study Status	Initial Outcome Date	Valid Till Date	Link
1	201612-00027		Testing Application (12/12/2012)		Dr Principal Investigator	PI	Draft			Forms
2	201612-00026		Testing Application (11/12/2012)		Mr Department Representative & Institution Representative	PI	Draft			Forms

“CIRB Forms” Listing

This listing provides greater details on the individual form(s) belonging to a study. Form details (e.g. form type/ form status) are shown. Users can click on the blue hyperlink text which will direct them to the form.

ISHaRe
Welcome, Mr Department Representative & Institution Representative
Logged in time 13-Dec-2016 10:44

Dashboard My Tasks Notifications Study Listing Form Listing Institution Studies Resources News

CIRB Studies CIRB Forms

iSHaRe Ref. No.: CIRB Ref No.: Protocol Title:

Form Status: All Form Type: All PI Name:

Institution: Singapore General Hospital (SGH) Submission Date: To

Department: All Outcome Date: To

Search Reset

Total records: 3043

S.No.	iSHaRe Ref. No.	CIRB Ref. No.	Form Type	Protocol Title	PI Name	Study Role	Form Status	Submission Date	Outcome Date
1	201612-00027		CIRB Exemption Application Form	Testing Application (12/12/2012)	Dr Principal Investigator	PI	Pending Endorsement		
2	201612-00026		CIRB Exemption Application Form	Testing Application (11/12/2012)	Mr Department Representative & Institution Representative	PI	Pending Endorsement		



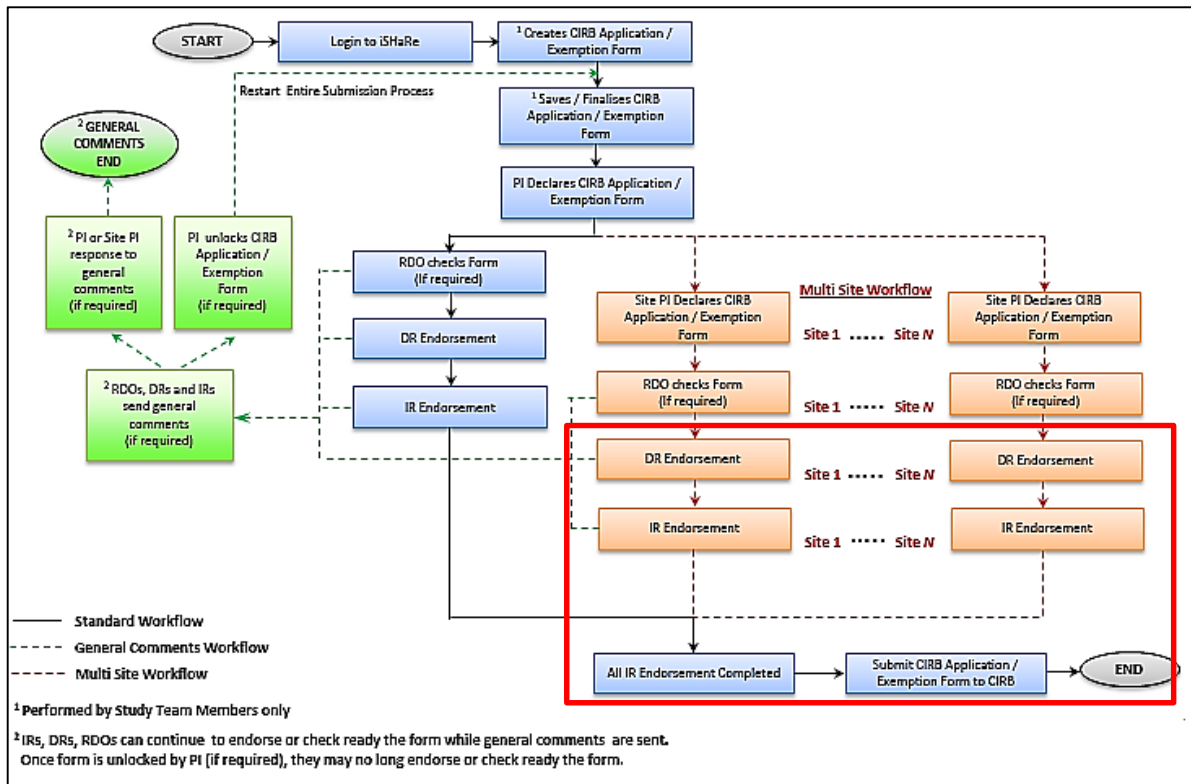
If a user is an Institution Representative of various institutions, he/she may use the drop-down list to select the institution and filter the studies to be displayed. Unless it is as aforementioned, the user will only be granted access to the studies in which he/she is assigned as the Institution Representative. By default, the institution will be that of his/her institution.

2.3 Endorsement Process

This section provides a detailed description of the endorsement process on iSHaRe. In general, there can be 4 different actions:

1. Endorse the application
2. Reject the application
3. Query the Principal Investigator regarding the application
4. Re-endorse the application

The flowchart below shows the general flow of a typical submission process. For a CIRB application to reach CIRB, it has to be supported and endorsed by all respective Department Representative(s) and Institution Representative(s) where the study is being conducted. The endorsement process for a multi-site study will run parallel (i.e. the different sites can endorse concurrently). Only after the entire endorsement process is completed will the CIRB application be submitted to CIRB for review.



2.3.1 Department Representative Endorsement Process

It is the responsibility of the Department Representative to ensure that the proposed study is in keeping with the set standards.

2.3.1.1 Accessing a CIRB application

The Department Representative will be informed of his/her pending endorsement via email and system notification. He/she then will be able to access the study through the hyperlink in the email notification, the hyperlink in the system notification or their pending task in the “My Tasks” page.

1. Once the Principal Investigator has finalised the CIRB application and declared, or if applicable, after the Site-Principal Investigator has declared or the Research Development Office has checked the application, the Department Representative will be informed that there is an application ready for endorsement. The various routes to access the study are as follow.

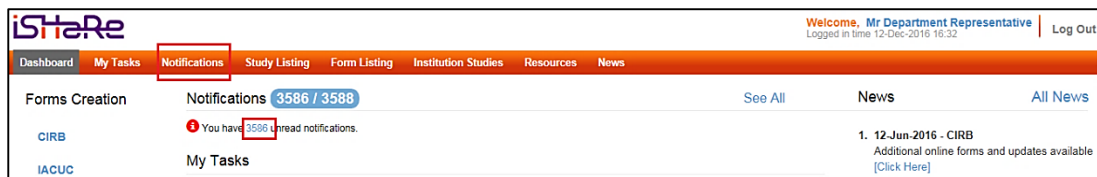
a. Accessing the study via the email notification

As shown in the image below is an example of how the email notification will look like. By clicking on the blue hyperlink text, the Department Representative will be directed to the iSHaRe log-in page. Upon logging in, he/she will be brought straight to the “Study Workspace” page.

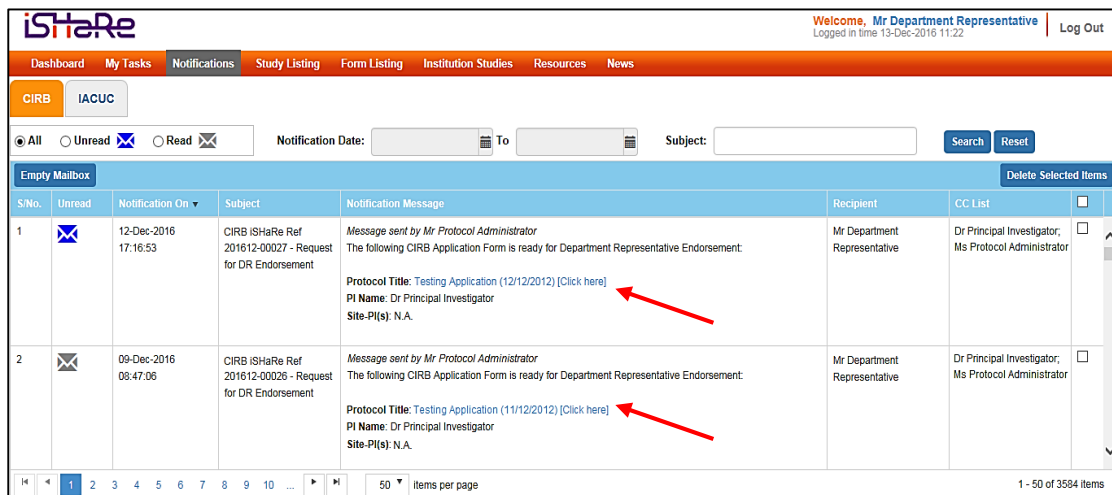


b. Accessing the study via the system notification

Upon logging into iSHaRe, click on “Notifications” on the orange menu bar or the numbers hyperlink to access the notifications page.



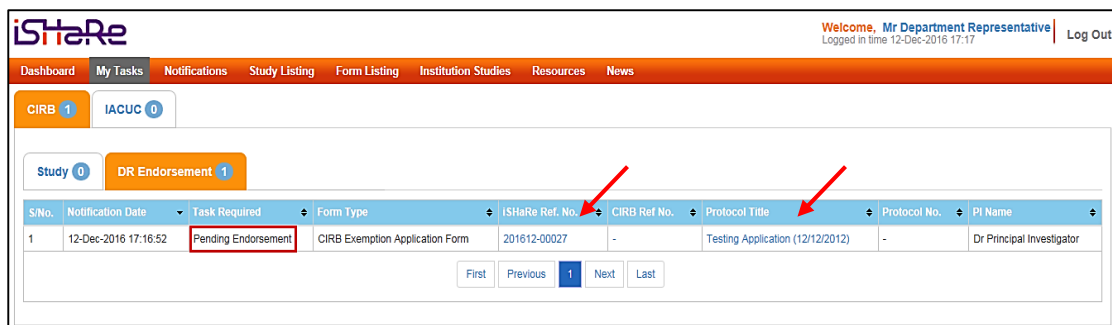
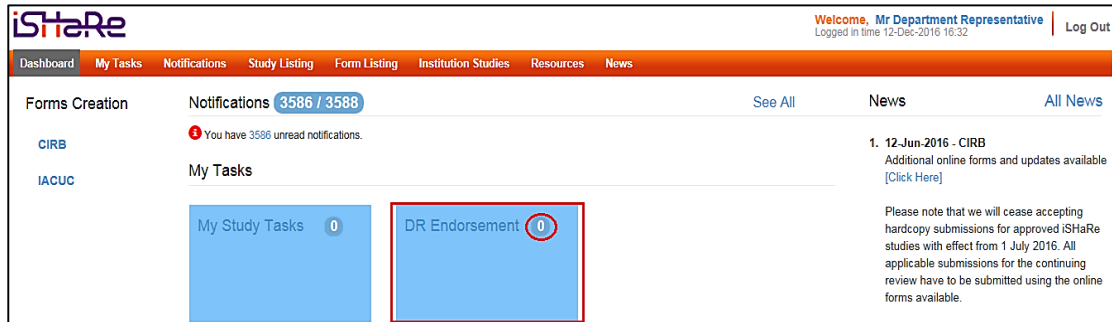
As shown in the image below is an example of how the system notification will look like. By clicking on the blue hyperlink text, the Department Representative will be directed to the “Study Workspace” page.



