# Hospital Authority CRER Portal

# **User Manual for Applicant**

Date: 28 Sep, 2022



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<ul> <li>6. N</li> <li>6.1.1</li> <li>6.1.2</li> <li>6.1.3</li> <li>6.1.4</li> <li>6.1.5</li> <li>6.1.6</li> <li>6.1.7</li> <li>6.1.8</li> <li>6.2</li> </ul>	ANAGE AN APPLICATION (POST-APPROVAL) CREATION OF POST APPROVAL ACTIVITIES FOR APPROVED INITIAL APPLICATION CREATE POST APPROVAL DOCUMENT DISCARD POST APPROVAL DOCUMENT SUBMIT POST APPROVAL DOCUMENT RETURNED POST APPROVAL DOCUMENT RE-SUBMIT / WITHDRAW RETURNED POST APPROVAL DOCUMENT CONFIRMED POST APPROVAL DOCUMENT FOR REVIEW POST APPROVAL DOCUMENT APPROVED/ACKNOWLEDGED/DISAPPROVED POST APPROVAL DOCUMENT	90 91 99 100 106 109 116 117 118 120
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# 1. Introduction

Welcome to the Hospital Authority Clinical Research Ethics Review Portal (Portal) User Manual. This user manual is designed to provide guidance for Applicant to use the new Portal. In the coming sections, we will go through the stage 2 functions of the portal.

If you have any enquiries, you can press **Contacts** button to get the contact info of CREC/IRB Office or Press **[Click here]** to the User Manual and Quick User Guide.

	Forgot Password
Remember Lines and Date	Except Descure
Applicant	*
Role	
Password	Ø
Email	
ion't have an account? Sign Up	Resend Account Activation

	User Manual and Quick User Guide	[Click here]
Enquirie	es (Mon - Fri, 09:00 - 17:30, except P	ublic Holiday)

Supported Browsers - Chrome or Firefox in Windows OS/Mac OS Optimized Screen resolution - 1920 x 1080 or 1280 x 1024

#### Figure 1.1 Action button for Contact Info and User Manual and Quick User Guide

Contacts					
CCO / Central IRB:					
Tel: 2300 6431 / 2300 70	54	Email: hacco@ha.o	org.hk		
Central IRB – Paed Pan	el:				
Tel: 3513 3193 / 3513 64	85	Email: hkch.ro@ha.	org.hk		
HKU/HA HKW IRB:					
Tel: 2255 4086 / 2255 39	23 / 2255 6788	Email: hkwirb@ha.c	org.hk		
The Joint CUHK-NTEC	CREC:				
Tel: 3505 3935 / 3505 42	75 / 2144 5926	Email: crec@cuhk.e	du.hk		
0050 //00 0// *	Oractural		*	Freed	
CREC/IRB Office 1	Contact		Ļ	Email	,†
HKEC	2595 6451 / 2595 9	5561		hkececsec@ha.org.hk	
KCC / KEC	3506 8152 / 3506 8	B642		kckecrec@ha.org.hk	
KWC	2990 1047 / 2990 3	3698 / 2990 1017		kwcrec@ha.org.hk	
NTWC	3767 7866			ntwcrec@ha.org.hk	
For General (HA Head Office)					
Tel: 2300 8527		Email: crerportal@h	na.org.hk		
					Close

Figure 1.2 Pop-up dialog for Contact Info



You can view the latest News from Head Office in the pop-up screen after pressing the **News** button in the Login Page.

Login	
Don't have an account? Sign Up	Resend Account Activation
Email	
Password	Q
Applicant	▼
Remember User And Role	Forgot Password
Login	
NEWS	CONTACTS

Figure 1.3 Action button for News

News	
Muti-cluster Applications	
With effect from 1 April 2021, the applicant could choose to submit the following multi-cluster applications to C Review Board (Central IRB) for review:	entral Institutional
- Multi-cluster clinical trials related to COVID-19	
- Multi-cluster retrospetive studies	
- Multi-cluster prospective stusies (except investigator-initiated clinical trials)	
For details, please visit Central IRB intranet	
	Close
	01036

Figure 1.4 Pop up dialog for News



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## 2. System Prerequisite

This Portal is accessible with Internet. You can use Portal with browsers, **Google Chrome** or **Firefox** in Windows OS/Mac OS. Optimized Screen resolution is 1920 x 1080 or 1280 x 1024.

Please type the URL (<u>https://hacrerportal.ha.org.hk</u>) in address bar to go to Login Page of the portal.

Broadcast message, such as server maintenance message will be shown in the top of the Login Page as Figure 2.1.

Server Maintenance Sched The Protal will be temporar	ule (Updated on 13 Apr 2021) ily unavailable as follows due to serv	ver maintenance. Please refrain f	from use to avoid data loss.
Date: Every Monday & Thursday 28 Apr 2021	Time: 04:00 - 06:00 20:00 - 23:59		
	Login		
	Don't have an account? Sign Up Email	Resend Account Activation	
	Password	2	
	Applicant	•	
	Remember User And Role	Forgot Password	
	Logir	1	
	NEWS	CONTACTS	

Supported Browsers - Chrome or Firefox in Windows OS/Mac OS Optimized Screen resolution - 1920 x 1080 or 1280 x 1024 User Manual and Quick User Guide [Click here]

Enquiries (Mon - Fri, 09:00 - 17:30, except Public Holiday)

Figure 2.1 Login Page of the Portal



## 3. Preparation Stage

## 3.1 Sign Up User Account for Applicant

Applicant users are required to register an applicant account on the new Portal before they can access to the system to submit an application for a clinical research ethics review.

