



SingHealth Centralised Institutional Review Board (CIRB)

e-CIRB User Guidebook: New Application

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1. GENERAL INFORMATION

Integrated System in Healthcare for Research (iSHaRe) is a SingHealth platform for investigators, administrators and institutions to track, monitor and manage their research portfolios more efficiently.

The iSHaRe has the following modules:

- e-CIRB
- e-IACUC
- Grant Management
- Grant Disbursement

The e-CIRB module is the first module launched. With effective from 15 September 2014, all new CIRB applications have to be submitted via iSHaRe e-CIRB for review and approval.

Applicable submissions include the following forms/ reports:

- CIRB Application Form
- CIRB Exemption Form
- Amendment
- *Study Renewal Report* (under development)
- *Study Closure Report* (under development)
- *Study Reactivation Report* (under development)
- *LSAE Report* (under development)
- *Protocol Deviation / Non Compliance Report* (under development)
- *Other Reportable Event Report* (under development)

This User-Guidebook is aimed to provide the information necessary for users (i.e. Principle Investigators, Site-Principal Investigators, Co-Investigators, Study Team Members and Protocol Administrators) to effectively use the e-CIRB module in their new CIRB applications. This guidebook includes a walkthrough of the basic system navigation and step-by-step procedures for system access and use.

1.1 System Requirements

iSHaRe can be accessed using any major Internet Browsers.

The minimal system requirements are:

- Microsoft Window 7 and above
- Internet Explorer 9 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 creation of a new CIRB application.



To complete the registration of your iSHaRe account, please update your user appointment upon the first log-in.

2.1 Understanding the User Interface

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

2.1.1 iSHaRe Icons

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



Unread Notification



Read Notification



Save Draft



PI Declaration



General Comment



RDO Check



**View Endorsers and
Endorsement Status**



Finalise



Print



Unlock IRB form



DR Endorsement



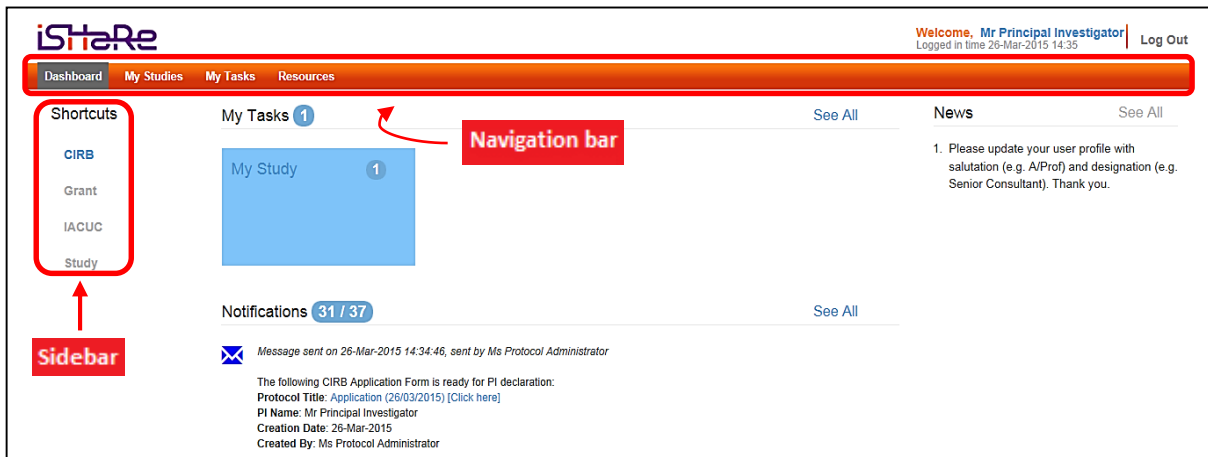
IR Endorsement

2.1.2 Dashboard

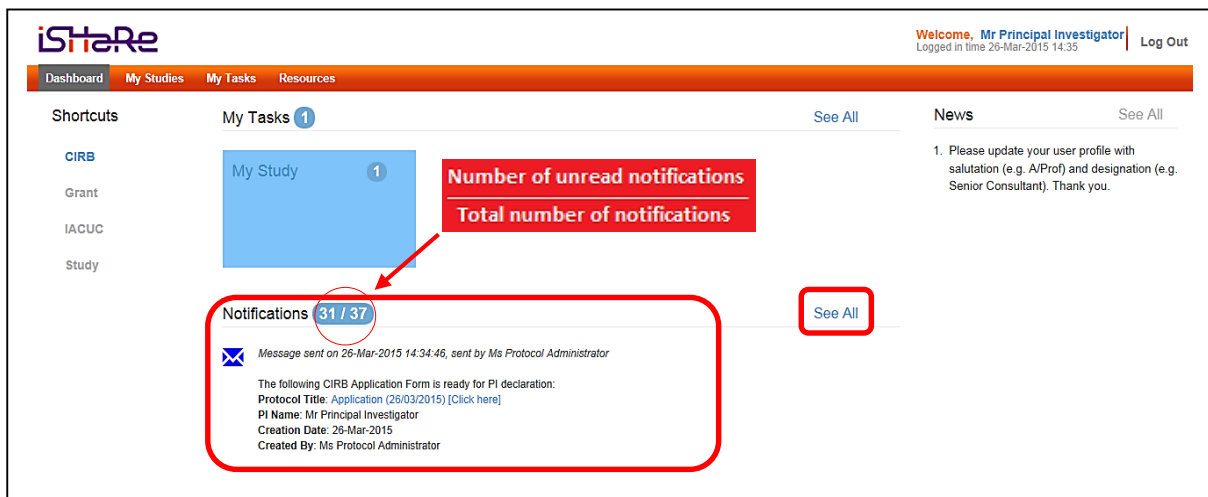
The “Dashboard” is the navigation hub of iSHaRe.

The functional areas are mostly incorporated in the 1) navigation bar that span horizontally across the top which enables users to quickly access the various sections available to them and 2) shortcut sidebar on the left hand side of the page.

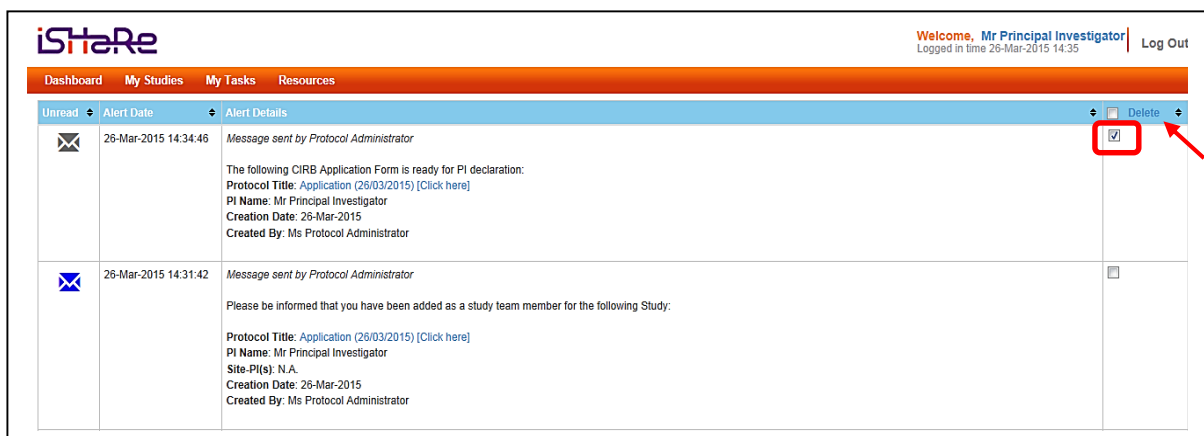
As user access right is dependent on one’s role in iSHaRe e-CIRB, different users may have a different view at the “Dashboard” page upon log-in.