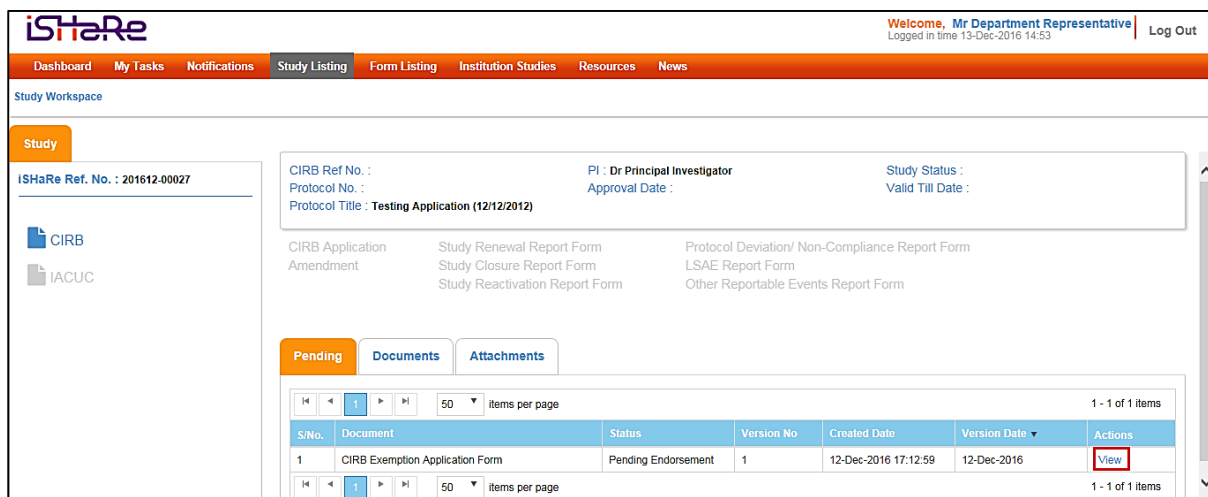
The subject header (“Request for DR Endorsement”) and content received by the Department Representative and Conflict of Interest Department Representative is the same. Notifications to the Back-up Department Representative can be differentiated by the subject header (“Acting DR Endorsement is required”) even though the content is similar. This is applicable to both email and system notification received.

c. Accessing the study via “My Tasks” page

The images below demonstrate how the Department Representative can access the study from the “My Task” page. Upon logging into iSHaRe, the figure next to the “DR Endorsement” tile indicates the number of pending task(s). By clicking the “DR Endorsement” tile, the Department Representative will then be directed to the “My Tasks” page where he/she can see the pending task(s). Clicking on the blue hyperlink text will navigate him/her to the “Study Workspace” page.



2. The “Study Workspace” page is where the Department Representative can perform his/her pending task. To start reviewing the CIRB application, click on “View”.




2.3.1.2 Endorsing a CIRB application

By endorsing the CIRB application, the Department Representative has agreed to support the conduct of the study and confirmed that it is in keeping with the standards set by the department.

1. To start reviewing the CIRB application, click on the links on the left hand panel to navigate to the relevant sections.

The screenshot shows the iStare web application interface. At the top, there is a navigation bar with 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The user is logged in as 'Mr Department Representative'. The main content area is titled 'Section A: Protocol Title & Protocol Administrators'. It contains a note about CIRB comments and a form with two main sections: 'A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study' and 'A2. You may assign Protocol Administrators for this study below'. The 'A1' section has input fields for 'Protocol Title' (containing 'Testing Application (12/12/2012)') and 'Protocol Number'. The 'A2' section has an 'Add Protocol Administrator' button. A sidebar on the left lists various sections, with 'Section A: Protocol Title & Protocol Administrators' highlighted.


2. After reviewing the CIRB application, click on the DR Endorsement icon () at the top of the page, just below the navigation bar.

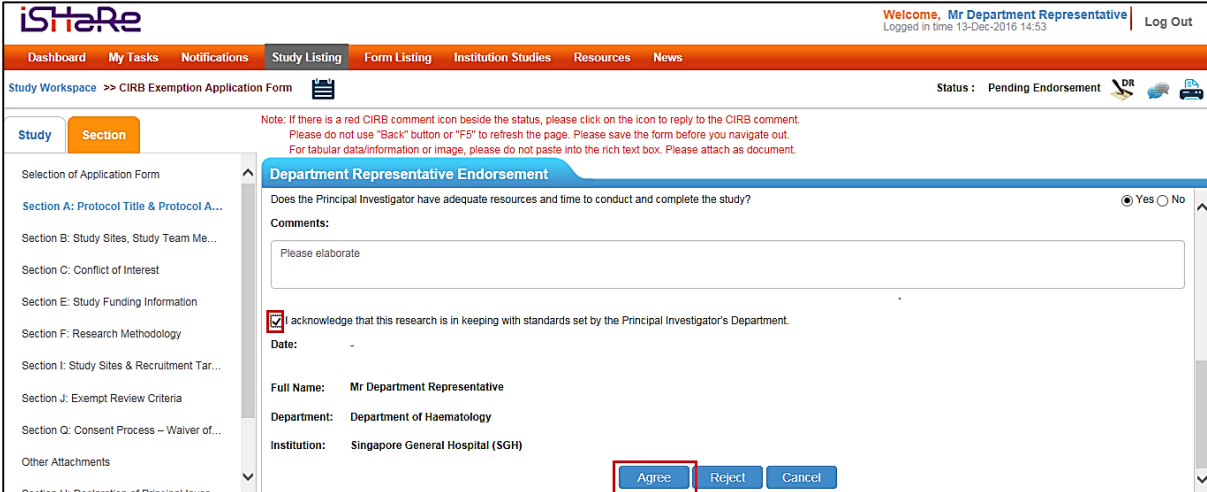
This screenshot is identical to the previous one, showing the 'Section A: Protocol Title & Protocol Administrators' form. The status is 'Pending Endorsement'. The form includes fields for Protocol Title and Protocol Number. The 'A1' section has input fields for 'Protocol Title' (containing 'Testing Application (12/12/2012)') and 'Protocol Number'. The 'A2' section has an 'Add Protocol Administrator' button. A sidebar on the left lists various sections, with 'Section A: Protocol Title & Protocol Administrators' highlighted.

3. The “Department Representative Endorsement” page will appear for endorsement. The Department Representative can proceed to complete the assessment checklist.

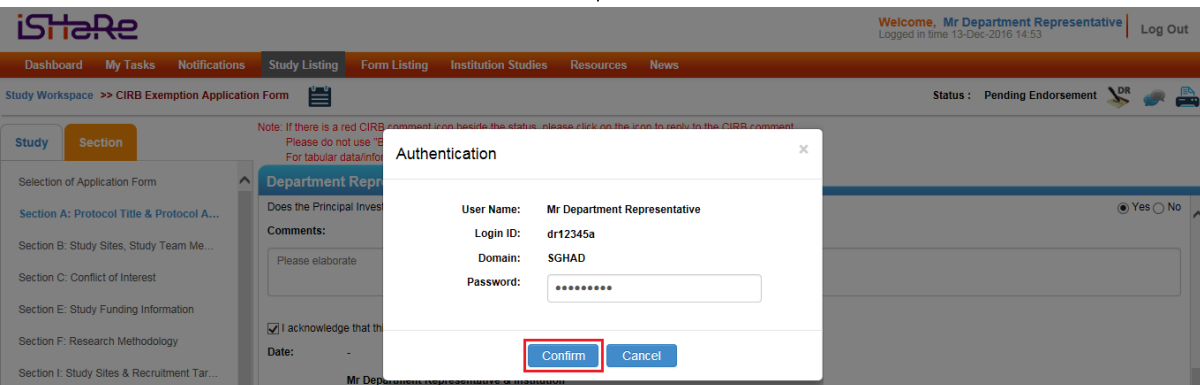
The screenshot shows the 'Department Representative Endorsement' page in the iStare application. The status is 'Pending Endorsement'. The page includes a checklist for the Department Representative to complete. The checklist has three sections: '1. Significance', '2. Approach', and '3. Innovation'. Each section has a question and a 'Yes' or 'No' radio button. The 'Yes' radio buttons are highlighted with a red box. The questions are: 'Does the study address an important problem? Will the study affect concepts and methods that drive the field?', 'Is the conceptual framework adequately developed? Are the design, methods and analyses adequately developed and appropriate?', and 'Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods?'. A sidebar on the left lists various sections, with 'Section A: Protocol Title & Protocol Administrators' highlighted.

4. After completing the checklist, the Department Representative can select the endorsement option i.e. “Agree” or “Reject”. To endorse an application, he/she will need to check the checkbox and click on “Agree”.

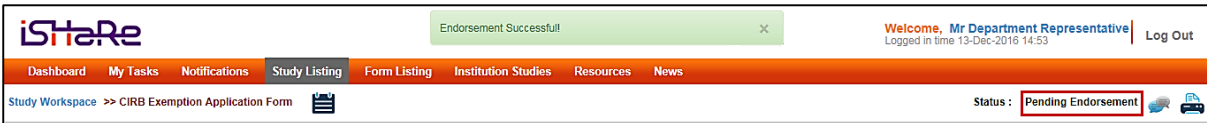
 The “Agree” link will only be available after the checkbox has been checked.



The screenshot shows the iSiteRe interface for a CIRB Exemption Application Form. The user is logged in as Mr. Department Representative. The status is 'Pending Endorsement'. The 'Department Representative Endorsement' section is active, with a question: 'Does the Principal Investigator have adequate resources and time to conduct and complete the study?'. Below this is a 'Comments' field with the placeholder text 'Please elaborate'. A checkbox is checked, indicating acknowledgment of standards. The user's full name, department (Department of Haematology), and institution (Singapore General Hospital (SGH)) are displayed. At the bottom, the 'Agree', 'Reject', and 'Cancel' buttons are visible, with 'Agree' highlighted by a red box.



This screenshot shows the same application form as above, but with an 'Authentication' dialog box overlaid. The dialog box contains the following information: User Name: Mr Department Representative, Login ID: dr12345a, Domain: SGHAD, and a Password field. At the bottom of the dialog, the 'Confirm' and 'Cancel' buttons are visible, with 'Confirm' highlighted by a red box.



The final screenshot shows the application form after the endorsement process. A green success message 'Endorsement Successful!' is displayed at the top. The status is now 'Pending Endorsement', which is highlighted with a red box. The 'Agree' button from the previous step is no longer visible.

- The CIRB application will now be ready for Institution Representative's endorsement. To verify if the application has been successfully endorsed or to check the endorsement status, click on the endorser icon (📄) at the top of the page, just below the navigation bar.



After endorsing a CIRB application, a system and email notification will be sent to the Institution Representative and relevant personnel – Protocol Administrator, Research Development Office and Principal Investigator – if applicable, to notify him/her of the pending task.

The screenshot shows the 'iSiteRe' application interface. The user is logged in as 'Mr Department Representative'. The page title is 'CIRB Exemption Application Form'. The status is 'Pending Endorsement'. A table lists the endorser details:

Stage	Name	Role	Endorsement Status	Date	Action
RDO	Ms Protocol Administrator	RDO	Checked	12-Dec-2016	
Department	Mr Department Representative	DR	Endorsed	13-Dec-2016	
Institution	Mr Institution Representative	IR	Pending	-	

Endorsement Status : Pending IR Endorsement

2.3.1.3 Rejecting a CIRB application

By rejecting the CIRB application, the Department Representative does not agree to support the conduct of the study and/or confirmed that it is not keeping with the standards set by the department.

- To start reviewing the CIRB application, click on the tabs on the left hand panel to navigate to the relevant sections.

The screenshot shows the 'iSiteRe' application interface. The user is logged in as 'Mr Department Representative'. The page title is 'CIRB Exemption Application Form'. The status is 'Pending Endorsement'. The left-hand panel shows the navigation menu with 'Section A: Protocol Title & Protocol Administrators' selected. The main content area displays the form for Section A:

Section A : Protocol Title & Protocol Administrators


A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study

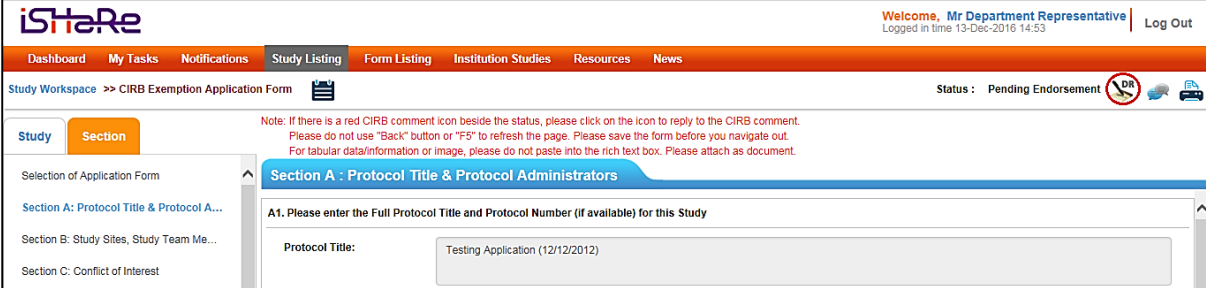
Protocol Title:

Protocol Number:

A2. You may assign Protocol Administrators for this study below ⓘ

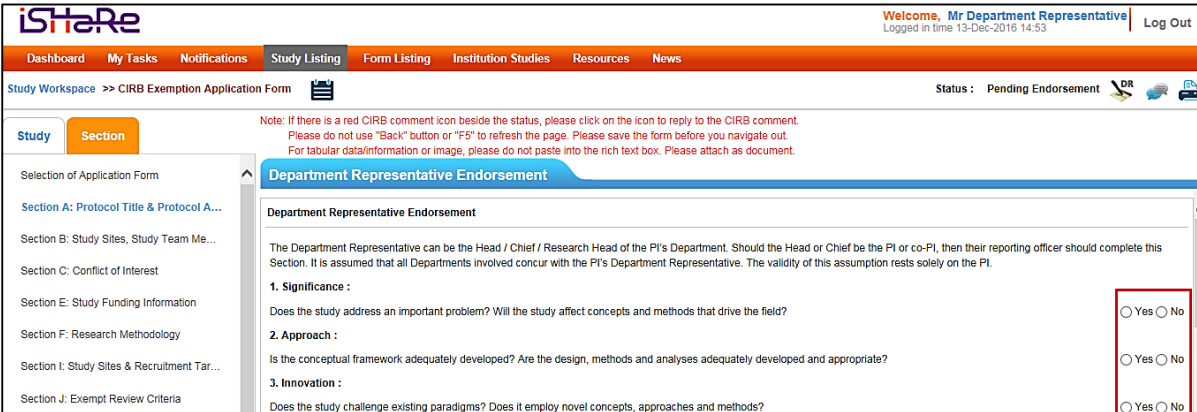
[Add Protocol Administrator](#)

- After reviewing the CIRB application, click on the DR Endorsement icon () at the top of the page, just below the navigation bar.



The screenshot shows the iStare web application interface. The user is logged in as 'Mr Department Representative'. The navigation bar includes 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The current page is 'Section A: Protocol Title & Protocol Administrators'. A note at the top states: 'Note: If there is a red CIRB comment icon beside the status, please click on the icon to reply to the CIRB comment. Please do not use "Back" button or "F5" to refresh the page. Please save the form before you navigate out. For tabular data/information or image, please do not paste into the rich text box. Please attach as document.' The form contains a field for 'Protocol Title' with the value 'Testing Application (12/12/2012)'. A red DR icon is visible in the top right corner.

- The "Department Representative Endorsement" page will appear for endorsement. The Department Representative can proceed to complete the assessment checklist.

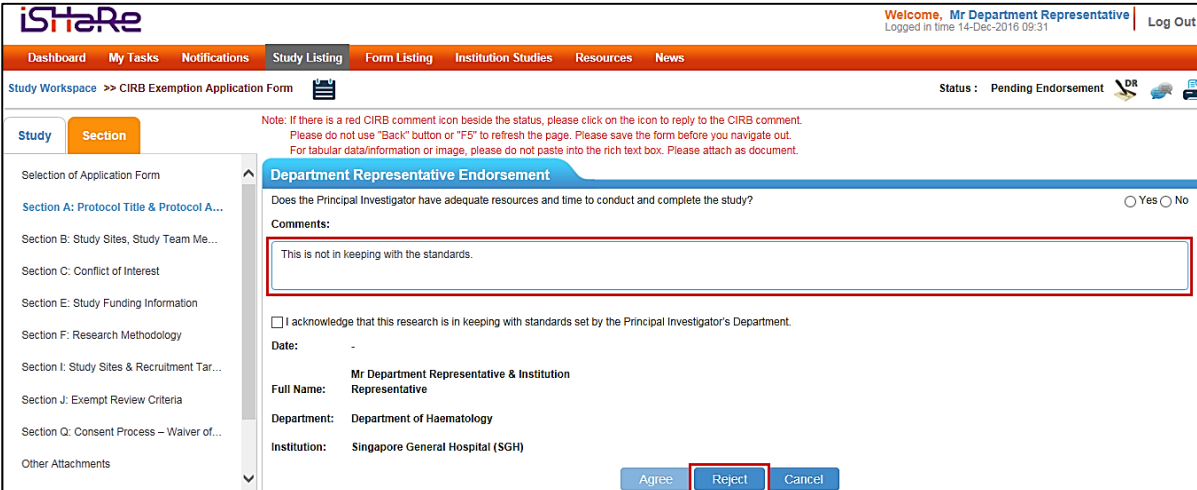


The screenshot shows the 'Department Representative Endorsement' page. The status is 'Pending Endorsement'. The assessment checklist includes the following questions:

- 1. Significance :** Does the study address an important problem? Will the study affect concepts and methods that drive the field? Yes No
- 2. Approach :** Is the conceptual framework adequately developed? Are the design, methods and analyses adequately developed and appropriate? Yes No
- 3. Innovation :** Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods? Yes No

The 'No' radio buttons for all three questions are highlighted with a red box.

- After completing the checklist, the Department Representative can select the endorsement option i.e. "Agree" or "Reject". To reject an application, he/she will need to enter the reason(s) in the comment box and click on "Reject".

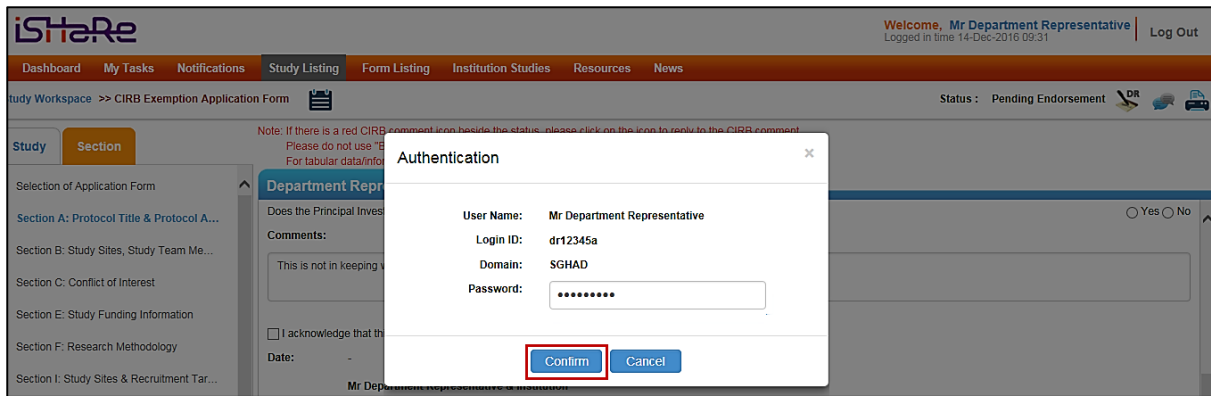



The screenshot shows the 'Department Representative Endorsement' page. The status is 'Pending Endorsement'. The assessment checklist includes the following question:

- Does the Principal Investigator have adequate resources and time to conduct and complete the study? Yes No


The 'Comments' field contains the text: 'This is not in keeping with the standards.' The 'Reject' button is highlighted with a red box.



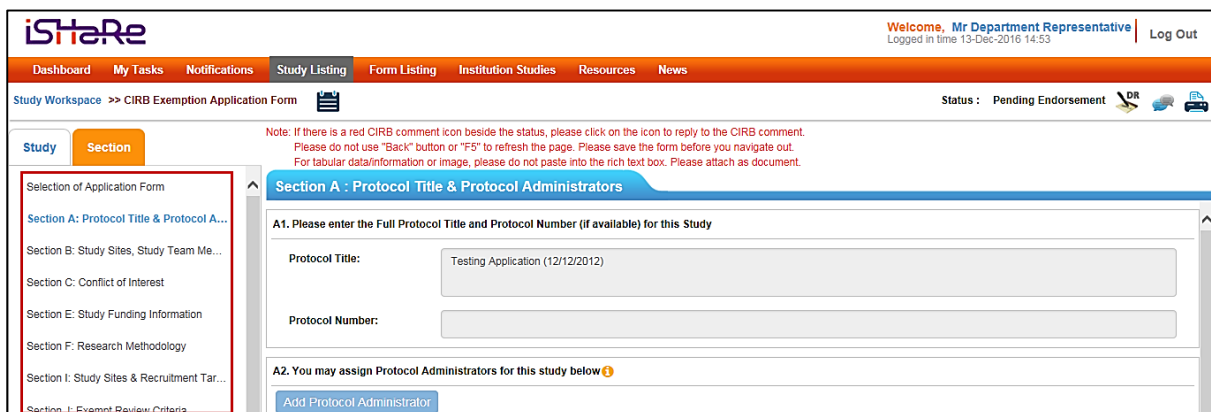



 By rejecting a CIRB application, a system and email notification will be sent to the Principal Investigator and relevant personnel – Protocol Administrator, Research Development Office and Site-Principal Investigator – if applicable. The Principal Investigator will need to review the comment(s) entered and unlock the application form to make changes. This reverts the form back to draft mode, which upon finalisation triggers the entire endorsement process again. See: [2.3.1.5 Re-endorsing a CIRB Application](#).

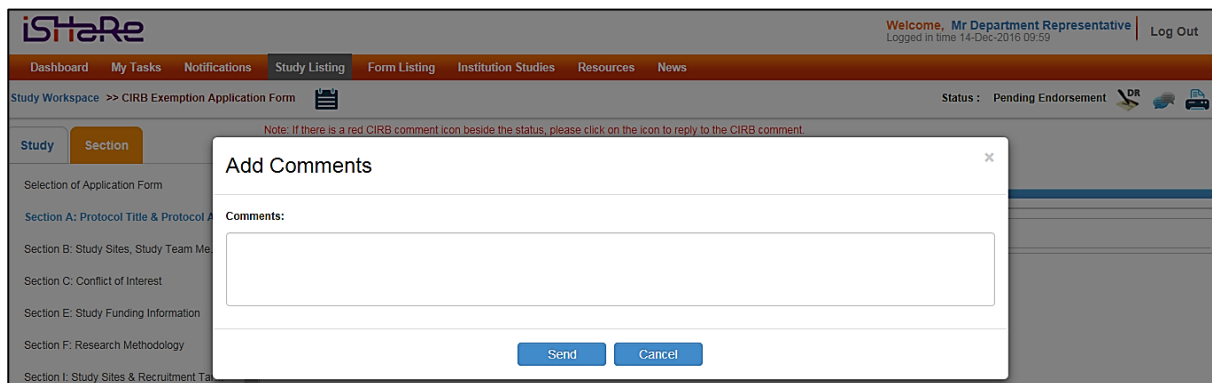
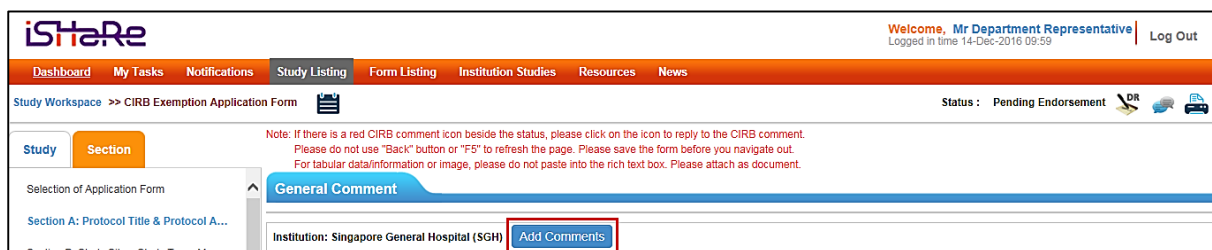
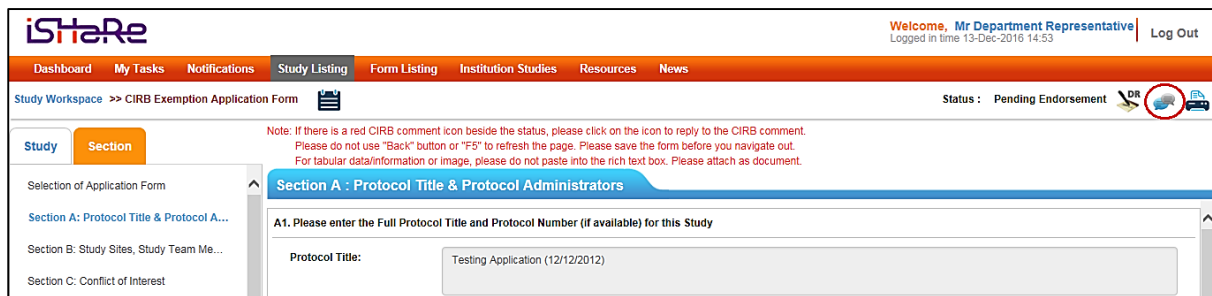
2.3.1.4 Query and reply the Principal Investigator



The query function is available via the general comment icon (). This option provides the opportunity for the Department Representative to obtain clarification from the Principal Investigator or request for certain changes to be made to the CIRB application.

1. To start reviewing the CIRB application, click on the tabs on the left hand panel to navigate to the relevant sections.




2. After reviewing the CIRB application, the Department Representative can raise a query by clicking on the general comment icon () at the top of the page, just below the navigation bar.



-  Multiple comments can be sent to query the Principal Investigator.
-  Additional comment will not be allowed after the Department Representative has endorsed.

3. When a comment is sent, a system and email notification will be sent to the Principal Investigator and relevant personnel – Site-Principal Investigator and Protocol Administrator – if applicable.

-  The comment(s) raised is site specific. For a multi-site study, only the Principal Investigator belonging to the same institution as the Department Representative who raised the query, will be able to see and reply to the comment(s).

- After the Principal Investigator has responded to the comment(s), the Department Representative and relevant personnel – Protocol Administrator – if applicable, will be notified via a system and email notification. An example of how the notifications will look like is as shown in the image below.

Email notification

Dear Mr Department Representative,

You have received a reply to your query on the following CIRB Application:

Protocol Title: [Application \(24/03/2015\) \[Click here\]](#)
PI Name: Mr Principal Investigator
Site-PI(s): N.A.

This is a system generated notification. Please do not reply to this email.


Should you have any enquiries, please contact irb@singhealth.com.sg.

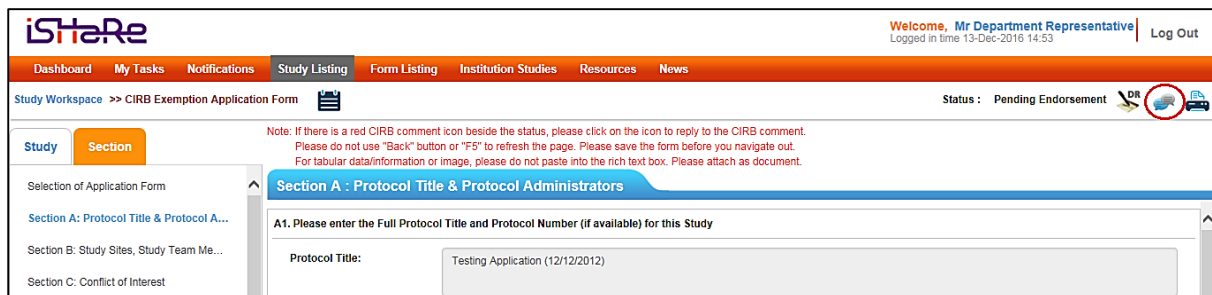
System notification

S/No.	Unread	Notification On	Subject	Notification Message	Recipient	CC List	
1		12-Dec-2016 17:16:53	CIRB iShaRe Ref 201612-00027 - Reply to DR query	<p><i>Message sent by Dr Principal Investigator</i></p> <p>You have received a reply to your query on the following CIRB Application:</p> <p>Protocol Title: Testing Application (12/12/2012) [Click here] PI Name: Dr Principal Investigator Site-PI(s): N.A.</p>	Mr Department Representative	Ms Protocol Administrator	<input type="checkbox"/>
2		09-Dec-2016 08:47:06	CIRB iShaRe Ref 201612-00027 - Request for DR Endorsement	<p><i>Message sent by Mr Protocol Administrator</i></p> <p>The following CIRB Application Form is ready for Department Representative Endorsement:</p> <p>Protocol Title: Testing Application (12/12/2012) [Click here] PI Name: Dr Principal Investigator Site-PI(s): N.A.</p>	Mr Department Representative	Dr Principal Investigator; Ms Protocol Administrator	<input type="checkbox"/>

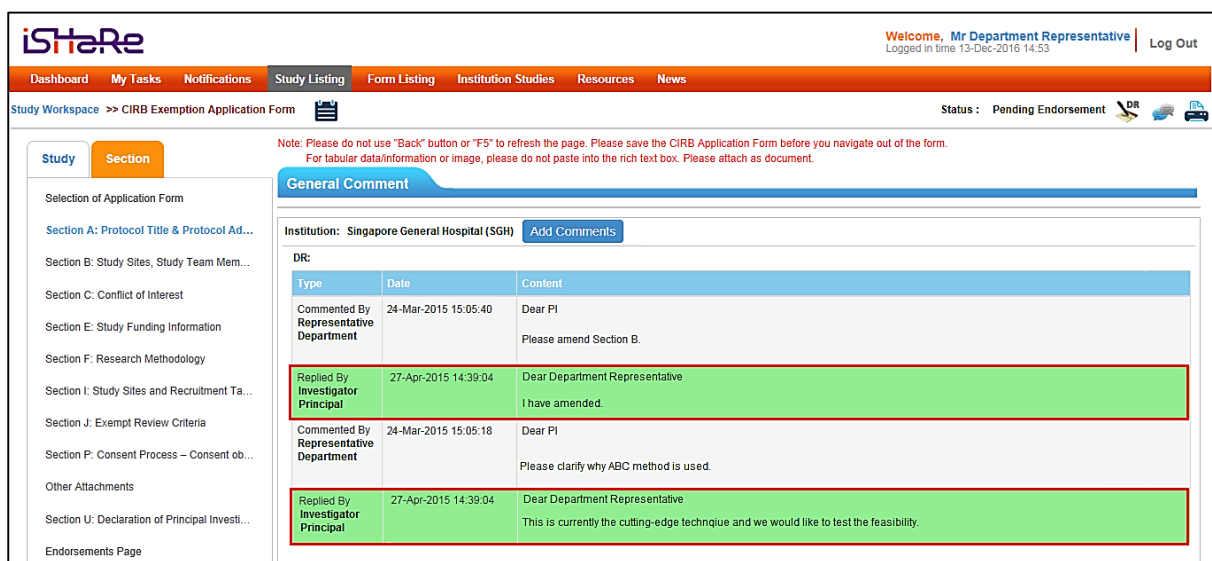


When there is a response from the Principal Investigator, this will not be reflected to the Department Representative as a new endorsement task.

5. The Department Representative may access the CIRB application as depicted in Section 2.3.1.1. He/she can view the reply by clicking on the general comment icon () at the top of the page, just below the navigation bar.



The screenshot shows the iStare application interface. At the top, it says 'Welcome, Mr Department Representative' and 'Logged in time 13-Dec-2016 14:53'. The navigation bar includes 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The main content area is titled 'Section A : Protocol Title & Protocol Administrators'. Below this, there is a note: 'Note: If there is a red CIRB comment icon beside the status, please click on the icon to reply to the CIRB comment. Please do not use "Back" button or "F5" to refresh the page. Please save the form before you navigate out. For tabular data/information or image, please do not paste into the rich text box. Please attach as document.' The main form field is 'A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study'. The 'Protocol Title' field contains the text 'Testing Application (12/12/2012)'. On the right side, there is a status indicator 'Status : Pending Endorsement' and a red comment icon.

The screenshot shows the 'General Comment' section of the iStare application. At the top, it says 'Welcome, Mr Department Representative' and 'Logged in time 13-Dec-2016 14:53'. The navigation bar is the same as in the previous screenshot. The main content area is titled 'General Comment'. Below this, there is a note: 'Note: Please do not use "Back" button or "F5" to refresh the page. Please save the CIRB Application Form before you navigate out of the form. For tabular data/information or image, please do not paste into the rich text box. Please attach as document.' The main content area shows a table of comments and replies. The table has columns for 'Type', 'Date', and 'Content'. The table is titled 'Institution: Singapore General Hospital (SGH)'. There is an 'Add Comments' button. The table contains the following data:

Type	Date	Content
Commented By Representative Department	24-Mar-2015 15:05:40	Dear PI Please amend Section B.
Replied By Investigator Principal	27-Apr-2015 14:39:04	Dear Department Representative I have amended.
Commented By Representative Department	24-Mar-2015 15:05:18	Dear PI Please clarify why ABC method is used.
Replied By Investigator Principal	27-Apr-2015 14:39:04	Dear Department Representative This is currently the cutting-edge technique and we would like to test the feasibility.

6. After reviewing the comments, the Department Representative may choose to further query the Principal Investigator, endorse the application or reject the application.

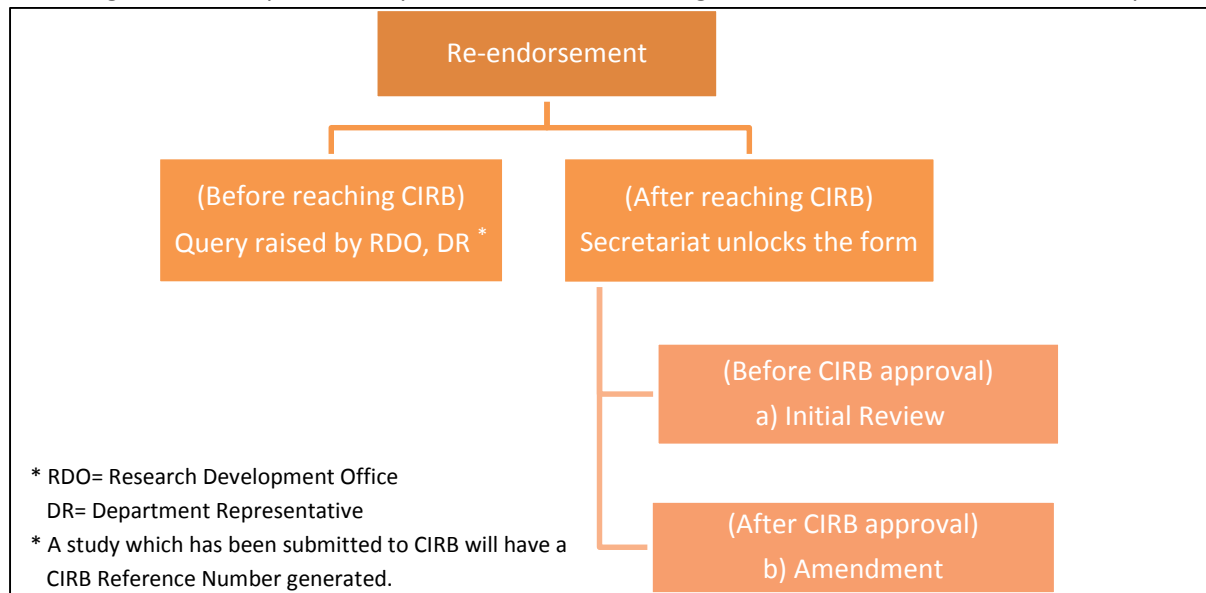


If the Principal Investigator feels that it necessary to make amend certain section of the CIRB application form, he/she may unlock the application form to make the changes. This action reverts the form back to draft mode, which upon finalisation triggers the entire endorsement process again. As such, the Department Representative will receive notification to re-endorse the study. See: [2.3.1.5 Re-endorsing a CIRB Application](#).

2.3.1.5 Re-endorsing a CIRB application

Re-endorsement implies that the endorsement process has been triggered again after a prior endorsement. The Department Representative will therefore need to endorse the study again.

The image below is a pictorial depiction of the various stages where re-endorsement can take place.



There can be various scenarios which may result in a re-endorsement after the CIRB application has reached CIRB. They are detailed in the table below. These scenarios for re-endorsement are applicable to an amendment form too.

Scenario	Re-endorsement required?
Addition of study sites	Yes
Change of PI/ Site-PI	Yes
Significant changes to study protocol	Yes
Change in form type (CIRB Application Form ↔ CIRB Exemption Application Form)	Yes

The steps to completing a re-endorsement are similar to that of endorsing for a CIRB application. See: [2.3.1.2 Endorsing a CIRB Application.](#)



Email and system notifications received during re-endorsement is also similar to those received during the initial endorsement.

2.3.2 Institution Representative Endorsement Process

It is the responsibility of the Institution Representative to ensure that the proposed study is in keeping with the set standards.

2.3.2.1 Accessing a CIRB application

The Institution Representative will be informed of his/her pending endorsement via email and system notification. He/she will then be able to access the study through the hyperlink in the email notification, the hyperlink in the system notification or their pending task in the “My Tasks” page.

1. Once the Department Representative has endorsed, the Institution Representative will be informed that there is an application ready for endorsement. The various routes to access the study are as follow.

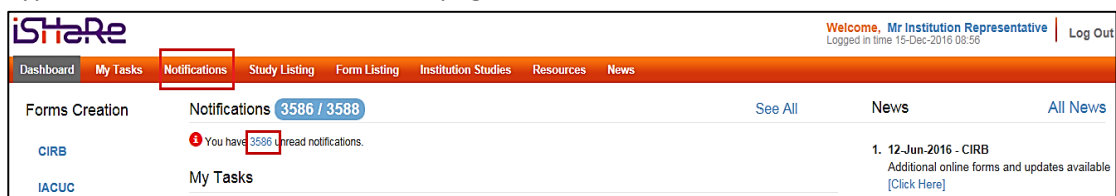
- a. Accessing the study via the email notification

As shown in the image below is an example of how the email notification will look like. By clicking on the blue hyperlink text, the Institution Representative will be directed to the iSHaRe log-in page. Upon logging in, users will be brought straight to the “Study Workspace” page.




- b. Accessing the study via the system notification

Upon logging into iSHaRe, click on “Notifications” on the orange menu bar or the numbers hyperlink to access the notifications page.



As shown in the image below is an example of how the system notification will look like. By clicking on the blue hyperlink text, the Institution Representative will be directed to the “Study Workspace” page.

S.No.	Unread	Notification On	Subject	Notification Message	Recipient	CC List
1	<input checked="" type="checkbox"/>	12-Dec-2016 17:16:53	(UAT) CIRB iSHaRe Ref 201612-00027 - Request for IR Endorsement	Message sent by Mr Department Representative The following CIRB Application Form is ready for Institution Representative Endorsement: Protocol Title: Testing Application (12/12/2012) [Click here] PI Name: Dr Principal Investigator Site-PI(s): N.A.	Mr Institution Representative	Dr Principal Investigator, Ms Protocol Administrator
2	<input checked="" type="checkbox"/>	09-Dec-2016 08:47:06	(UAT) CIRB iSHaRe Ref 201612-00028 - Request for IR Endorsement	Message sent by Mr Department Representative The following CIRB Application Form is ready for Institution Representative Endorsement: Protocol Title: Testing Application (11/12/2012) [Click here] PI Name: Dr Principal Investigator Site-PI(s): N.A.	Mr Institution Representative	Dr Principal Investigator, Ms Protocol Administrator

 The subject header (“Request for IR Endorsement”) and content received by the Institution Representative and Conflict of Interest Institution Representative is the same. Notifications to the Back-up Institution Representative can be differentiated by the subject header (“Acting IR Endorsement is required”) even though the content is similar. This is applicable to both email and system notification received.

c. Accessing the study via “My Tasks” page

The images below demonstrated how the Institution Representative can access the study from the “My Task” page. Upon logging into iSHaRe, the figure next to the “IR Endorsement” tile indicates the number of pending task(s). By clicking the “IR Endorsement” tile, the Institution Representative will then be directed to the “My Tasks” page where he/she can see the pending task(s). Clicking on the status (e.g. Pending Endorsement) will navigate him/her to the “Study Workspace” page.

Dashboard My Tasks Notifications Study Listing Form Listing Institution Studies Resources News

Forms Creation Notifications **3586 / 3588** See All News All News

CIRB IACUC

You have 3586 unread notifications.

My Study Tasks 0 IR Endorsement 0

1. 12-Jun-2016 - CIRB
Additional online forms and updates available [Click Here]

Please note that we will cease accepting hardcopy submissions for approved iSHaRe studies with effect from 1 July 2016. All applicable submissions for the continuing review have to be submitted using the online forms available.

Dashboard My Tasks Notifications Study Listing Form Listing Institution Studies Resources News

CIRB 1 IACUC 0

Study 0 IR Endorsement 1

S/No.	Notification Date	Task Required	Form Type	iSHaRe Ref. No.	CIRB Ref. No.	Protocol Title	Protocol No.	PI Name
1	12-Dec-2016 17:16:52	Pending Endorsement	CIRB Exemption Application Form	201612-00027	-	Testing Application (12/12/2012)	-	Dr Principal Investigator

First Previous 1 Next Last

- The “Study Workspace” page is where the Institution Representative can perform his/her pending task. To start reviewing the CIRB application, click on “View”.

The screenshot shows the iStare Study Workspace interface. At the top, there is a navigation bar with options like Dashboard, My Tasks, Notifications, Study Listing, Form Listing, Institution Studies, Resources, and News. The main content area displays details for a CIRB application with the following information:

- CIRB Ref No.:** 201612-00027
- Protocol No.:** Testing Application (12/12/2012)
- PI:** Dr Principal Investigator
- Study Status:** Pending Endorsement
- Approval Date:** 12-Dec-2016
- Valid Till Date:** 12-Dec-2016

Below this information, there are tabs for Pending, Documents, and Attachments. A table lists the documents, with the following data:

S.No.	Document	Status	Version No	Created Date	Version Date	Actions
1	CIRB Exemption Application Form	Pending Endorsement	1	12-Dec-2016 17:12:59	12-Dec-2016	View

2.3.2.2 Endorsing a CIRB application

By endorsing the CIRB application, the Institution Representative has agreed to support the conduct of the study and confirmed that it is in keeping with the standards set by the institution.


- To start reviewing the CIRB application form, click on the tabs on the left hand panel to navigate to the relevant sections.


The screenshot shows the iStare CIRB Exemption Application Form page. The left-hand panel contains a list of sections, with the following items:

- Selection of Application Form
- Section A: Protocol Title & Protocol Administrators
- Section B: Study Sites, Study Team Me...
- Section C: Conflict of Interest
- Section E: Study Funding Information
- Section F: Research Methodology
- Section I: Study Sites & Recruitment Tar...
- Section J: Exempt Review Criteria

The main content area displays the form for Section A: Protocol Title & Protocol Administrators. It includes the following fields and instructions:

- A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study**
- Protocol Title:** Testing Application (12/12/2012)
- Protocol Number:** (empty field)
- A2. You may assign Protocol Administrators for this study below**
- Add Protocol Administrator** (button)

- After reviewing the CIRB application, click on the IR Endorsement icon () at the top of the page, just below the navigation bar.

This screenshot is identical to the previous one, showing the iStare CIRB Exemption Application Form page. The IR Endorsement icon () is highlighted with a red circle and a mouse cursor, indicating the next step in the process.

3. The “Institution Representative Endorsement” page will appear for endorsement.

The screenshot shows the iStare web application interface. The top navigation bar includes 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The user is logged in as 'Mr Institution Representative'. The main content area is titled 'Institution Representative Endorsement'. It contains a note: 'Note: If there is a red CIRB comment icon beside the status, please click on the icon to reply to the CIRB comment. Please do not use "Back" button or "F5" to refresh the page. Please save the form before you navigate out. For tabular data/information or image, please do not paste into the rich text box. Please attach as document.' Below the note is a text area for 'Comments' with the placeholder 'Please elaborate'. At the bottom, there is a checkbox labeled 'I acknowledge that this research is in keeping with standards set by my institution.' The status is 'Pending Endorsement'.

4. The Institution Representative can select the endorsement option i.e. “Agree” or “Reject”. To endorse an application, he/she will need to check the checkbox and click on “Agree”.



The “Agree” link will only be available after the checkbox has been checked.

This screenshot shows the same 'Institution Representative Endorsement' page as the previous one, but with the checkbox 'I acknowledge that this research is in keeping with standards set by my institution.' checked. Below the checkbox, there are fields for 'Date', 'Full Name' (Mr Institution Representative), 'Department' (Department of Haematology), and 'Institution' (Singapore General Hospital (SGH)). At the bottom right, there are three buttons: 'Agree', 'Reject', and 'Cancel'. The 'Agree' button is highlighted with a red box.



This screenshot shows an 'Authentication' dialog box overlaid on the application. The dialog box contains the following information: 'User Name: Mr Institution Representative', 'Login ID: dr12345a', 'Domain: SGHAD', and a 'Password' field with masked characters. At the bottom of the dialog box, there are two buttons: 'Confirm' and 'Cancel'. The 'Confirm' button is highlighted with a red box.



The screenshot shows the iStarRe dashboard with a green notification bar at the top stating "Endorsement Successful". The user is logged in as "Mr Institution Representative" and the status is "Pending CIRB Review". The navigation bar includes "Dashboard", "My Tasks", "Notifications", "Study Listing", "Form Listing", "Institution Studies", "Resources", and "News". The main content area shows "Study Workspace >> CIRB Exemption Application Form" with a status of "Pending CIRB Review" and a red comment icon.

- The CIRB application will now be routed to CIRB for review. To verify if the application has been successfully endorsed or to check the endorsement status, click on the endorser icon (📄) at the top of the page, just below the navigation bar.



The CIRB application will be automatically routed to CIRB for review after the Institution Representative has endorsed. For multi-site studies, the application will be routed to CIRB if there is no more pending endorsement(s) from the other site's Institution Representative(s). A system and email notification will be sent to the Principal Investigator and relevant personnel – Site-Principal Investigator, Study Team Members and Protocol Administrator, Research Development Office – if applicable, to notify that the application has been submitted to CIRB and is now pending CIRB review.

The screenshot shows the iStarRe dashboard with the "Endorsers (Singapore General Hospital (SGH))" section expanded. A table lists the endorsers with columns for Stage, Name, Role, Endorsement Status, Date, and Action. The "Institution" row is highlighted in red, showing "Mr Institution Representative" as the endorser with a status of "Endorsed" on "15-Dec-2016".

Stage	Name	Role	Endorsement Status	Date	Action
RDO	Ms Protocol Administrator	RDO	Checked	02-Dec-2016	
Department	Mr Department Representative	DR	Endorsed	03-Dec-2016	
Institution	Mr Institution Representative	IR	Endorsed	15-Dec-2016	


Endorsement Status : Endorsed

2.3.2.3 Rejecting a CIRB application

By rejecting the CIRB application, the Institution Representative does not agree to support the conduct of the study and confirmed that it is not keeping with the standards set by the institution.

1. To start reviewing the CIRB application form, click on the tabs on the left hand panel to navigate to the relevant sections.

The screenshot shows the iStare web application interface. The user is logged in as 'Mr Institution Representative'. The navigation bar includes 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The current page is 'CIRB Exemption Application Form'. The status is 'Pending Endorsement'. The left sidebar shows a list of sections, with 'Section A: Protocol Title & Protocol Administrators' selected. The main content area displays 'Section A : Protocol Title & Protocol Administrators' with two sub-sections: 'A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study' and 'A2. You may assign Protocol Administrators for this study below'. The 'A1' section has input fields for 'Protocol Title' (containing 'Testing Application (12/12/2012)') and 'Protocol Number'. The 'A2' section has an 'Add Protocol Administrator' button.

2. After reviewing the CIRB application, click on the IR Endorsement icon () at the top of the page, just below the navigation bar.

This screenshot is identical to the previous one, showing the 'Section A : Protocol Title & Protocol Administrators' form. The 'IR Endorsement' icon is visible in the top right corner of the page, next to the 'Status : Pending Endorsement' text.

3. The "Institution Representative Endorsement" page will appear for endorsement.

The screenshot shows the 'Institution Representative Endorsement' page. The navigation bar and status are the same as in the previous screenshots. The left sidebar shows the same list of sections. The main content area displays 'Institution Representative Endorsement' with a text area for 'Comments' and a checkbox for 'I acknowledge that this research is in keeping with standards set by my Institution.' The text area contains the placeholder text 'Please elaborate'.

4. The Institution Representative can select the endorsement option i.e. “Agree” or “Reject”. To reject an application, he/she will need to enter the reason(s) in the comment box and click on “Reject”.

The screenshot shows the iStare web application interface. The user is logged in as 'Mr Institution Representative'. The page title is 'Study Workspace >> CIRB Exemption Application Form'. The status is 'Pending Endorsement'. The main content area is titled 'Institution Representative Endorsement'. It contains a note about CIRB comments, a text area for comments (containing 'This is not in keeping with the standards.'), a checkbox for acknowledging standards, and a date field. Below these are fields for 'Full Name', 'Department', and 'Institution'. At the bottom, there are three buttons: 'Agree', 'Reject', and 'Cancel'. The 'Reject' button is highlighted with a red box.



The screenshot shows the iStare web application interface with an 'Authentication' dialog box open. The dialog box contains the following information: 'User Name: Mr Institution Representative', 'Login ID: dr03445b', 'Domain: SGHAD', and a 'Password' field with masked characters. At the bottom of the dialog box, there are two buttons: 'Confirm' and 'Cancel'. The 'Confirm' button is highlighted with a red box.




The screenshot shows the iStare web application interface after the application has been rejected. A green message box at the top says 'Rejected Successfull'. The status at the bottom right is 'Endorsement Rejected', which is highlighted with a red box.

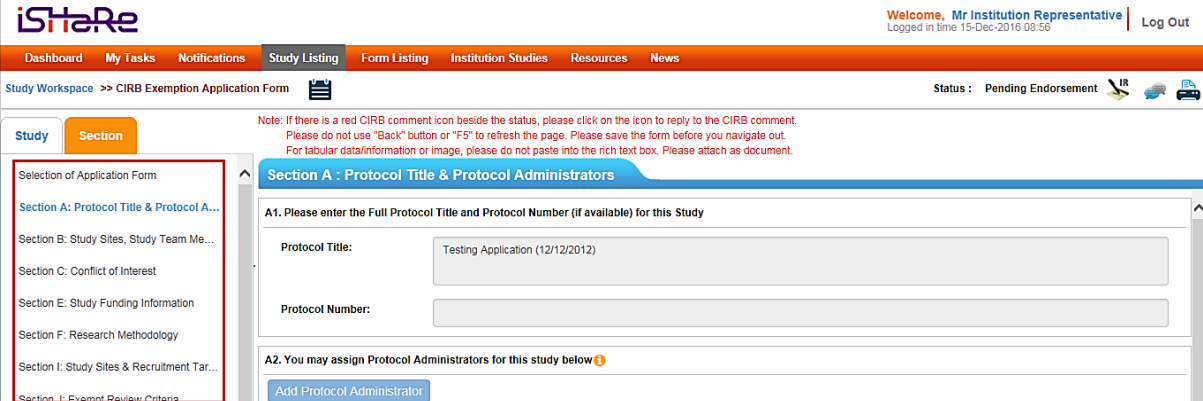


By rejecting a CIRB application, a system and email notification will be sent to the Principal Investigator and relevant personnel – Protocol Administrator, Research Development Office and Site-Principal Investigator – if applicable. The Principal Investigator will need to review the comment(s) entered and unlock the application form to make changes. This reverts the form back to draft mode, which upon finalisation triggers the entire endorsement process again. See: [2.3.2.5 Re-endorsing a CIRB Application.](#)


2.3.2.4 Query and reply the Principal Investigator

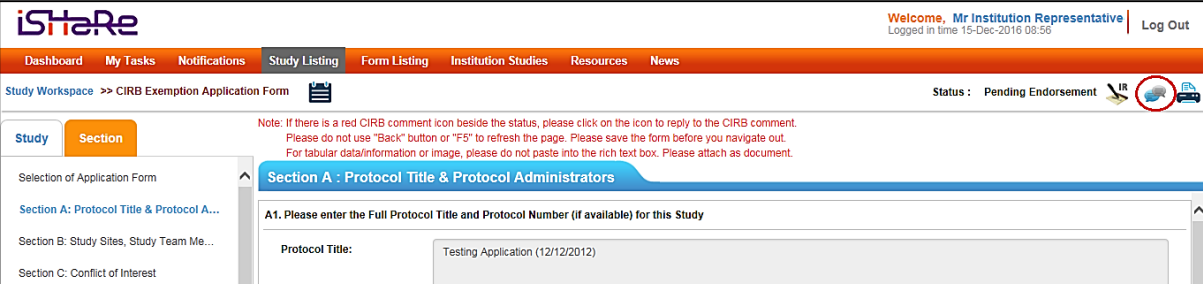
The query function is available via the general comment icon (). This option provides the opportunity for the Institution Representative to obtain clarification from the Principal Investigator or request for certain changes to be made to the CIRB application.

1. To start reviewing the CIRB application, click on the tabs on the left hand panel to navigate to the relevant sections.

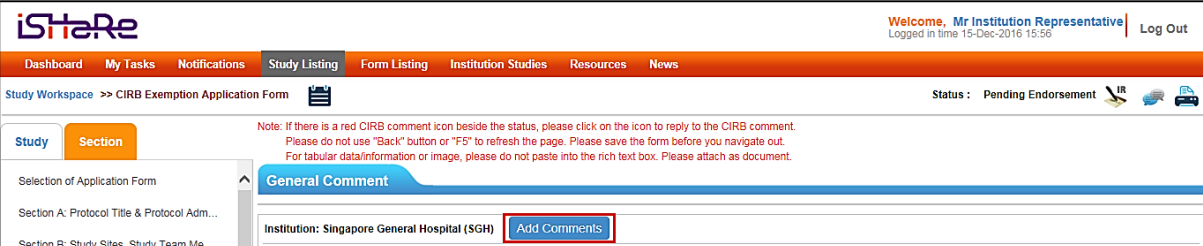


The screenshot shows the iStare web application interface. The top navigation bar includes 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The user is logged in as 'Mr Institution Representative' at 08:56. The main content area is titled 'CIRB Exemption Application Form' and shows 'Section A: Protocol Title & Protocol Administrators'. The left sidebar contains a 'Section' menu with options like 'Selection of Application Form', 'Section A: Protocol Title & Protocol A...', 'Section B: Study Sites, Study Team Me...', 'Section C: Conflict of Interest', 'Section E: Study Funding Information', 'Section F: Research Methodology', 'Section I: Study Sites & Recruitment Tar...', and 'Section J: Event Review Criteria'. The main form area has a note about CIRB comments and input fields for 'Protocol Title' (Testing Application (12/12/2012)) and 'Protocol Number'. A red comment icon is visible in the top right corner of the page.

2. After reviewing the CIRB application, the Institution Representative can raise a query by clicking on the general comment icon () at the top of the page, just below the navigation bar.

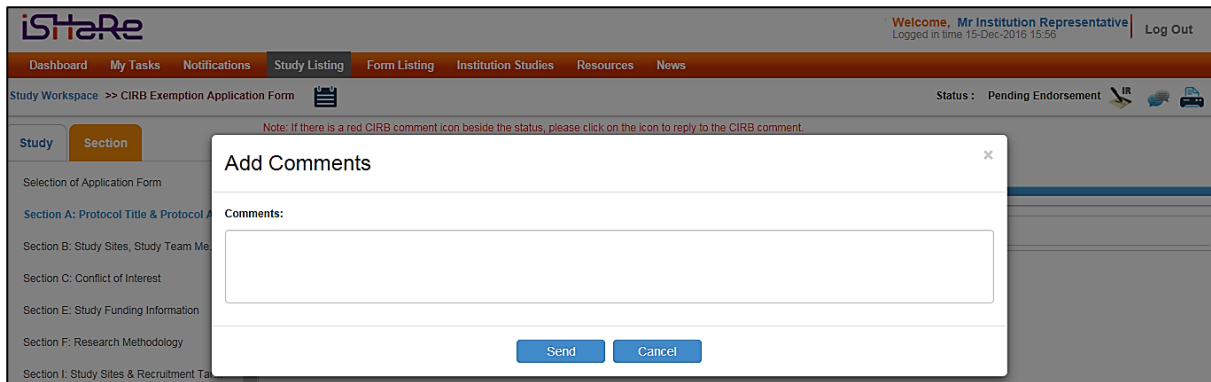


This screenshot is identical to the one above, showing the 'Section A: Protocol Title & Protocol Administrators' form. The red comment icon in the top right corner is circled in red, indicating the next step in the process.



This screenshot shows the 'General Comment' section of the application. The left sidebar is highlighted with a red box, showing the 'Section' menu. The main content area has a note about CIRB comments and a text input field for the comment. The 'Add Comments' button is highlighted with a red box.





Multiple comments can be sent to query the Principal Investigator.



Additional comment will not be allowed after the Institution Representative has endorsed.

- When a comment is sent, a system and email notification will be sent to the Principal Investigator and relevant personnel – Site-Principal Investigator and Protocol Administrator – if applicable



The comment(s) raised is site specific. For a multi-site study, only the Principal Investigator belonging to the same institution as the Institution Representative who raised the query, will be able to see and reply to the comment(s).

- After the Principal Investigator has responded to the comment(s), the Institution Representative and relevant personnel – Protocol Administrator – if applicable, will be notified via a system and email notification. An example of how the notifications will look like is shown in the image below.

Email notification

Dear Mr Institution Representative,

You have received a reply to your query on the following CIRB Application:

Protocol Title: [Application \(24/03/2015\) \[Click here\]](#)
PI Name: Mr Principal Investigator
Site-PI(s): N.A.

This is a system generated notification. Please do not reply to this email.

Should you have any enquiries, please contact irb@singhealth.com.sg.

System notification

The screenshot shows the iShare Notifications page. At the top, there is a navigation bar with tabs for Dashboard, My Tasks, Notifications, Study Listing, Form Listing, Institution Studies, Resources, and News. Below this, there are filters for CIRB and IACUC, and search options for Notification Date, To, and Subject. The main content is a table of notifications:

S.No.	Unread	Notification On	Subject	Notification Message	Recipient	CC List
1		12-Dec-2016 17:16:53	CIRB iShare Ref 201612-00027 - Reply to IR query	<p><i>Message sent by Dr Principal Investigator</i> You have received a reply to your query on the following CIRB Application:</p> <p>Protocol Title: Testing Application (12/12/2012) [Click here] PI Name: Dr Principal Investigator Site-PI(s): N.A.</p>	Mr Institution Representative	Ms Protocol Administrator
2		09-Dec-2016 08:47:06	CIRB iShare Ref 201612-00027 - Request for IR Endorsement	<p><i>Message sent by Mr Department Representative</i> The following CIRB Application Form is ready for Institution Representative Endorsement:</p> <p>Protocol Title: Testing Application (12/12/2012) [Click here] PI Name: Dr Principal Investigator Site-PI(s): N.A.</p>	Mr Institution Representative	Dr Principal Investigator; Ms Protocol Administrator



When there is a response from the Principal Investigator, this will not be reflected to the Institution Representative as a new endorsement task.

- The Institution Representative may access the CIRB application as depicted in Section 2.3.2.1.

He/she can view the reply by clicking on the general comment icon () at the top of the page, just below the navigation bar.

The screenshot shows the iShare Study Workspace for a CIRB Exemption Application Form. The status is 'Pending Endorsement'. A red comment icon is circled in the top right corner. The form is divided into sections: Section A: Protocol Title & Protocol Administrators. The first task is 'A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study'. The 'Protocol Title' field contains 'Testing Application (12/12/2012)'. A red arrow points from the circled comment icon in the previous screenshot to this field.



The screenshot shows the iStHeRe web application interface. At the top, there is a navigation bar with 'Dashboard', 'My Tasks', 'Notifications', 'Study Listing', 'Form Listing', 'Institution Studies', 'Resources', and 'News'. The user is logged in as 'Mr Institution Representative' on 15-Dec-2016. The main content area is titled 'Study Workspace >> CIRB Application Form' and shows a 'General Comment' section for 'Singapore General Hospital (SGH)'. A table lists comments and replies:

Type	Date	Content
Commented By Representative Institution	24-Mar-2015 15:05:40	Dear PI Please amend Section B.
Replied By Investigator Principal	27-Apr-2015 14:39:04	Dear Institution Representative I have amended.
Commented By Representative Institution	24-Mar-2015 15:05:18	Dear PI Please clarify why ABC method is used.
Replied By Investigator Principal	27-Apr-2015 14:39:04	Dear Institution Representative This is currently the cutting-edge technique and we would like to test the feasibility.

6. After reviewing the comments, the Institution Representative may choose to further query the Principal Investigator, endorse the application or reject the application.

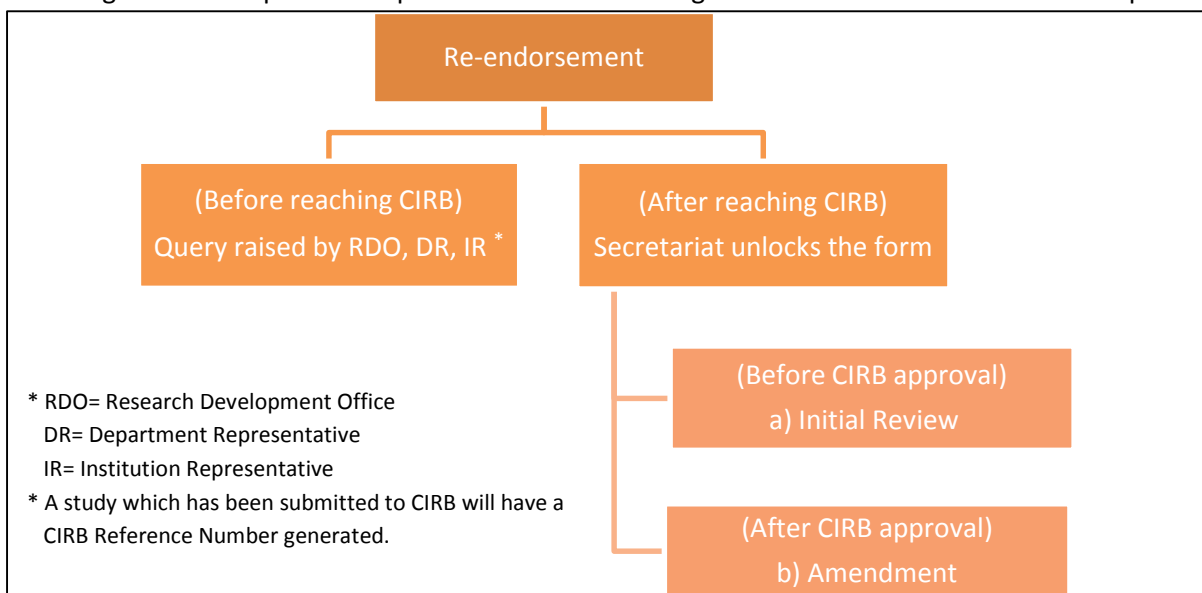


If the Principal Investigator feels that it is necessary to amend certain sections of the CIRB application form, he/she may unlock the application form to make the changes. This action reverts the form back to draft mode, which upon finalisation triggers the entire endorsement process again. As such, the Institution Representative will receive notification to re-endorse the study. See: [2.3.5.2 Re-endorsing a CIRB Application](#).

2.3.2.5 Re-endorsing a CIRB application

Re-endorsement implies that the endorsement process has been triggered again after a prior endorsement. The Institution Representative will therefore need to endorse the study again.

The image below is a pictorial depiction of the various stages where re-endorsement can take place.



There can be various scenarios which may result in a re-endorsement after the CIRB application has reached CIRB. They are detailed in the table below. These scenarios for re-endorsement are applicable to an amendment form too.

Scenario	Re-endorsement required?
Addition of study sites	Yes
Change of PI/ Site-PI	Yes
Significant changes to study protocol	Yes
Change in form type (CIRB Application Form ↔ CIRB Exemption Application Form)	Yes

The steps to completing a re-endorsement is similar to that of endorsing for a CIRB application. See: [2.3.2.2 Endorsing a CIRB Application.](#)



Email and system notifications received during re-endorsement is also similar to those received during the initial endorsement.

2.4 Routing Process for Endorsement

CIRB application form pending endorsement(s) will be routed depending on whether there is Back-up Department Representative or Back-up Institution Representative assigned.

When there is no Back-up Department Representative or Back-up Institution Representative assigned, the CIRB application form will not be routed. Instead, reminder emails and system notifications will be sent to notify the Department Representative or Institution Representative to endorse the study.

For Conflict of Interest Department Representative or Conflict of Interest Institution Representative, once he/she has been added, the CIRB application form will not be routed. Similarly, reminder emails and system notifications will be sent to notify the Conflict of Interest Department Representative or Conflict of Interest Institution Representative of his/her pending task(s).

The emails that one will receive are as follow.

Department Representative/ Conflict of Interest Department Representative

- iSHaRe CIRB (xxxxxx-xxxxx) - Request for DR Endorsement (1st Reminder)
- iSHaRe CIRB (xxxxxx-xxxxx) - Request for DR Endorsement (2nd Reminder)
- iSHaRe CIRB (xxxxxx-xxxxx) - Request for DR Endorsement (Last Reminder)

- iSHaRe CIRB (xxxxxx-xxxxx) - DR Endorsement is still pending

Institution Representative/ Conflict of Interest Institution Representative

- iSHaRe CIRB (xxxxxx-xxxxx) - Request for IR Endorsement (1st Reminder)
- iSHaRe CIRB (xxxxxx-xxxxx) - Request for IR Endorsement (2nd Reminder)
- iSHaRe CIRB (xxxxxx-xxxxx) - Request for IR Endorsement (Last Reminder)
- iSHaRe CIRB (xxxxxx-xxxxx) - IR Endorsement is still pending

When there is Back-up Department Representative or Back-up Institution Representative assigned, the CIRB application will be routed to the back-up or the next back-up in line if not endorsed after a certain number of days. Email and system notifications will be sent to notify the Back-up Department Representative or Back-up Institution Representative to endorse the study. The emails that one will receive are as follow.

Back-up Department Representative

- iSHaRe CIRB (xxxxxx-xxxxx) - Acting DR Endorsement is required
- iSHaRe CIRB (xxxxxx-xxxxx) - DR Endorsement is still pending

Back-up Institution Representative

- iSHaRe CIRB (xxxxxx-xxxxx) - Acting IR Endorsement is required
- iSHaRe CIRB (xxxxxx-xxxxx) - IR Endorsement is still pending



The “DR Endorsement is still pending” or “IR Endorsement is still pending” email will be sent to the Principal Investigator and relevant personnel – Research Development Office and Protocol Administrator – if applicable, if the endorsement is still not completed after the last reminder has been sent out or when there is no more back-ups to route to. The Principal Investigator may need to contact the Department Representative or Institution Representative to inform him/her about the pending task as there will not be any further routing of the study.

The image below shows the routing table.

Number of Back-up Department/ Institution Representative \ Number of Working Day(s)	0	1	2	3	4 (~8am)	5	6	7	8 (~8am)	9	10	11	12 (~8am)	13	14	15	16 (~8am)
0	Pending DR/IR	✓	✓	✓	1 st Reminder	✓	✓	✓	2 nd Reminder	✓	✓	✓	Last Reminder	✓	✓	✓	Email PI
1	Pending DR/IR	✓	✓	✓	Route to Back-up 1	✓	✓	✓	Email PI	-	-	-	-	-	-	-	-
2	Pending DR/IR	✓	✓	✓	Route to Back-up 1	✓	✓	✓	Route to Back-up 2	✓	✓	✓	Email PI	-	-	-	-
3	Pending DR/IR	✓	✓	✓	Route to Back-up 1	✓	✓	✓	Route to Back-up 2	✓	✓	✓	Route to Back-up 3	✓	✓	✓	Email PI

* PI = Principal Investigator

DR= Department Representative

IR =Institution Representative

* Day 0 = Principal Investigator/ Site-Principal Investigator has declared or Research Development Office has checked (if applicable) and the CIRB application form is currently pending Department Representative Endorsement.



For multi-sites studies, the endorsement process runs parallel. The different sites can endorse concurrently and the routing process will be site-specific.