## 3.1.1 New Applicant with an authorized email account

Email addresses configurable by HO administrator as following are the authorized email accounts.

- @ha.org.hk
- @hku.hk
- @hkucc.hku.hk
- @pathology.hku.hk
- @cuhk.edu.hk
- @connect.hku.hk
- @clo.cuhk.edu.hk
- @ent.cuhk.edu.hk
- @ort.cuhk.edu.hk
- @link.cuhk.edu.hk
- @nur.cuhk.edu.hk
- @surgery.cuhk.edu.hk

If you have a system authorized email account, please follow the below steps to create a new user account on the portal.

1. Click Sign Up button in the Login Page, Figure 3.1.1.1;

THA Clinical Research Ethics Review Portal				
Server Maintenance Sched The Protal will be temporar	Server Maintenance Schedule (Updated on 13 Apr 2021) The Protal will be temporarily unavailable as follows due to server maintenance. Please refrain fror			
Date: Every Monday & Thursday 28 Apr 2021	Time: 04:00 - 06:00 20:00 - 23:59			
	Login			
	Don't have an account? Sign Up	Resend Account Activation		
	Password	\$		
	Applicant Remember User And Role	▼ Forgot Password		
	Login	CONTACTS		
			User Manual and Onick User Guide [Olicy have]	
Supported Browsers - Chrome or Firefox in Windows OS/Mac OS Optimized Screen resolution - 1920 x 1080 or 1280 x 1024			Enquiries (Mon - Fri, 09:00 - 17:30, except Public Holiday)	

Figure 3.1.1.1 Login Page



2. A Sign-Up Form as Figure 3.1.1.2 will be popped up to type authorized email account with domain mentioned above;

Sign Up	
demo@ha.org.hk	
Title	
First Name	Surname
Hospital / Institution	Ŧ
Contact Number	
Password	S.
Confirm Password	Ø
< Back	Submit

Figure 3.1.1.2 Sign-Up Form for an authorized email account

- 3. Fill in User Information, such as Title, Name and Contact Number;
- 4. Select Hospital/Institution from dropdown menu;
- 5. Type Password according to its rules and Confirm Password;
  - a. Min length 8, contains at least 1 numeric character, 1 upper case and 1 lower case character
  - b. Password & Confirm Password are the same
- 6. Press **Submit** button for sign up;
- 7. You will receive an account activation email as Figure 3.1.1.3 after registration. Please follow the instructions for next step.

Dear Sir/Madam,

Welcome to Hospital Authority Clinical Research Ethics Review Portal (HA CRER Portal).

Please click here to activate your account.

Should you have any queries, please contact HA Central Coordinating Office at <u>hacco@ha.org.hk</u>. More contact information is available at <u>https://hacrerportal.ha.org.hk</u>.

Yours faithfully, HA CRER Portal

[This is an auto-generated email. Please DO NOT REPLY.]

#### Figure 3.1.1.3 Example of Account Activation Email



## 3.1.2 New Applicant with an unauthorized email account

If you <u>do not have</u> an authorized email account (refer to <u>Section 3.1.1</u> for authorized email domain), you can still create a user account on the portal as below steps.

1. Click Sign Up button on the Login Page as Figure 3.1.2.1;

HA Clinical Res	earch Ethics Review Portal					
	Server Maintenance Schedu The Protal will be temporari	le (Updated on 13 Apr 2021 ly unavailable as follows due	I) e to server maintenanc	e. Please refrain fr	rom use to avoid data loss.	
	Date: Every Monday & Thursday 28 Apr 2021	Time: 04:00 - 0 20:00 - 2:	06:00 3:59			
		Login	Resence	Account Activation		
		Email				
		Password Role Applicant		Ø.		
		Remember User And Role		Forgot Password		
		NEWS	Login	ACTS		
Supported Browsers - Chrom Optimized Screen resolution -	e or Firefox in Windows OS/Mac OS - 1920 x 1080 or 1280 x 1024				User Manual and Quick User Guide Enquiries (Mon - Fri, 09:00 - 17:30, except #	[Click here] Public Holiday)



- 2. A Sign-Up Form as Figure 3.1.2.2 will pop up for you to type non-System authorized email account without domain mentioned in <u>Section 3.1.1</u>;
- 3. Fill in User Information, such as Title, Name and Contact Number;
- 4. Select Hospital/Institution from dropdown menu, or fill in Hospital/Institution in text box;
- 5. Type Password according to its rules and Confirm Password;
  - a. Min length 8, contains at least 1 numeric character, 1 upper case and 1 lower case character
  - b. Password & Confirm Password are the same
- 6. Provide details in Justification, which will be sent to CCO for review;
- 7. Press Submit button for CCO's approval;



Sign Up	
demo@testing.com	
Title	
First Name	Surname
Hospital / Institution	
Contact Number	
Password	Ø
Confirm Password	Ø
Justification *	
*Please give justification for using non-HA	authorized email address
< Back	Submit

Figure 3.1.2.2 Sign-Up Form for unauthorized email account

8. Once CCO approves the request for account registration, you will receive an account activation email as Figure 3.1.2.3. Please follow the instructions for next step.

Dear Sir/Madam,	
Welcome to Hospital Authority Clinical Research Ethics Review Porta	l (HA CRER Portal).
Please click here to activate your account.	
Should you have any queries, please contact HA Central Coordinating More contact information is available at <u>https://hacrerportal.ha.org.hk</u> .	Office at <u>hacco@ha.org.hk</u> .
Yours faithfully, HA CRER Portal	
[This is an auto-generated email. Please DO NOT REPLY.]	

Figure 3.1.2.3 Example of Account Activation Email



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## 3.2 Resend Account Activation

If you do not activate your registered email within 30 days, the activation link will be expired. Account reactivation email needs to be requested by clicking **Resend Account Activation** button in the Login Page as Figure 3.2.1.

HA Clinical Research Ethics Review Portal			
Server Maintenance Schedu The Protal will be temporari	ule (Updated on 13 Apr 2021) ily unavailable as follows due to serve	er maintenance. Please refrain f	rom use to avoid data loss.
Date: Every Monday & Thursday 28 Apr 2021	Time: 04:00 - 06:00 20:00 - 23:59		
	Login		
	Don't have an account? Sign Up	Resend Account Activation	
	Password	Q	
	Applicant	▼ Forgot Password	
	Login	CONTACTS	
			User Manual and Ouick User Guide Tolini, haral
Supported Browsers - Ohrome or Firefox in Windows OS/Mac OS Optimized Screen resolution - 1920 × 1080 or 1280 × 1024			Enquiries (Mon - Fri, 09:00 - 17:30, except Public Holiday)

Figure 3.2.1 Action button for Account Reactivation

- 1. Type your registered email as Figure 3.2.2;
- 2. Press Send button for requesting reactivation link;

Resend Account Activation?
Please enter your email or contact support@ha.org.hk for other enquiry
Email
Send
Back to Login

Figure 3.2.2 Popup dialog for Account Reactivation



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3. Activation link will be sent to your registered email as Figure 3.2.3.

Dear Sir/Madam,

We have received your account reactivation request through Hospital Authority Clinical Research Ethics Review Portal (HA CRER Portal).

Please click <u>here</u> to reactivate your account.

Should you have any queries, please contact HA Central Coordinating Office at <u>hacco@ha.org.hk</u>. More contact information is available at <u>https://hacrerportal.ha.org.hk</u>.

Yours faithfully, HA CRER Portal

[This is an auto-generated email. Please DO NOT REPLY.]

#### Figure 3.2.3 Example of Account Reactivation Email



## 3.3 Login

Once your account registration is activated, you can login to the portal as the following steps:

- 1. Type Email Address you registered and Password;
- 2. Select "Applicant" Role from dropdown menu;
- 3. Tick the checkbox if remembering User and Role is needed;
- 4. Press Login button to proceed.

Forgot Password
•
Ø
Resend Account Activation

Figure 3.3.1 Login Page

Timeout Session of CRER Portal is 12 hours since login. "Session Expired" message will be prompted if the session is timeout.



Figure 3.3.2 Popup message for session expired

Only 1 session is allowed per user. If multiple logins are detected, "Your account has been logged-in in another location" will be prompted.



Figure 3.3.3 Popup message for multiple users' login



You are advised to make sure your email address, password and user roles are matched when login. Your account will be locked after 5 failed logins with incorrect password or user roles. A pop-up message as Figure 3.3.4 will be prompted. You can then contact HO Admin for help or use "Forgot Password" to reset your password if you have forgotten your password. Refer to <u>Forgot Password</u>.

Error from server	
Account is locked / disabled. Please contact HO Adm	iin.
	Confirm

Figure 3.3.4 Popup message after 5 failed logins



## 3.4 Forgot Password

If you have forgotten your password, you can follow the below steps to reset your password.

1. Click Forgot Password button in the Login Page as Figure 3.4.1;

啦 HA Clinical Research Ethics Review Portal		
Server Maintenance Schedu The Protal will be temporari	ile (Updated on 13 Apr 2021) Iy unavailable as follows due to server maintenance. Please refra	in from use to avoid data loss.
Date: Every Monday & Thursday 28 Apr 2021	Time: 04:00 - 06:00 20:00 - 23:59	
	last	
	Login Dont have an account? Sign Up Resend Account Activatio	n. T
	Password 🔌	
	Applicant	70
	Login NEWS CONTACTS	ī
Supported Browsers - Chrome or Firefox in Windows OS/Mac OS		User Manual and Quick User Guide [Olick here]
Uptimized Screen resolution - 1920 x 1080 or 1280 x 1024		

Figure 3.4.1 Action button for Password Reset

2. A pop-up dialog for requesting password reset will appear as Figure 3.4.2;



Figure 3.4.2 Popup dialog for Password Reset

- 3. Type your registered email in the text box;
- 4. Press Reset Password button to proceed;



5. Reset Password Link will be sent to your registered email as Figure 3.4.3.

#### Dear Sir/Madam,

We have received your reset password request through Hospital Authority Clinical Research Ethics Review Portal (HA CRER Portal). Please click <u>here</u> to reset your password.

Should you have any queries, please contact HA Central Coordinating Office at <u>hacco@ha.org.hk</u>. More contact information is available at <u>https://hacrerportal.ha.org.hk</u>.

Yours faithfully, HA CRER Portal

[This is an auto-generated email. Please DO NOT REPLY.]

Figure 3.4.3 Example of Reset Password Email



# 4. Introduction of Applicant's Landing Page4.1 Landing Page Layout of Applicant

Logout
ר
rd

Figure 4.1.1 Landing Page of Applicant

#### 1. Left Menu Bar

The Left Menu Bar contains all the available functions accessed by Applicant, including Dashboard, Search, User Profile, Initial Application List, Post Approval Document List and Useful Information/ User Manual Section by clicking on the menu items.

The icon is designed to minimize the menu bar and enlarge the function display area.

2. Login User & Last Login Datetime & Current Role

After user login, the user's name (First name + Last name), Last Login Datetime and Current Role will be displayed. User is allowed to switch to other assigned roles, if any, by selecting from dropdown list.

3. Notification

After clicking the **Notification Bell** button, notification messages will be displayed. Notification with blue line on the left means unread message. The retention period of notification will be 90 days.

• No. = the no. of unread notifications. No. will be 999+ if over 1000 unread notifications

When mouse clicks on the specific notification message, the message will be marked as read and direct to the particular application form for further action.

Click **Mark All As Read** button will mark all the notifications read. The number of unread messages will be reset.

4. Logout

After clicking **Logout** button, you will log out from the current user account and direct to Login Page.



## 4.2 Dashboard

Dashboard is designed to display the number of Initial Applications or Post Approval Documents in Draft or Returned status. You can click the number to direct to the list of Initial Application/Post Approval Document in Draft/Returned status.

= 🍈 HA Clinical Resear	rch Ethics Review Portal		Taiman Chan Last Login: 2022-04-27 10:14	Applicant -
A Dashboard	Home			
Q, Search	Dashboard		ſ	Current
Profile	Applications		L	Role
Initial Applications 🗸	Draft <u>5/5</u>	Returned		
Post Approval Document ~		Expire in ≥ 30 days (Q)		
Useful Information/User Manual		Expire in < 30 days (0)		
FN Version: v0.936				
BN: VU.468 Dulid at 20220426 14:45	Post Approval Documents			
	Draft 2/2	Returned		
		Expire in ≥ 30 days (Q)		
		Expire in < 30 days (Q)		
			Dashboard	

Figure 4.2.1 Dashboard Page of Applicant

Below is the summary of the status on Dashboard.

Status	Description
Draft (a/b)	Initial Applications/Post Approval Documents in draft status
	<b>a:</b> No. of draft Initial Application or Post Approval Document required further action by Applicant
	<b>b:</b> No. of draft Initial Application or Post Approval Document related to Applicant
Returned (a/b)	Initial Applications/ Post Approval Documents returned from CCO/Cluster Admin/ Secretary.
	<b>a:</b> No. of returned Initial Applications or Post Approval Documents required further action by Applicant
	<b>b:</b> No. of returned Initial Applications or Post Approval Documents related to Applicant
Expire in < 30 days (a)	Less than 30 days before the expiry date set by CCO/Cluster Admin/Secretary for the returned Initial Application or Post Approval Document
Expire in ≥ 30 days (a)	More than 30 days before the expiry date set by CCO/Cluster Admin/Secretary for the returned Initial Application or Post Approval Document



## 4.3 Search Page

You can search Initial Application or each type of Post Approval Document. In search page, you can select the criteria from the dropdown menu or input keywords in the field of basic or advanced search criteria as Figure 4.3.1. You can press **Reset** button to clear all inputted values.

= 💠 HA Clinical Researc	ch Ethics Review Portal	Taiman Chan Applicant 🗸 👫 Logout
A Dashboard	Home > Search	
Q Search	Search Reset Export To XLS Download	
Profile	— Search Criteria	
Initial Applications 🗸	Basic Search	
🚯 Post Approval Document 🗸 🗸	Document Type - CRER Application No Submission Ref No.	IRB/REC Ref No.
Useful Information/User Manual	Scientific Title	
FN Version: v0.936	- Advanced Search	
BN: v0.468 build at 20220426 14:45	Submission Date (From)	Study Article
	Name of Sponsor	
	Search Results	
	Hide/Show Columns	Filter keyword Page Size: 10 -
	Pending         CRER Application No.         T <sub>j</sub> IRB/REC Reference No.         T <sub>j</sub> Submission No.         T <sub>j</sub>	$\begin{array}{cc} \mbox{Scientific Title} & \uparrow_{\downarrow} & \mbox{Coordinating} & \uparrow_{\downarrow} \\ \mbox{Investigator (CI)} & \end{array}$
	🛕 No Data	
	4	+
	Showing 0 to 0 of 0 entries	< >

Figure 4.3.1 Application Search

Result will be shown in below result table as Figure 4.3.2, based on the inputted values in search criteria after pressing **Search** button. **Export to XLS** button will be enabled for user to export the result data of Initial Application in excel file.

= 💠 HA Clinical Resea	rch Ethics I	Review	Portal			Tair <sub>Last</sub>	man Chan Login: 2022-08-23 10:47	Applicant 👻	Z12 Logou	ut
A Dashboard	<u>Home</u> >	Search								
Q, Search	Search	Rese	et Exp	ort To XLS Download						^
Profile	— Sear	rch Criteri	a							1
New Draft Sent Returned Approved	Basic S Docum Initia Scien + A Search Re	Search nent Type — al Applicati itific Title dvanced S esults	earch	CRER Applicatio     NTEC-2022-	in No	Submission Ref No.	IRB/	REC Ref No.		
Completed Acknowledged Expired	Hide/Sh	ow Colum	ns Coll	CREP Application	IRB/REC Deference		Filter keyword		Page Size	l
Archived			Pending	No.	No.	Submission No. $\uparrow_{\downarrow}$	Scientific	Title ↑↓	Investigator	
All	+		()	NTEC-2022-065		20220516-015-000	Test	:	site pi'	-
HA REC Standardxlsx A									Show all	×

Figure 4.3.2 Result table after application search



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## 4.3.1 Initial Application Search

To adjust the column display for Initial Application, you can press **Hide/Show Columns** button to select/unselect checkboxes for columns shown in the Initial Application result table.

- Press "+" button to display all Post Approval Documents under the specific Initial Application. If there is no Post Approval Document under the Initial Application, "+" button will be disabled.
- Press "^" button to collapse all Post Approval Documents and display the specific Initial Application only.
- Press **Collapse All** button to display the Initial Application list only and hide the Post Approval Document list if any.
- Press **Expand All** button to display the Post Approval Document list under the corresponding Initial Application if any.

Also, in Initial Application result table, a checkbox will be shown on the left for downloading Initial Applications. Only one checkbox can be selected at a time.

You can follow the below steps to download Initial Applications:

- Select "Initial Application" in Document Type and input search criteria if any; (The disabled **Download** button will then change to disabled **Download Application** button.)
- Click Search button, select checkbox for the specific Initial Application. The Download Application button will be enabled accordingly; (If the Initial Application is in Draft status, the checkbox will be disabled and not allow user to download the corresponding document.)
- 3. Press the **Download Application** button to download the selected document;
- 4. A zip file named <Submission No.> <Scientific Title> which includes all relevant documents will be downloaded if a specific Initial Application is selected as Figure 4.3.1.1.
  - a. If the selected Initial Application is in Approved status, only approved or acknowledged Post Approval Documents will be included in zip file.

$\equiv$ $$ HA Clinical Researce	Taiman Chan Applicant 👻 🔓 Logout						
A Dashboard	Home > Search						
Q Search	Search Reset Export To XLS Download Application						
Profile	— Search Criteria						
<ul> <li>Initial Applications ~</li> <li>Post Approval Document ~</li> <li>Useful Information/User Manual</li> </ul>	Basic Search     Document Type       Initial Application     CRER Application No       Scientific Title	IRB/REC Ref No.					
FN Version: v1.007 BN Version: v0.530	Hide/Show Columns Collapse All Expand All Filter keyword						
	Pending         CRER Application No.         1 L         IRB/REC Reference No.         1 L         Submission No.         1 L         Scientific	Title 1 Coordinating 1 Status					
	▶ VIEC-2022-066 REC-2022-016 20220516-016-000 Tes	t site pl1 Approved					
	Submission no 1 Document Type 1 Status 1 Last Modification Date 1	Expiry Date $\uparrow_{\downarrow}$ Action					
	20220516-016-001 <u>Amendment Form (CUHK)</u> Withdrawn 2022-05-16 15 08:00	2022-08-14 -					
	20220516-016-002 <u>SUSAR Report (Study Info)</u> Withdrawn 2022-05-16 14:40:50	2022-05-19 -					
📨 20220516-016-000zip 🔨		Show all X					

Figure 4.3.1.1 Download Initial Application



## 4.3.2 Post Approval Document Search

To adjust column display for Post Approval Document, you can press **Hide/Show Columns** button to select/unselect checkboxes for columns shown in the Post Approval Document result table.

- Press **Scientific Title** in the result table to view relevant Post Approval Document(s) under the same Initial Application in right context menu as Figure 4.3.2.1;
- Press the hyperlink of **Scientific Title** in the right context menu to download the Initial Application in PDF format;
- Press the hyper link of **Document Type** in the right context menu to download the uploaded signed document of specific Post Approval Document;
- Press "<" or ">" in the context menu to expand or collapse the details of relevant Post Approval Documents as Figure 4.3.2.2.

= 💠 HA Clinical Researc	ch Ethics I	Review Portal		Lucky Lee Last Login: 202	2-07-12 17:22 Applicant ▼ Logout
Dashboard	<u>Home</u> >	Search			
Q Search	Search	Reset Export		nent	Post approval document ×
e Profile	— Sear	ch Criteria			
New Draft Sent Returned	Basic S Docum Progr Scient	earch ent Type ress Report 👻 CR ific Title dvanced Search	ER Application No Submission Ref No.	IRB/REC Ref No.	Initial Application IRB/REC Reference No.: irb flow'~~ Scientific Title: Initial Application contains all Post Approval Documents CI-Lucky Lee Status:Approved
Approved	Search Re	sults			Other Relevant Post-Approval Documents:
Completed Acknowledged	Hide/Sho	ow Columns	Filter keyword	Page Size	Local SAE Report (NLTH) Protocol Deviation Report (NLTH) Final Report (Study Info)
Expired Archived		Submission No. $\uparrow_{\downarrow}$	Scientific Title $\uparrow_\downarrow$	Document Type 1	Miscellaneous Report (Study Info)
All		20220609-001-007	Initial Application contains all Post	Progress Report (NLTH)	CTC Report
Post Approval Document 🗸 🗸		20220516-005-003	Test	Progress Report (NLTH)	<u>CTI Report</u> Amendment Form (Study Info)
Useful Information/User Manual		20220530-003-003	QAQAQA	Progress Report (NLTH)	
FN Version: v0.978		20220630-004-001	Test	Progress Report (CUHK)	
BN Version: v0.520		20220627-001-001	20220627	Progress Report (OLMH)	
		20220609-003-005	REPORT PDF	Progress Report (NLTH)	
		20220530-003-002	QAQAQA	Progress Report (NLTH)	
		20220620-004-002	Test	Progress Report (NLTH)	

• Press "X" to minimize the right context menu bar.

Figure 4.3.2.1 Right Context Menu of specific Post Approval Document



#### Hospital Authority CRER Portal User Manual for Applicant

= 🍈 HA Clinical Researc	Post approval document 20220609-001-007					×
Initial Applications	Initial Application					
New	IRB/REC Reference No.: irb flow`~~					
Draft	Scientific Title:	Approval Documents				
Sent	Cl:Lucky Lee	<u>pproval bocamenta</u>				
Returned	Status:Approved					
Approved						
Completed	Other Relevant Post-Approval Docu	ments:				
Acknowledged	> Document Type †	Coordinating Investigator $$\hat{\uparrow}_{\downarrow}$$	Create Date $\uparrow_{\downarrow}$	Status	Last Modified Date	$\uparrow_\downarrow$
Expired	Local SAE Report (NLTH)	Lucky Lee	2022-06-09	For Review	2022-07-12 15:56:10	
Archived	Protocol Deviation Report (NLTH)	Lucky Lee	2022-06-09	For Review	2022-07-12 15:56:10	
	Final Report (Study Info)	Lucky Lee	2022-06-09	For Review	2022-07-12 15:56:10	
Draft	Miscellaneous Report (Study Info)	Lucky Lee	2022-06-09	For Review	2022-07-12 15:56:10	
Sent	SUSAR Report (Study Info)	Lucky Lee	2022-06-09	For Review	2022-06-10 11:21:27	
Returned	CTC Report	Lucky Lee	2022-06-09	For Review	2022-07-12 15:56:10	
Approved	CTI Report	Lucky Lee	2022-06-09	For Review	2022-07-12 15:56:10	
Completed	Amendment Form (Study	Lucky Lee	2022-06-09	Re-Submitted	2022-06-09 10:18:14	
Acknowledged	<u>Into)</u>					
Expired						
Archived						
All						
Useful Information/User Manu						

Figure 4.3.2.2 Details of Relevant Post Approval Documents

Also, in Post Approval Document result table, a checkbox will be shown on the left for downloading Post Approval Documents. Only one checkbox can be selected at a time.

You can follow the below steps to download Post Approval Documents:

- Select specific "Post Approval Document" in Document Type and input search criteria if any; (The disabled **Download** button will then change to disabled **Download Post Approval Document** button.)
- Click Search button, select checkbox for the specific Post Approval Document. The Download Post Approval Document button will be enabled accordingly;
   (If the Post Approval Document is in Draft status, the checkbox will be disabled and not allow user to download the corresponding document.)
- 3. Press the Download Post Approval Document button to download the selected document;
- 4. A zip file named <Submission No.> which includes all relevant documents will be downloaded if a specific Post Approval Document is selected as Figure 4.3.2.3.

AUTOMATED ASL

$\equiv$ ( HA Clinical Researce	sh Ethics Review Portal	Taiman Chan Applicant 🗸 🚺 Lo	ogout
A Dashboard	Home > Search		
Q Search	Search Reset Export To XLS Download Post Approval Docur	nent	<b>^</b>
Profile	— Search Criteria		
Initial Applications	Basic Search		
Post Approval Document	Progress Report  CRER Application No	Submission Ref No. IRB/REC Ref No.	
Draft	Scientific Title		- 1
Sent			- 1
Returned			- 1
Approved	Search Results		- 1
Completed	Hide/Show Columns	Page Size	e –
Acknowledged		Filter keyword	
Expired	Submission No. 1 Scientific Title	Document Type 1 Status Last Modified Date	Ϋ́,
Archived	00200516.012.001 Test	Program Depart (01144/) Draft 2022-08-24 10:21:50	18
All	20220310-013-001	Progress Report (COHK) Dran 2022-08-24 10.31.30	
Useful Information/User Manu	20220516-014-002 Test	Progress Report (CUHK) Draft 2022-06-27 16:17:04	
✓	20220516-012-001 Test	Progress Report (CUHK) For Review 2022-06-01 10:53:31	-
a 20220516-012-001.zip 🔨		Show all	×

Figure 4.3.2.3 Download Post Approval Document



## 4.4 User Profile

If you want to update your user information (except login email address) or change password, please click "Profile" in left menu bar to direct to User Profile Page as Figure 4.4.1.

Please follow the steps to update your personal information:

- 1. Update your personal information;
- 2. Click **Update** button to update your user profile.
- 3. If you want to clear all draft amendment and remain unchanged as last update, you can click **Reset** button.

If you want to change your password, you can follow the below steps:

- 1. Enter the Old Password;
- 2. Enter the New Password and Confirm Password (The New Password cannot be same as the Old Password);
- 3. Make sure you have entered the same password in "New Password" and "Confirm Password";
- 4. Press **Update** button and you can use new password for next login.

= 🍿 HA Clinical Resear	ch Ethics Review Portal		Taiman Chan Last Login: 2022-04-27 10:14	Applicant -	Logout
A Dashboard	<u>Home</u> > Profile				
Q Search	User Profile				<u>^</u>
Profile	Email:	taimanchan@testing.com			
Initial Applications	Title:	Tote Testing			
Post Approval Document      V	First Name:	First Name Taiman			
Useful Information/User Manual	Surname:	- Sumame			
FN Version: v0.936 BN: v0.468 build at 20220426 14:45	Hospital / Institution:	- Hospital / Institution CCH			_
	Contact Number.	Contact Number			
	Reset				
	Change Password				
	Old Password:	Old Password 🗞			
	New Password:	New Password			
	Confirm Password:	Confirm Password			
	Password Policy:				
	1. Min Length Password is 8				
	2. Contains at least one numeri	c character			
	3. Contains at least one upper o	case			
	4. Contains at least one lower of	ase			
	Update				-

Figure 4.4.1 User Profile Page



## 4.5 Application/Post Approval List in Different Status

If you want to view document in different status, you can click the Status Folder to direct to the list of Initial Application or Post Approval Document in the left menu bar as Figure 4.5.1.

Action buttons of Application List are similar to those of result table of Search Page, refer to Section 4.3 <u>Search Page</u>. You can click **Refresh** button to get the latest Application/Post Approval List.

= 🍈 HA Clinical Resea	arch Ethics Review Portal Taiman Chan Applicant	- 🖣 Logout
A Dashboard	Home > Initial Applications > Sent	
Q, Search	Application List	
e Profile	Hide/Show Columns Collapse All Expand All Download Application Refresh	
Initial Applications	Filter keyword	Page Size: 10 🔻
New		
Draft	Pending CRER Application T <sub>1</sub> IRB/REC Reference T <sub>1</sub> Submission No. T <sub>3</sub> Scientific Title	† <sub>4</sub> Status
Sent		
Returned	No Data	
Approved		
Completed		
Acknowledged	Showing 0 to 0 of 0 entries	< >
Expired		
Archived		
All		
▲ Post Approval Document		
Draft		
Sent		
Returned		
Approved		
Completed		
Acknowledged		
Expired		
Archived		
All .		

Figure 4.5.1 Status Folder of Initial Application or Post Approval Document

Below table is the summary of various folders for Initial Application/Post Approval Documents.

Folder	Description
	To create a new Initial Application
New	Refer to Creation of New Application (by Coordinating Investigator)
Draft	Initial Applications/Post Approval Documents in draft status that are not yet submitted to CCO/Secretary
	Submitted Initial Application/Post Approval Documents with following statuses:
Sent	<ul> <li>Submitted</li> <li>Re-submitted</li> <li>Requested for Return</li> </ul>
	- Confirmed



Returned	Initial Applications/Post Approval Documents returned from CCO/Cluster Admin/Secretary
Approved	Initial Applications/Post Approval Documents approved by Central IRB/Secretary
Completed	Completed Initial Applications (i.e. with Final Report approved) are listed here.
Acknowledged	Acknowledged Documents are listed here.
Expired	Initial Applications/Post Approval Documents returned from CCO/Cluster Admin/Secretary that are expired
Archived	To view the Initial Applications/Post Approval Documents in following statuses: - Withdrawn - Disapproved - Terminated
All	Initial Applications/Post Approval Documents in all statuses that are related to Applicant can be found here.

For Initial Applications in draft status, you can view the completion status of the Initial Application by **Warning Signal** in Pending column and submission status of different Site Info through the **Indicator** button in Site Info Column as Figure 4.5.2.

= 💠 HA Clinical Resear	rch Ethics	Review	Portal				Taiman Chan Last Login: 2022-01-10 09:	Applicant	- 🥵 Logout	
1 Dashboard	<u>Home</u> >	Home > Initial Applications > Draft								
Q Search	Applicati	on List								
Profile	Hide/Sho	ow Colum	Colla	pse All Expand A	Export	Refresh				
Initial Applications							Filter keyword		Page Size: 10 💌	
New Draft			Pending	$\begin{array}{c} \text{CRER Application} \\ \text{No.} \end{array} \uparrow_{\downarrow}$	IRB/REC Reference $_{\uparrow_{\downarrow}}$ No.	Submission No. $\uparrow_{\downarrow}$	Scientific Title	† <sub>↓</sub> Status	Site Info	
Sent	+		()			20220107-001-000	Test234	Draft	Incomplete	
Returned			()			20220107-003-000	Testing	Draft	FYKH X	
Approved	4								Þ	
Acknowledged	Showing 1	to 2 of 2	entries						< 1 >	
Expired										
Archived										
All										
Post Approval Document										
Draft										
Sent										
Returned										
Approved										
Completed										
Acknowledged										





	Warning Sign of Pending Column	Comp	pletion Status of Site Info Column
Status	Description	Status	Description
!	<ul> <li><u>CI/Delegates</u>: Initial Application not yet submitted to CCO/Secretary, need to handle by CI/Delegate(s)</li> <li><u>Site PI/Delegates</u>: Initial Application not yet submitted to CI, need to follow up by Site PI/Delegate(s)</li> </ul>	~	Site info sent to Cl
-	<ul> <li><u>CI/Delegates</u>: Initial Application submitted to CCO/Secretary</li> <li><u>Site PI/Delegates</u>: Initial Application submitted to CI</li> </ul>	Х	Site info not yet sent to CI
		<b>Info</b> icon	Initial Application is submitted

## **Remarks:**



## 4.6 Useful information/User Manual

User Manual and Common Forms can be downloaded here. You may also take a look at the FAQ section here.

$\equiv$ ( HA Clinical Resear	Stinical Research Ethics Review Portal       Applicant       Applicant </th											
A Dashboard	Home > Useful Information/User Ma	anual										
Q Search	Forms / Templates	Forms / Templates										
e Profile	Subject	†Ļ	Central IRB	HKU/HA HKW IRB	201 Applicant  Cogout C							
♣ Initial Applications ∨	Investigator's Declaration of Confli	ct of Interest Form	Attachmer	nt Attachment	Attachn	nent						
🚯 Post Approval Document 🗸 🗸	User Manual											
Useful Information/User Manual	For Applicant	For Rev	iewer	For Cluster Admin	]		- 1					
FN Version: v0.938 BN: v0.468 build at 20220426 14:45	For Secretary	For CCO S	ecretary	For Central IRB			- 1					
Div. YU-408 Duliu al 20220420 14:43	<ul> <li>EAQ</li> <li>1. I am planning to submit a multi IRB/CREC. Can Central IRB gra IRB/CREC?</li> <li>A. This is to clarify that the review and NTEC). On the other hand, maintain their own jurisdiction in parallel to Central IRB, HKU/i</li> <li>2. What are the differences between</li> </ul>	-cluster application inw nt ethics approval to all r decision of Central IRE standalone application to oversee research eth 4A HKW IRB and Joint-	Diving all HA clusters HA sites? Do I need will be applicable to to HKU/HA HKW IRE icis review related to CUHK CREC with res gator(CI) and Site Pr	I understand that HKWC and NTEC have it osubmit separate application to these 2 J all HA hospitals (i.e. including QMH and P and Joint CUHK-NTEC CREC is required a their clusters. Study team may consider to pective jurisdictional applying sites.	a Joint HA-Universit loint HA-University WH, and HA sites ur s the Universities w s submit separate ap	<b>y</b> nder HKV ould like oplicatior	VC to hs					

Figure 4.6.1 Screen of Useful Information/User Manual Page



## 5. Manage an Application (Initial)

There are 3 Initial Application submission flows, namely IRB flow as Figure 5.1, HKWC and NTEC (University) flow as Figure 5.2. You will need to select Workflow "Central IRB" or "HKU/HA HKW IRB" or "Joint CUHK-NTEC CREC" when creating the Initial Application and can change the flow before submit to CCO/Secretary.



Figure 5.1 IRB flow of Initial Application submission





Figure 5.2 HKWC/NTEC flow of Initial Application submission



## 5.1 Applicant Roles and Functions

There are 4 major types of applicant roles, Coordinating Investigator (CI) and his/her delegate(s), Site Principal Investigator (PI) and his/her delegates(s).

	Applicant Roles					
Function	CI/Delegate(s)	Site PI(s)/Delegate(s)				
Manage Initial Application	Create & Submit & Withdraw	/				
Complete Study Into	Edit	View Only				
Complete Site Info	Create & Return to PI/Delegate(s) & View only	Edit & Submit to Cl				
Assign Delegation	Add/Edit CI Delegation before submission (Only CI can use "Change Delegation" after submission)	Add/Edit Site PI Delegation before submission (Only Site PI can use "Change Delegation" after submission)				

Below is the summary of their rights and involved functions in stage 1.

## **Remarks:**

If CI and his/her delegate(s) or Site PI(s) and his/her delegates are editing the same field in Study Info or Site Info of Initial Application Form at the same time, the data of the person who saves first will be overwritten by the data of the person who save last.



## 5.2 Creation of New Application (by Coordinating Investigator)

- 1. Navigate to [Initial Application] in left menu bar;
- 2. Click **New** to create an Initial Application Form.

= 🍈 HA Clinical Resear	ch Ethics Review Portal				Taiman Chan Last Login: 2022-04-27 10:14	Applicant 👻	147
A Dashboard	Home						
Q Search	Dashboard						
Profile	Applications						
Initial Applications		Draft		Returned			
New Draft	·	_	Expire in ≥ 30 days	<u>(Q)</u>			
Sent			Expire in < 30 days	<u>(Q)</u>			
Returned							
Completed	Post Approval Documents						
Acknowledged	1	Draft		Returned			
Expired	L	2/2	L	0/0			
Archived			Expire in ≥ 30 days	. <u>(0)</u> .			
All			Expire in < 30 days	<u>(Q)</u>			
🚯 Post Approval Document 🗸 🗸							

#### Figure 5.2.1 Initial Application Creation

#### 5.2.1 Acknowledgement

You must read and acknowledge "Important Notes: Roles and Responsibilities" before proceeding to next step.



Figure 5.2.1.1 Acknowledgement on Important Notes



## 5.2.2 Fill in Team Member Form

Team Member Form allows you to assign roles to your team member, such as CI, Site PI and/or CI delegates, for the new application.

Please follow the instructions below:

- 1. Select Submission Flow of the Initial Application from dropdown menu of Applying IRB/REC<sup>(?)\*</sup> as Figure 5.2.2.1:
  - Central IRB: IRB Flow
  - HKU/HKW IRB: HKU/HA HKW IRB Flow
  - Joint CUHK-NTEC CREC: NTEC Flow

= 🍈 HA Clinical Researc	ch Ethics Review Portal	Taiman Chan Applicant 🗸 149 Logout							
A Dashboard	Home > Initial Application > Create								
Q, Search	Create								
Profile	Team Member Form Choose One								
Initial Applications	Applying IRB / REC (7): Central IRB								
New Draft	Scientific title Joint CUHK-NTEC CREC								
Sent	Coordinating Investigato.								
Returned	Email	Profile Contact Number							
Approved Completed	Title (7) Surname	First Name							
Acknowledged	Pacifian (7)	- