

e-CIRB Quick Reference Guide – CIRB Comment

1. General Information

- a) With effect from 13 June 2016, a new feature (CIRB Comment) will be added to iSHaRe e-CIRB. This feature will change the mode of correspondences with the Principal Investigator (PI). Future correspondences initiated by the CIRB Secretariat in response to the submission received (i.e. clarifications and modifications required to the research proposal) will be through the CIRB Comment.
- b) Once the comment is received, anyone in the study team can assist to draft the reply or amend the form (if applicable). However, only the PI is able to make the submission to CIRB.
 Note: This is with the exception of LSAE Report Form. The Site-PI and Co-I would be able to perform the actions of the PI.
- c) There can be multiple correspondences on a submission.

2. <u>How to use the CIRB Comment feature?</u>

In general, there would be 2 scenarios wherein CIRB comment are received - without form return and with form return. The step-by-step guide is detailed in Section 2.1 and 2.2 respectively.

When the CIRB comment is sent, the PI, Site-PI (if applicable) and Protocol Administrator (PA) would be notified via system and email notification. An example of the notification is as follow:

Dear Dr Principal Investigator The SingHealth CIRB has raised some comments to your submission. Please log-in to iSHaRe e-CIRB and address the comments.

CIRB Ref: 2015/2015 Protocol Title: Study Closure Report Form (02/03/15) [Click here] Board: Board A Submission Type: Study Closure Report Form PI Name: Dr Principal Investigator Site-PI(s): N.A.

Thank you.

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

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

Image: Email notification when CIRB comment is sent



The comments are accessible via the CIRB Comment icon in the respective forms.

A general rule of thumb: Red icon () = Comment pending reply

Blue icon () = Comment replied

2.1. CIRB comment received without form return

Steps:

- 1a Click on the blue hyperlink text on the email notification.
- 1b If already in iSHaRe,
 - <u>Study team</u> Search for the study via the "Study Listing" or Form Listing".
 - <u>Pl</u>

Click on the "My Study Tasks" blue tile and select the applicable submission.



2 At the study workspace, click on "View" to access the submission which has comments from the CIRB secretariat.

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ishboard My Tasks Notifications	Study Listing Form Listing	Resources News					
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laRe Ref. No. : 201503-00036	CIRB Ref. No. : Protocol No. :		PI : Principal Inve	stigator	Study Sta Valid Till	atus : Date :	
CIRB	Protocol Title : Application (01	/04/2016)			2010-10-000		
IACUC	Amendment S	tudy Renewal Report tudy Closure Report tudy Reactivation Re	rt Form Form eport Form	Protocol Deviation LSAE Report Forr Other Reportable	V Non-Compliance Rep m Events Report Form		
	Pending Documents	Attachments					
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	S/No. Document					Version Date 🔻	Actions
	1 CIRB Application Form	n	Draft	1	01-Apr-2016 18:17:04	11-Apr-2016	View
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3 Click on the red "CIRB Comment" icon.

iShe	Re						Welcome, Ms Protocol Administrator Logged in time 11-Apr-2016 14:30	Log Out
Dashboard	My Tasks	Notifications	Study Listing	Form Listing	Resources	News		
Study Workspa	ace >> CIRB /	Application Form	ab ∖⇒ac				Status : Pending PI Rept	P 🚔



4 Click on the "Reply" hyperlink and you will be directed to the inbox where you can view the comments.

	Subject	Form Returned for Amendment	Status	Received Date	Replied Date	Updated Date	Last Updated By	Action
1	CIRB Comments - CIRB Ref 2016/2016 : Application (01/04/2016)	No	Pending Reply	11-Apr-2016 17:01	-	-	-	Reply

CIRB Comment

CIRB Comment

Inbox > Comment	é	
CIRB Application Form (Versi	<u>on 1)</u>	
CIRB Comments - CIRB Ref 2016/201	6 : Application (01/04/2016)	
- Sent Date : 11-Apr-2016 17:01		
Dear A/Prof Principal Investigator		
CIRB Ref No.:	2016/2016	
Protocol Title:	Application (01/04/2016)	
Submission Type:	CIRB Application Form (Version 1)	
The CIRB reviewed the submission	and would like to request for the following clarification/amendment:	
1. Please clarify		
2. Please clarify		

5 After reading the comments, scroll down to the bottom of the panel and click "Reply".

Note: The button to click will be "Edit Reply", if you're re-accessing the comments after it has been saved before.

CIRB Comment

	Protocol Title:	Application (01/04/2016)		•	
	Submission Type:	CIRB Application Form (Version 1)			
	The CIRB reviewed the submission	and would like to request for the following clarification/amendment:			
	1. Please clarify				
	2. Please clarify				
	Thank you.				
	Ms Board Secretariat	I Deview Beard			
	Email: boardsecretariat@singhealt	h.com.sg			
	DID: 6111 111				
	Form was not returned for amend	Iment. You would not be able to edit the form.			
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		Reply Cancel			

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Proceed to enter your reply in the relevant textboxes. 6

CIRB Comment	×
Inbox > Comment > Reply	
CIRB Application Form (Version 1)	
CIRB Comments - CIRB Ref 2016/2016 : Application (01/04/2016)	
The CIRB reviewed the submission and would like to request for the following clarification/amendment:	
1. Please clarify	
2. Please clarify	
Other Comments (if applicable)	

Click on "Save" after you are done drafting the reply. 7 **CIRB** Comment

i.			

I clarify that		
hor Commonts (if applicable)	 	
May I know		
nank you.		

Study team drafts the reply 8 -

Inform your PI the reply has been drafted and ready for submission. Following Step 1 - 4 to access the CIRB comment, the PI would need to click on the "Send Reply" button to submit the reply to CIRB.

If further changes are required to the drafted reply, click in the "Edit Reply" button. Thereafter, to submit the reply to CIRB, inform your PI. He/she would need to click on the "Send Reply" button.

PI drafts the reply _

After clicking on the "Save" button at Step 7, the PI will be directed to the panel as shown below. Click on the "Send Reply" button if the reply is ready for submission to CIRB.



If further changes are required to the drafted reply, click on the "Edit Reply" button. Thereafter, to submit the reply to CIRB, click on the "Send Reply" button.

CIRB Comment

Submission Type:	CIRB Application Form (Version 1)	-
The CIRB reviewed the subr	mission and would like to request for the following clarification/amendment:	
1. Please clarify		
 Please clarify Glarify that Other Comments 		
May I know Thank you.		1
Ms Board Secretariat SingHealth Centralised Instit Email: boardsecretariat@sin DID: 6111 111	tutional Review Board Ighealth.com.sg	
Form was not returned for a	amendment. You would not be able to edit the form.	
	Edit Reply Send Reply Cancel	

2.2. CIRB comment received with form return

Steps:

1a Click on the blue hyperlink text on the email notification.

- 1b If already in iSHaRe,
 - <u>Study team</u> Search for the study via the "Study Listing" or Form Listing".
 - <u>Pl</u>

Click on the "My Study Tasks" blue tile and select the applicable submission.





2 At the study workspace, click on "Edit" to access the submission which has comments from the CIRB secretariat.

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Workspace	Study Listerig	Resources news					
dy							
Re Ref. No. : 201503-00036	CIRB Ref. No. : Protocol No. : Brotocol Title : Application (0)	11/04/2016)	PI : Principal Investigate Approval Date :	or	Study Sta Valid Till	itus : Date :	
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IACUC	CIRB Application Amendment	Study Renewal Report Study Closure Report F Study Reactivation Rep	Form Pro Form LS port Form Ot	otocol Deviatior SAE Report Forr ther Reportable	i/ Non-Compliance Rep n Events Report Form		
	Pending Documents	Attachments					
	H I F H	50 • items per page					1 - 1 of 1 item:
	S/No. Document					Version Date v	Actions
		(m)	Deall	1	01-Apr-2016 18:17:04	11-Apr-2016	6
	1 CIRB Application Fo		Dialt	10		11-Apr-2010	Ealt

3 Click on the red "CIRB Comment" icon.

iSHa	Re						Welcome, Ms Protocol Administrator Logged in time 11-Apr-2016 14:30
Dashboard	My Tasks	Notifications	Study Listing	Form Listing	Resources	News	
Study Worksp	ace >> CIRB /	Application Form	ab ∖≻ac				Status : Pending PI Rept

4 Click on the "Reply" hyperlink and you will be directed to the inbox where you can view the comments.

CIRB Comment

	Subject	Form Returned for Amendment	Status	Received Date	Replied Date	Updated Date	Last Updated By	Action
1	CIRB Comments - CIRB Ref 2016/2016 : Application (01/04/2016)	No	Pending Reply	11-Apr-2016 17:01	-	-	-	Reply