Notifications serve to provide a quick overview of any updates of a study. The figure indicates the number of unread notifications as opposed to the total number of notifications. Click on “[See All](#)” to view all notifications or to delete specific notifications.



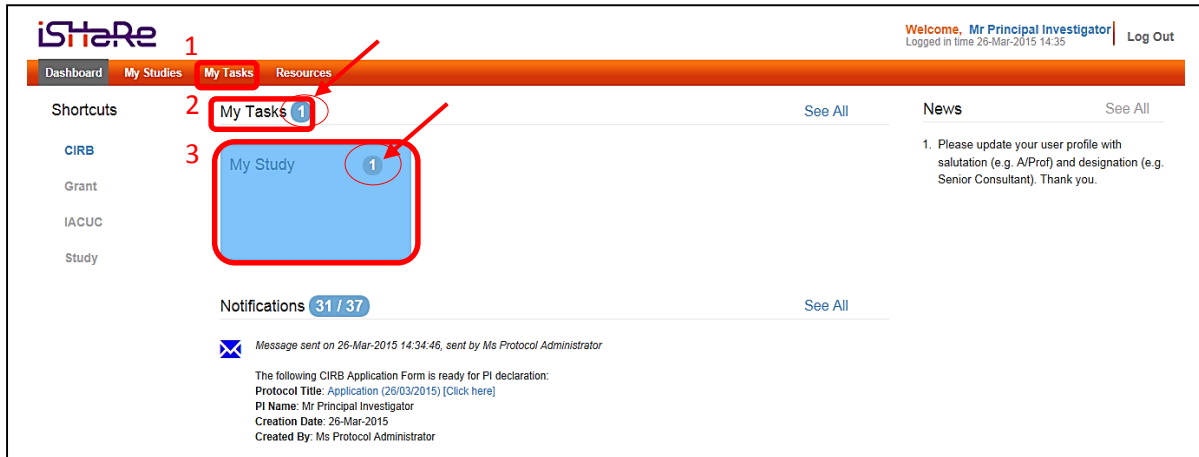
To delete the notifications, tick the checkbox next to the notification you wish to delete and click “[Delete](#)” on the header of the list.



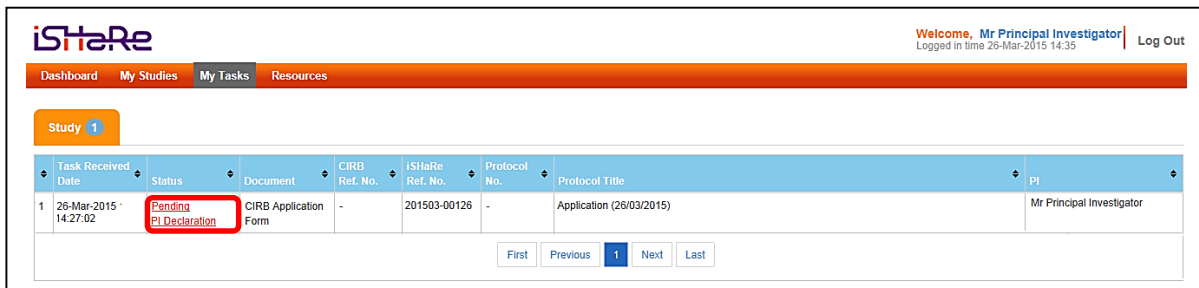
2.1.3 My Tasks

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

As shown in the image below, there are various routes to access the “My Tasks” page. The figure beside each tab provides an overview and reflects the number of pending task(s) to be done.



While in the “My Tasks” page, users will be able to see the status of the pending task(s). Clicking on the status (e.g. Pending PI Declaration) will navigate the users to the study where they can perform their pending task(s).



2.1.4 My Studies

The “My Studies” page is where users can view or access the list of studies, including draft applications, which they are part of or have a role in.

The statuses of the studies are reflected under the “CIRB Status” column.

Clicking on whichever, the iSHaRe Reference Number, CIRB Reference Number (generated when the application is submitted to CIRB) or Protocol Title, will lead users to the “Study Workspace”. See:

[2.1.5 Study Workspace](#)

CIRB application in the draft stage which has not been finalised can be deleted from this page.



Only the Principal Investigator named on the application of that study is able to delete the application form from the system.

The screenshot shows the iSHaRe dashboard with a search filter for 'Draft' status and 'PI' role. The table below lists the results:

iSHaRe Ref. No.	CIRB Ref. No.	Submission Type	CIRB Status	Protocol No.	Protocol Title	Study Role	PI	Submission Date	Creation Date	Update Date	Action
1	201503-00127	CIRB Exemption Application Form	Draft		Application (26/03/2015)	PI	Mr Principal Investigator		26-Mar-2015	26-Mar-2015	Delete
2	201503-00126	CIRB Application Form	Pending PI Declaration		Application (24/03/2015)	PI	Mr Principal Investigator		24-Mar-2015	26-Mar-2015	
3	201502-00119	CIRB Application Form	Draft		Application (22/02/2015)	Co-I	Mr Principal Investigator		22-Feb-2015	24-Feb-2015	
4	201503-00116	CIRB Application Form	Pending CIRB Review	2015/2249	Application (22/01/2015)	Co-I	Mr Principal Investigator		22-Jan-2015	24-Feb-2015	

2.1.5 Study Workspace

The “Study Workspace” page is where the CIRB application can be viewed or edited. All study related details and documents are found here.

If the study has not been finalised, it will be editable. The page will appear as shown in the image below.

The screenshot shows the 'Study Workspace' page for a CIRB application form. The application details are as follows:

- CIRB Ref. No.:** 201503-00127
- Protocol No.:** Application (26/03/2015)
- PI:** Principal Investigator
- Creation Date:** 26-Mar-2015

The application is currently in a 'Pending / Draft' state. A table of documents is shown below:

Document	Status	Version No	Version Date	Actions
CIRB Exemption Application Form	Draft	1	26-Mar-2015	Edit

If the study has been finalised, it will only be viewable in all circumstances. The page will appear as shown in the image below. The application form will only be editable when the Principal Investigator unlocks the form before performing the declaration. See: [Section 2.2 Creating New CIRB Application \(Point 9\)](#)

iSHaRe Welcome, Mr Principal Investigator | Log Out
Logged in time 26-Mar-2015 14:35

Dashboard My Studies My Tasks Resources

Study Workspace > CIRB Application Form

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.

Study
iSHaRe Ref. No. : 201503-00127

- CIRB
- Grant / Fund
- IACUC
- Study Management

CIRB Ref. No. : PI : Principal Investigator Creation Date : 26-Mar-2015
 Protocol No. : Approval Date : Valid Till Date :
 Protocol Title : Application (26/03/2015)

CIRB Application Study Status Report Protocol Deviation/Non-Compliance Report
 Amendment LSAE Report Study Closure Report
 Study Reactivation Report Other Reportable Event

Pending / Draft

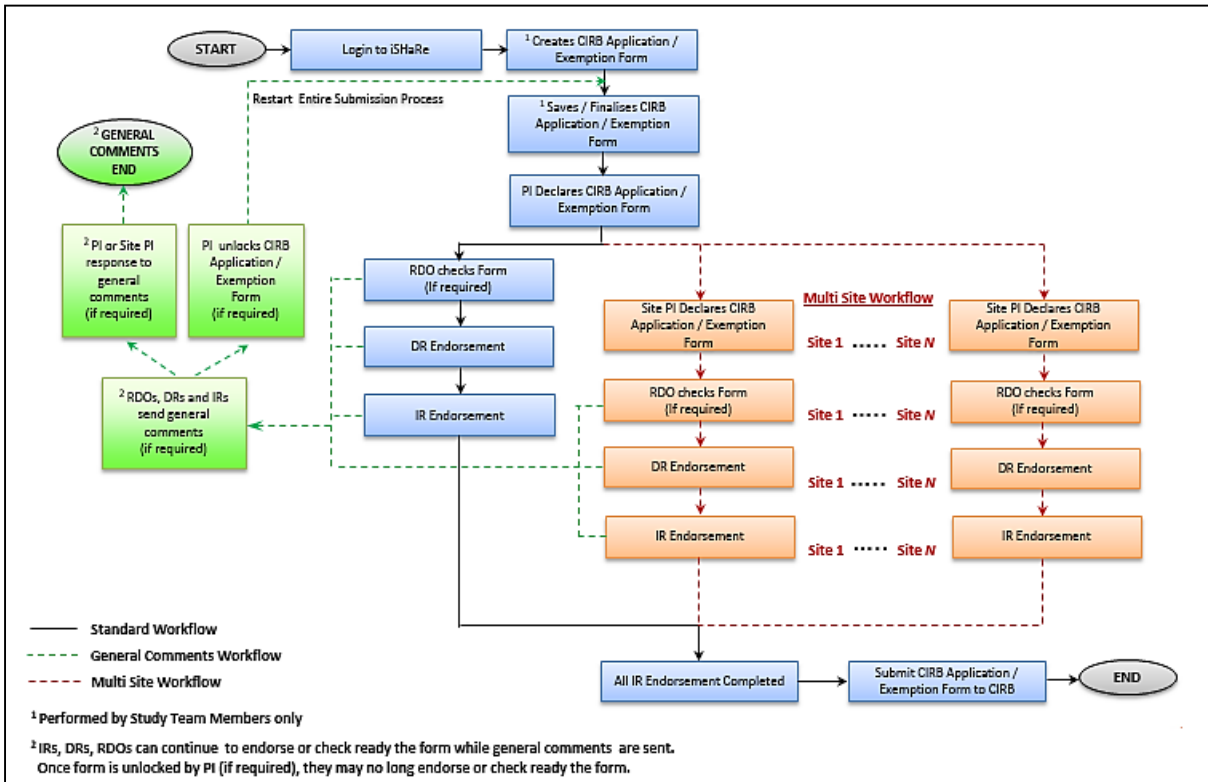
Document	Status	Version No	Version Date	Actions
CIRB Exemption Application Form	Pending PI Declaration	1	26-Mar-2015	View

2.2 Creating New CIRB Application

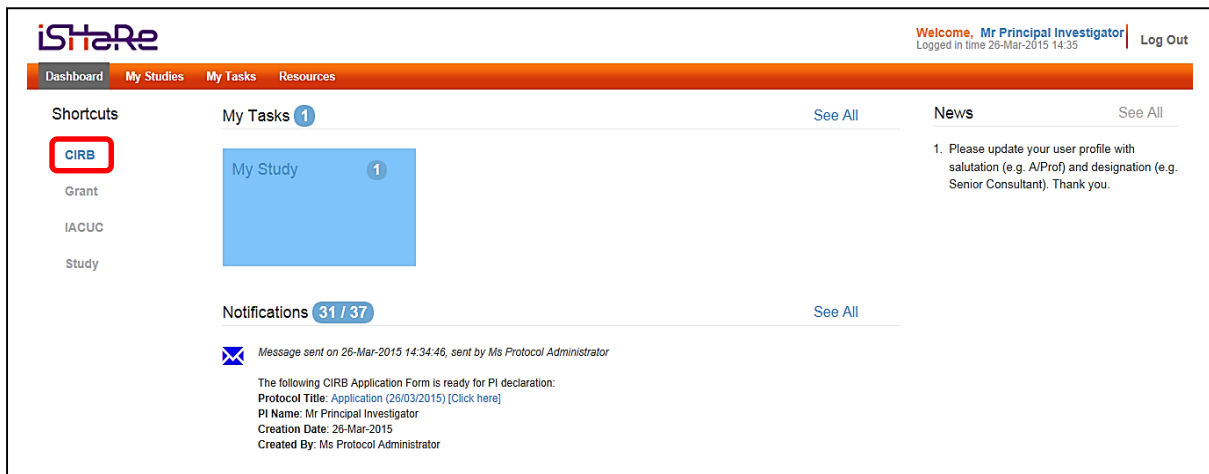
This section provides a detailed description for creating a new CIRB application on iSHaRe. In general, there are 2 types of CIRB application:

- CIRB Application Form
- CIRB Exemption Application Form

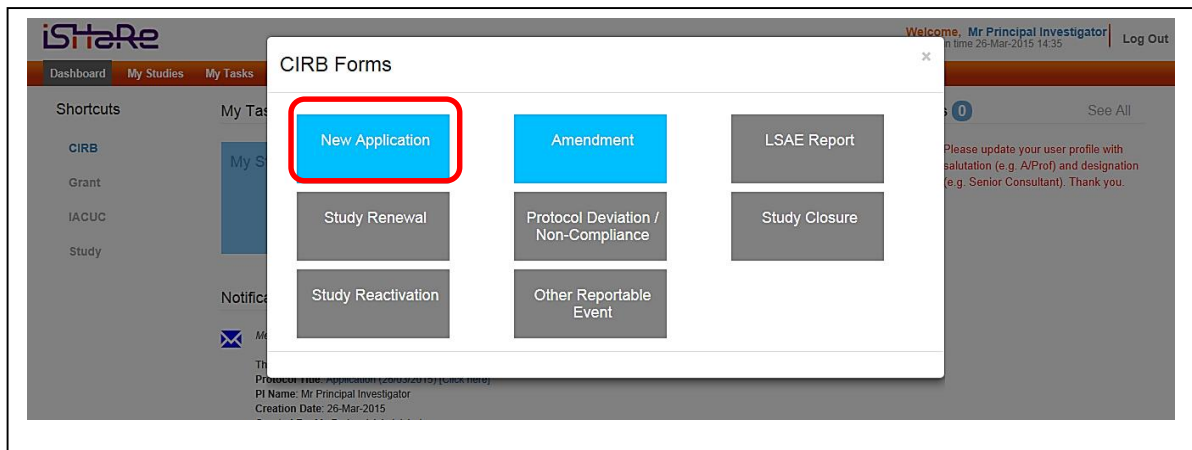
The flowchart below shows the general flow of a typical submission process.



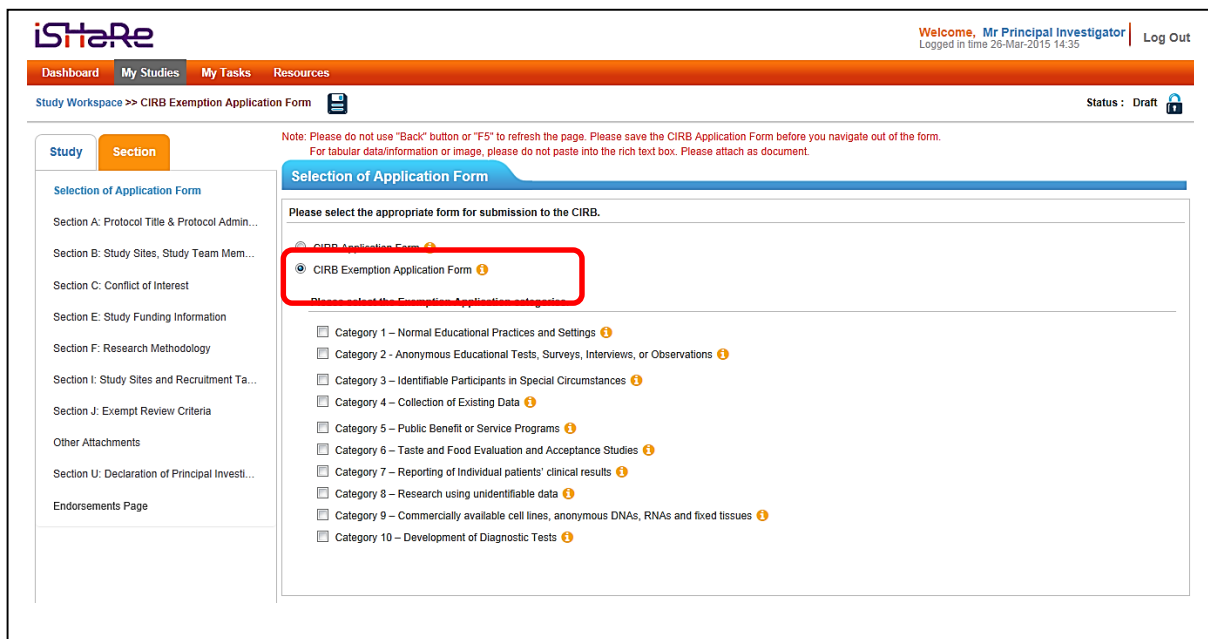
1. To generate a new CIRB application form, click on “CIRB” at the shortcut sidebar on the left.





2. Click on the tile “New Application”.

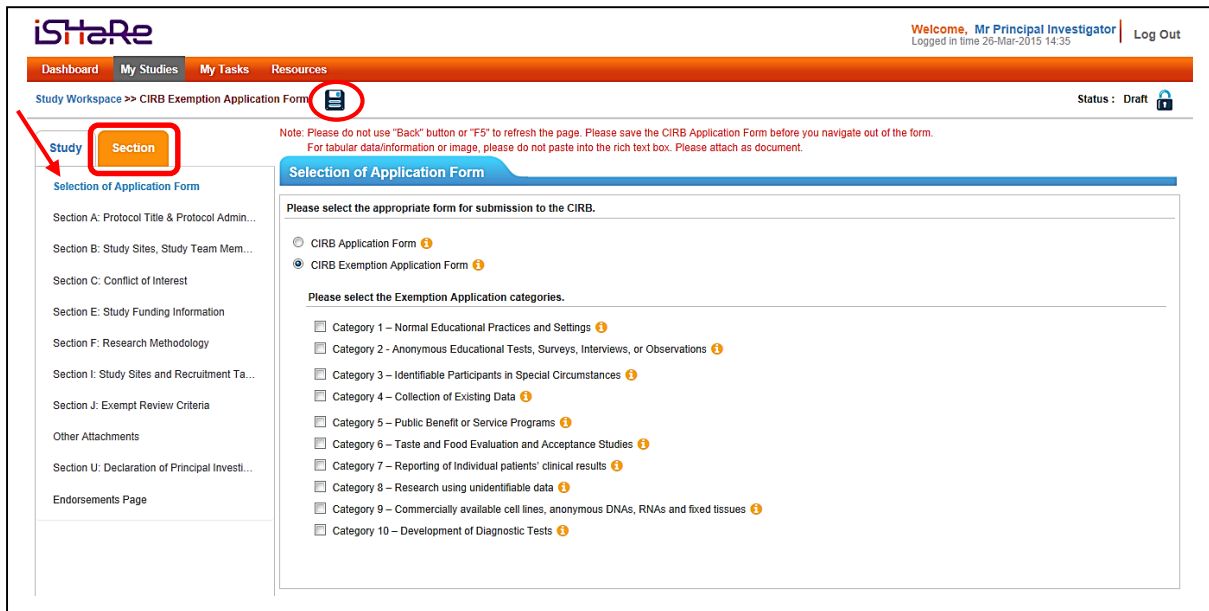


3. Select the appropriate form type for submission to CIRB.




 Users may click on the icon () for further information while creating a CIRB application, if required.


4. Click on the tabs on the left panel to navigate to the relevant sections to fill up the application form.





The screenshot shows the iShare application interface. At the top, there is a navigation bar with 'Dashboard', 'My Studies', 'My Tasks', and 'Resources'. Below this, the current page is identified as 'Study Workspace >> CIRB Exemption Application Form'. A 'Status: Draft' indicator is visible. The main content area is titled 'Selection of Application Form' and contains a 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.' Below the note, there are two radio buttons: 'CIRB Application Form' (unselected) and 'CIRB Exemption Application Form' (selected). Underneath, there is a section for 'Please select the Exemption Application categories.' with ten checkboxes, each followed by a category name and an information icon. The categories are: Category 1 - Normal Educational Practices and Settings; Category 2 - Anonymous Educational Tests, Surveys, Interviews, or Observations; Category 3 - Identifiable Participants in Special Circumstances; Category 4 - Collection of Existing Data; Category 5 - Public Benefit or Service Programs; Category 6 - Taste and Food Evaluation and Acceptance Studies; Category 7 - Reporting of Individual patients' clinical results; Category 8 - Research using unidentifiable data; Category 9 - Commercially available cell lines, anonymous DNAs, RNAs and fixed tissues; Category 10 - Development of Diagnostic Tests.

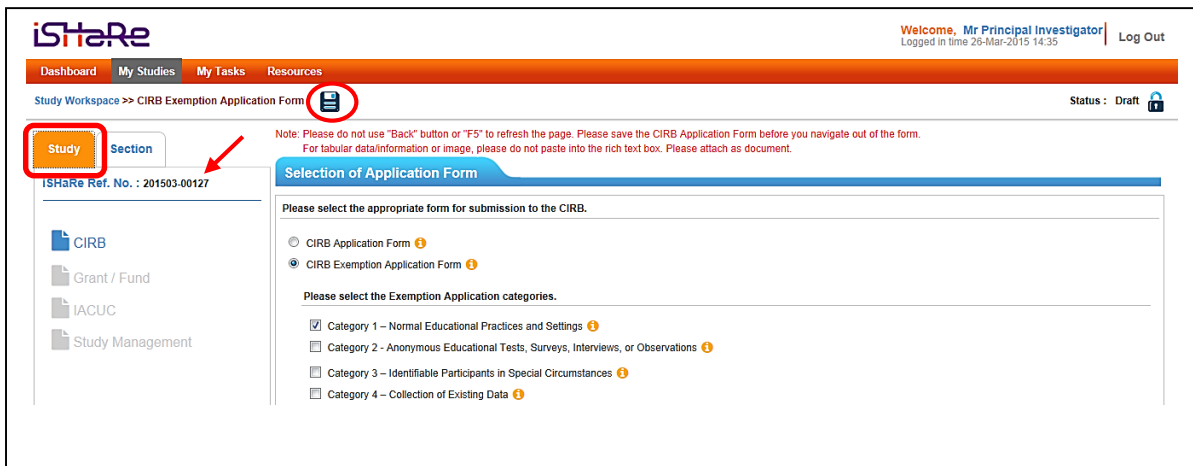
 Certain sections will only be displayed depending on the form type or questions selected.



Section D	When CIRB Application Form is selected.
Section G	When CIRB Application Form is selected and "Clinical Trials" is selected in Question D1.
Section J	When CIRB Exemption Application Form is selected.
Section L, M, N,O	When CIRB Application Form is selected and relevant options in Question K7 is selected.
Section P, Q	When CIRB Application Form/ CIRB Exemption Application Form is selected and relevant options in Question F17/ J2(v) is selected.

 When filling up the application form, refrain from copying and pasting as this may affect the formatting of the pasted text.

 Please remember to click on the save icon () at the top of the page, just below the navigation bar before navigating out of the application form.

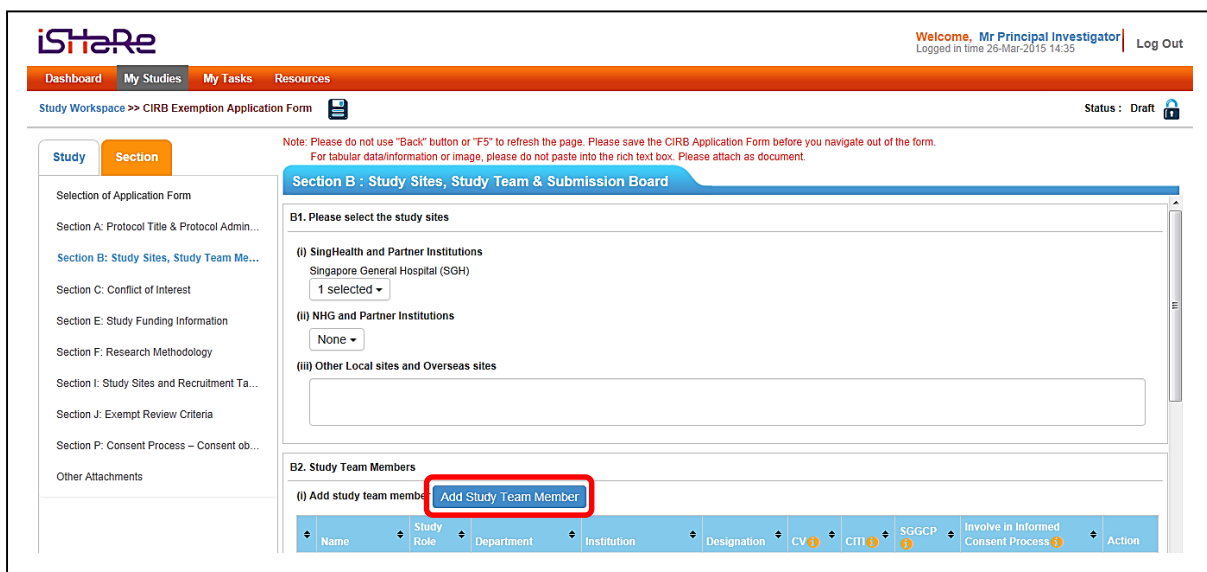
- Click on “Study” on the left panel to view the iSHaRe Reference Number.

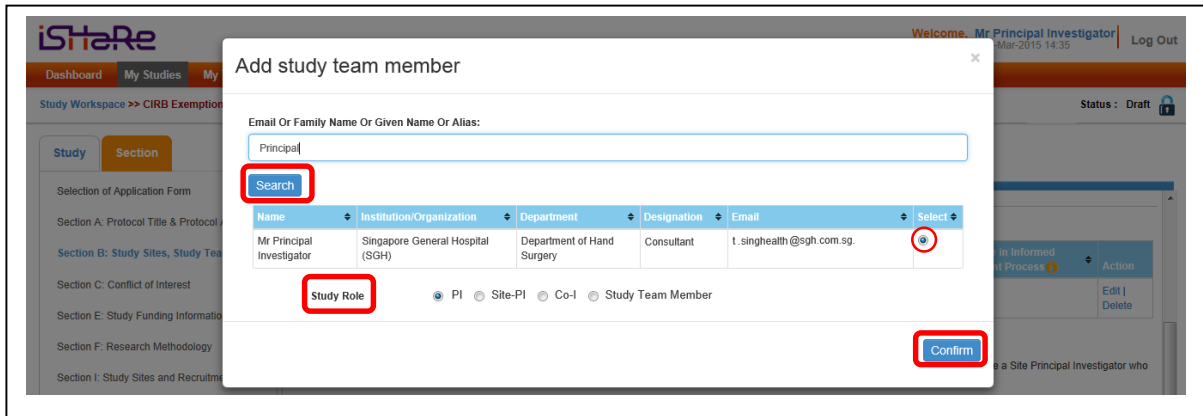



 The iSHaRe Reference Number will only be generated when the form has been saved. To save a created application form, users will need to fill up the Protocol Title and add at least the Principal Investigator. The save icon () can be found on the top of the page, just below the navigation bar.

- Click on “Section” on the left panel (if not currently in this tab) and select “Section B: Study Sites, Study Team & Submission Board”.

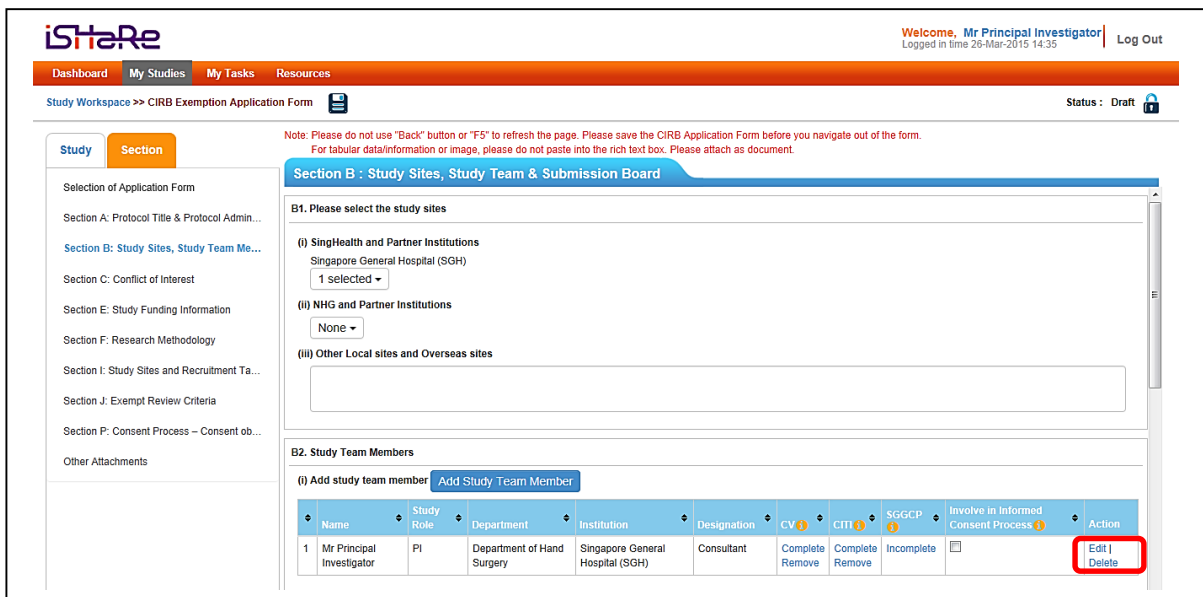
To add study team members, click on “Add Study Team Member”. Users can search by the email address, family name, given name or alias. Select the correct profile (if there is multiple appointments) and study role before clicking “Confirm”. Click on “Add Study Team Member” again if there are more members to be added.





 A person can only be found after having registered an iSHaRe account and updated his/her user appointment upon the first log-in. Please proceed to register for an account using your official email address (preferably) if you have not. SingHealth and CGH users can log into iSHaRe using their existing ADID and password.

To make any changes to the study role, click "Edit". To remove a member, click "Delete".



Please ensure that for each Principal Investigator/ Site- Principal Investigator appointed, there is a respective site selected in Section B1.

Please also ensure that the profile of the Principal Investigator selected is correct and it matches the capacity under which he/she is performing the study. In the event the Principal Investigator is conducting the study under another capacity (i.e. not his primary appointment), he/she should update the user profile by adding another user appointment. This can be done by clicking on the name at the top right hand corner of the page.

Welcome, Mr Principal Investigator
Logged in time 26-Mar-2015 14:35 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form

Status : Draft

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.

Section B : Study Sites, Study Team & Submission Board

B1. Please select the study sites

(i) SingHealth and Partner Institutions
Singapore General Hospital (SGH)
1 selected

(ii) NHG and Partner Institutions
None

(iii) Other Local sites and Overseas sites

B2. Study Team Members

(i) Add study team member [Add Study Team Member](#)

Name	Study Role	Department	Institution	Designation	CV	CITI	SGGCP	Involve in Informed Consent Process	Action
Mr Principal Investigator	PI	Department of Hand Surgery	Singapore General Hospital (SGH)	Consultant	Complete Remove	Complete Remove	Incomplete	<input type="checkbox"/>	Edit Delete

7. Once the application form has been duly filled up, click on the finalise icon (🔒) found at the top of the page, just below the navigation bar.

Welcome, Mr Principal Investigator
Logged in time 26-Mar-2015 14:35 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form

Status : Draft

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.

Selection of Application Form

Please select the appropriate form for submission to the CIRB.

CIRB Application Form

CIRB Exemption Application Form

Please select the Exemption Application categories.

Category 1 – Normal Educational Practices and Settings

Category 2 – Anonymous Educational Tests, Surveys, Interviews, or Observations

Category 3 – Identifiable Participants in Special Circumstances

Category 4 – Collection of Existing Data

Category 5 – Public Benefit or Service Programs

Category 6 – Taste and Food Evaluation and Acceptance Studies

Category 7 – Reporting of Individual patients' clinical results

Category 8 – Research using unidentifiable data

Category 9 – Commercially available cell lines, anonymous DNAs, RNAs and fixed tissues

Category 10 – Development of Diagnostic Tests



Welcome, Mr Principal Investigator
Logged in time 26-Mar-2015 14:35 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form

Status : Draft

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.

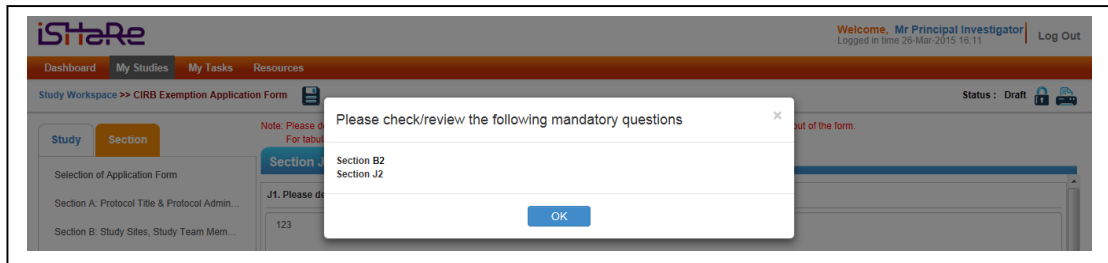
Proceed to Finalise?

[Finalise](#) [Cancel](#)

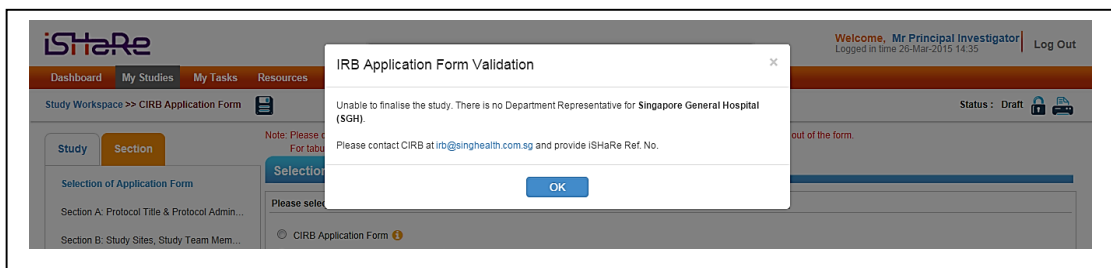


Any user who is part of the study will be able to edit and finalise the application form. Once it is finalised, the application form can only be edited by the Principal Investigator.

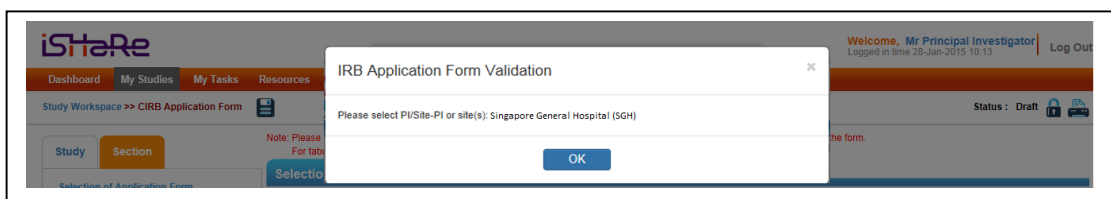
8. By proceeding to finalise, some users may be prompted with certain system messages.
- Users may be prompted that mandatory questions in the application form are not filled up. Please proceed to fill up the relevant sections before finalising. If Section B2 is shown, please ensure that the CV and CITI for all Study Team Members and SGGCP for all Principal Investigators and Site-Principal Investigators conducting clinical trials have been uploaded.



- Users may be prompted that there is no Department Representative. Please provide a screenshot of the message and email CIRB together with the iSHaRe Reference Number of the application form.



- Users may be prompted with system message as shown below. Please ensure that there is a respective site selected for each Principal Investigator/ Site-Principal Investigator appointed in Section B2 (vice versa). If doing the above does not resolve the issue, please provide a screenshot and email CIRB together with the iSHaRe Reference Number of the application form.



9. Upon successful finalisation, the Principal Investigator will be prompted with both system and email notification requesting for PI declaration. This is only applicable when the Principal Investigator is not the creator of the application form. Before proceeding to do so, the Principal Investigator can unlock the application form to make further changes by clicking on the unlock icon (🔓) found at the top of the page, just below the navigation bar.

Welcome, Mr Principal Investigator | Logged in time 26-Mar-2015 14:35 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form

Status : Pending PI Declaration

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.

Selection of Application Form

Please select the appropriate form for submission to the CIRB.

- CIRB Application Form
- CIRB Exemption Application Form

Please select the Exemption Application categories.

- Category 1 – Normal Educational Practices and Settings
- Category 2 - Anonymous Educational Tests, Surveys, Interviews, or Observations
- Category 3 – Identifiable Participants in Special Circumstances
- Category 4 – Collection of Existing Data
- Category 5 – Public Benefit or Service Programs
- Category 6 – Taste and Food Evaluation and Acceptance Studies
- Category 7 – Reporting of Individual patients' clinical results
- Category 8 – Research using unidentifiable data
- Category 9 – Commercially available cell lines, anonymous DNAs, RNAs and fixed tissues
- Category 10 – Development of Diagnostic Tests



Welcome, Mr Principal Investigator | Logged in time 26-Mar-2015 14:35 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form


Status : Pending PI Declaration

Are you sure to unlock this form?

Yes Cancel



Once the application form has been finalised, it will not be editable to any other members in the study unless the Principal Investigator unlocks the form. This can only be done before the Principal Investigator performs the declaration.

10. If there is no changes to be made to the application form after finalisation, the Principal Investigator may proceed to perform the declaration by clicking on the PI Declaration icon () at the top of the page, just below the navigation bar.

Welcome, Mr Principal Investigator | Logged in time 26-Mar-2015 14:35 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form

Status : Pending PI Declaration

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.

Selection of Application Form

Please select the appropriate form for submission to the CIRB.

- CIRB Application Form
- CIRB Exemption Application Form

Please select the Exemption Application categories.

- Category 1 – Normal Educational Practices and Settings
- Category 2 - Anonymous Educational Tests, Surveys, Interviews, or Observations
- Category 3 – Identifiable Participants in Special Circumstances
- Category 4 – Collection of Existing Data
- Category 5 – Public Benefit or Service Programs
- Category 6 – Taste and Food Evaluation and Acceptance Studies
- Category 7 – Reporting of Individual patients' clinical results
- Category 8 – Research using unidentifiable data
- Category 9 – Commercially available cell lines, anonymous DNAs, RNAs and fixed tissues
- Category 10 – Development of Diagnostic Tests



iStare Welcome, Mr Principal Investigator | Log Out
 Logged in time 26-Mar-2015 17:16

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form Status : Pending PI Declaration

Section

- Selection of Application Form
- Section A: Protocol Title & Protocol Admin...
- Section B: Study Sites, Study Team Mem...
- Section C: Conflict of Interest
- Section E: Study Funding Information
- Section F: Research Methodology
- Section I: Study Sites and Recruitment Ta...
- Section J: Exempt Review Criteria
- Section P: Consent Process – Consent ob...
- Other Attachments

Principal Investigator Declaration

Declaration of Principal Investigator

Site : Singapore General Hospital (SGH) Principal Investigator : Mr Principal Investigator

This is the Principal Investigator's Declaration.

I will not initiate this study until I receive approval notification from CIRB and regulatory authority approval (if applicable).

I will not initiate any change in the protocol without prior written approval from CIRB, except when it is necessary to reduce or eliminate any immediate risks to the Study Participant. Thereafter, I will submit the proposed amendment to the CIRB and other relevant authority for approval.

I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that occur in the course of this study.

I will maintain all relevant documents and recognize that the CIRB staff and regulatory authorities may inspect these records.

I understand that failure to comply with all applicable regulations, institutional and CIRB policies and requirements may result in the suspension or termination of this study.

I declare that there are no existing or potential conflicts of interest for any of the study team members participating in this research study and their immediate family members. If there are, I have declared them in the relevant section of this application form.

I confirm that I have read, understood and accept the Principal Investigator's Declaration above.

I Agree Cancel



iStare Welcome, Mr Principal Investigator | Log Out
 Logged in time 26-Mar-2015 14:35

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form Status : Pending PI Declaration

Section

- Selection of Application Form
- Section A: Protocol Title & Protocol Admin...
- 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 and Recruitment Ta...
- Section J: Exempt Review Criteria
- Section P: Consent Process – Consent ob...
- Other Attachments

PI Declaration

Declaration of Principal Investigator

Site : Singapore General Hospital (SGH) Principal Investigator : Mr Principal Investigator

This is the Principal Investigator's Declaration.

I will not initiate this study until I receive approval notification from CIRB and regulatory authority approval (if applicable).

I will not initiate any change in the protocol without prior written approval from CIRB, except when it is necessary to reduce or eliminate any immediate risks to the Study Participant. Thereafter, I will submit the proposed amendment to the CIRB and other relevant authority for approval.

I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that occur in the course of this study.

I will maintain all relevant documents and recognize that the CIRB staff and regulatory authorities may inspect these records.

I understand that failure to comply with all applicable regulations, institutional and CIRB policies and requirements may result in the suspension or termination of this study.

I declare that there are no existing or potential conflicts of interest for any of the study team members participating in this research study and their immediate family members. If there are, I have declared them in the relevant section of this application form.


I confirm that I have read, understood and accept the Principal Investigator's Declaration above.

I Agree Cancel


Authentication

User Name: Investigator Principal
 Login ID: 12345
 Password: [masked]

Confirm Cancel

 Changes to the application form are not allowed after the Principal Investigator has performed the declaration. Any further changes is permitted only if Department Representative, Institution Representative or Research Department Office raises queries on the CIRB application to the Principal Investigator or if the CIRB application has been rejected.

11. The CIRB application will now be ready for Research Department Office check (not applicable to National Cancer Centre and external institutions), Department Representative Endorsement and Institution Representative. The endorser list can be viewed by clicking on the endorser icon (📄) at the top of the page, just below the navigation bar.

 The Department Representative and Institutional Representative have to endorse the study before it can be submitted to CIRB. For multi-site study, the declaration and endorsement for the study site(s) will only occur after the main Principal Investigator has declared.



If there is Conflict of Interest (COI)* for the study, please remember to add in the COI DR/ IR after the endorser list has been generated.

The screenshot shows the 'iStare' interface for a 'CIRB Exemption Application Form'. The 'Endorsers' section is highlighted with a red circle. Below it, two tables list endorser details for SGH and KKH. Red arrows point to the '+ DR' and '+ IR' buttons, indicating where to add Conflict of Interest (COI) information.

Endorsers (Singapore General Hospital (SGH))
 + DR No alternative DR available in the system , please select one
 Note: If there are more than one RDO names , only one RDO check will be performed.

Stage	Name	Role	Endorsement Status	Date	Action
RDO	Ms Research Development Office (RDO)	RDO	Pending	-	
RDO	Mr Research Development Office (RDO)	RDO	Pending	-	
RDO	Mr Research Development Office (RDO)	RDO	Pending	-	
Institution	Mr Institution Representative	IR	Pending	-	

Endorsement Status : Pending RDO Check

Endorsers (KK Women's and Children's Hospital (KKH))
 + IR No alternative IR available in the system , please select one
 Note: If there are more than one RDO names , only one RDO check will be performed.

Stage	Name	Role	Endorsement Status	Date	Action
RDO	Ms Research Development Office (RDO)	RDO	Pending	-	
RDO	Mr Research Development Office (RDO)	RDO	Pending	-	
RDO	Ms Research Development Office (RDO)	RDO	Pending	-	
Department	Mr Department Representative	DR	Pending	-	

Endorsement Status : Pending Site-PI Declaration

*COI occurs when the Department Representative and/or Institution Representative is part of the study.

12. The Research Department Office, Department Representative or Institution Representative may raise a query at any point in time regarding the CIRB application. The Principal Investigator will be notified via system notification if any query is raised.

The screenshot shows the 'iStare' dashboard with a notification highlighted in a red box. The notification is titled 'Message sent on 26-Mar-2015 15:05:40, sent by Ms Research Development Office (RDO)'. It contains details about a query raised by the RDO on a CIRB application, including the protocol title, PI name, and site-PI information. A red arrow points to the 'Protocol Title' link.

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Message sent on 26-Mar-2015 15:05:40, sent by Ms Research Development Office (RDO)

Please respond to query raised by your Research Development Office on the following CIRB Application:

Protocol Title: Application (26/03/2015) [Click here]
 PI Name: Mr Principal Investigator
 Site-PI(s): N.A.
 Query From: Research Development Office (RDO)

By clicking on the Protocol Title, the Principal Investigator will be brought to the application form where he/she may view the comments by clicking on the general comment icon () at the top of the page, just below the navigation bar. The unlock icon () has also appeared on the page for the Principal Investigator to unlock the application form. The Principal Investigator or members involved in the study can make relevant changes to the application form if necessary.

Welcome, Mr Principal Investigator | Logged in time 26-Mar-2015 17:16 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form
Status : Pending Endorsement

Section

Selection of Application Form
 Section A: Protocol Title & Protocol Admin...
 Section B: Study Sites, Study Team Mem...
 Section C: Conflict of Interest
 Section E: Study Funding Information
 Section F: Research Methodology
 Section I: Study Sites and Recruitment Ta...
 Section J: Exempt Review Criteria
 Section P: Consent Process – Consent ob...
 Other Attachments
 Section U: Declaration of Principal Investi...
 Endorsements Page

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.

Selection of Application Form

Please select the appropriate form for submission to the CIRB.

CIRB Application Form
 CIRB Exemption Application Form

Please select the Exemption Application categories.

Category 1 – Normal Educational Practices and Settings
 Category 2 – Anonymous Educational Tests, Surveys, Interviews, or Observations
 Category 3 – Identifiable Participants in Special Circumstances
 Category 4 – Collection of Existing Data
 Category 5 – Public Benefit or Service Programs
 Category 6 – Taste and Food Evaluation and Acceptance Studies
 Category 7 – Reporting of Individual patients' clinical results
 Category 8 – Research using unidentifiable data
 Category 9 – Commercially available cell lines, anonymous DNAs, RNAs and fixed tissues
 Category 10 – Development of Diagnostic Tests

To respond to the comments, the Principal Investigator can click "Reply" in the action column and proceed to enter his/ her comments.

Welcome, Mr Principal Investigator | Logged in time 26-Mar-2015 15:06 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form
Status : Pending Endorsement

Section

Selection of Application Form
 Section A: Protocol Title & Protocol Ad...
 Section B: Study Sites, Study Team Mem...
 Section C: Conflict of Interest
 Section E: Study Funding Information
 Section F: Research Methodology
 Section I: Study Sites and Recruitment Ta...
 Section J: Exempt Review Criteria
 Section P: Consent Process – Consent ob...
 Other Attachments

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.

General Comment

Institution: Singapore General Hospital (SGH)

RDO:

Type	Date	Content	Action
Commented By Development Office (RDO) Research	26-Mar-2015 15:05:40	Dear PI Please amend Section B.	Reply
Commented By Development Office (RDO) Research	26-Mar-2015 15:05:18	Dear PI Please amend Section A.	Reply



Welcome, Mr Principal Investigator | Logged in time 26-Mar-2015 17:16 | Log Out

Dashboard My Studies My Tasks Resources

Study Workspace >> CIRB Exemption Application Form
Status : Pending Endorsement

Section

Selection of Application Form
 Section A: Protocol Title & Protocol Admin...
 Section B: Study Sites, Study Team Mem...
 Section C: Conflict of Interest
 Section E: Study Funding Information
 Section F: Research Methodology
 Section I: Study Sites and Recruitment Ta...
 Section J: Exempt Review Criteria
 Section P: Consent Process – Consent ob...
 Other Attachments
 Section U: Declaration of Principal Investi...

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.

General Comment

Institution: Singapore General Hospital (SGH)

RDO:

Type	Date	Content	Action
Commented By Development Office (RDO) Research	26-Mar-2015 15:05:40	Dear PI Please amend Section B.	
Replied By Investigator Principal	26-Mar-2015 15:08:17	Ok. Done.	
Commented By Development Office (RDO) Research	26-Mar-2015 15:05:18	Dear PI Please amend Section A.	Reply

13. If there are no more queries, the endorsement process will continue.

14. After all endorsements are completed, the CIRB application will be submitted to CIRB for review.

The screenshot displays the iStareRe web application interface. At the top, the user is logged in as 'Mr Principal Investigator' with a 'Log Out' button. The navigation menu includes 'Dashboard', 'My Studies', 'My Tasks', and 'Resources'. The current page is 'Study Workspace >> CIRB Exemption Application Form', with a status indicator 'Pending CIRB Review' highlighted in a red box. The main content area is titled 'Selection of Application Form' and contains 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.' Below the note, there are two sections: 'Please select the appropriate form for submission to the CIRB.' with radio buttons for 'CIRB Application Form' and 'CIRB Exemption Application Form' (the latter is selected), and 'Please select the Exemption Application categories.' with a list of ten categories, each with a checkbox. Category 1 is checked. A left sidebar lists various sections of the application form, such as 'Section A: Protocol Title & Protocol Admin...', 'Section B: Study Sites, Study Team Mem...', 'Section C: Conflict of Interest', 'Section E: Study Funding Information', 'Section F: Research Methodology', 'Section I: Study Sites and Recruitment Ta...', 'Section J: Exempt Review Criteria', 'Section P: Consent Process - Consent ob...', 'Other Attachments', 'Section U: Declaration of Principal Investi...', and 'Endorsements Page'.



Once the CIRB application has been submitted to CIRB, the CIRB Reference Number will be generated. The CIRB Reference Number can be found in “My Studies” and “Study Workspace”.