CIRB Comment

Inbox > Comment			
CIRB Application Form (Version 1)			
CIRB Comments - CIRB Ref 2016/2016 : Application (01/04/2016)			
- Sent Date : 11-Apr-2016 17:01			
Dear A/Prof Principal Investigator			
CIRB Ref No.:	2016/2016		
Protocol Title:	Application (01/04/2016)		
Submission Type:	CIRB Application Form (Version 1)		
The CIRB reviewed the submission and would like to request for the following clarification/amendment:			
1. Please clarify			
2. Please clarify			
1			

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5a You may choose to either amend the form or reply to the CIRB comment. Both actions can be done in either sequence.

To reply to the comments, scroll down to the bottom of the panel and click "Reply".

Note: The button to click will be "Edit Reply", if you're re-accessing the comments after it has been saved before.

CIRB Comment

Protocol Title:	Application (01/04/2016)
Submission Type:	CIRB Application Form (Version 1)
The CIRB reviewed the su	bmission and would like to request for the following clarification/amendment:
1. Please clarify	
2. Please clarify	
Thank you.	
Ms Board Secretariat SingHealth Centralised In Email: boardsecretariat@s DID: 6111 111	stitutional Review Board inghealth.com.sg
Form was returned for ar	nendment.
	Reply Cancel

Proceed to enter your reply in the relevant textboxes.

CIRB Comment	×
Inbox > Comment > Reply	 •
CIRB Application Form (Version 1)	
CIRB Comments - CIRB Ref 2016/2016 : Application (01/04/2016)	
The CIRB reviewed the submission and would like to request for the following clarification/amendment:	
1. Please clarify	
Other Comments (if applicable)	Ŧ

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5b To edit the form, scroll down to the bottom of the panel, click "Cancel" and close the panel.

After you are done making changes to the form, follow Step 3 – 5a to access the comment and reply accordingly.

CIRB Comment

Protocol Title:	Application (01/04/2016)	
Submission Type:	CIRB Application Form (Version 1)	
The CIRB reviewed the su	bmission and would like to request for the following clarification/amendment.	
1. Please clarify		
2. Please clarify		
Thank you.		
Ms Board Secretariat		
SingHealth Centralised Ins Email: boardsecretariat@s	indhealth.com.so	
DID: 6111 111	ing react, contag	
Form was returned for an	nendment.	
	_	
	Reply Cancel	

6 Click on the "Save" button to save the reply entered.

If no more change is required, check the checkbox and click "Save".

Note: Once checkbox is checked, the "Finalise" icon will appear in the form. CIRB Comment

	•
Other Comments (if applicable)	
Thank you.	
Please check if the reply is ready for submission. - Once the checkbox is checked, the form can then be finalized for submission together with the reply. - If changes need to be made to the finalized form and reply, the PI would need to unlock the form. - To submit, the PI would need to click on the "PI Submit" icon.	
Save Cancel	Ŧ

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7 Click on the "Finalise" icon.

iS HaRe			Welcome, Ms Protocol Administrator Logged in time 11-Apr-2016 14:30 Log Out
Dashboard My Tasks Notifications	Study Listing Form Listing	Resources News	
Study Workspace >> CIRB Application Form			Status : Pending PI Reply 🎧 🍙 🚔

<u>Study team drafts and finalise</u>
 The status of the form will be changed to "Pending PI Submit".

Inform your PI the reply and form are ready for submission. Following Step 1 and 2, the PI would need to click on the "PI Submit" icon to submit the reply and form to CIRB.



Note: After finalisation, the form and reply will not be editable.

If further changes are required to the drafted reply or form, please contact the PI to unlock the form by clicking on the "Unlock" icon. Only the PI has access to perform this action.

Study Workspace	>> CIRB Application Form			ab Sac
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Thereafter, finalise the form again. To submit the reply and form to CIRB, inform your PI. He/she would need to click on the "PI Submit" icon.

- PI drafts and finalise

PI will be prompted as shown below. Clicking "Ok" will submit the form and reply to CIRB.

Do you want to submit the Application Form to CIRB?

Ok Close

If further changes are required to the drafted reply or form, click on the "Close" button. Thereafter, to submit the reply and form to CIRB, finalise and proceed with the submission to CIRB.

3. Contact Us

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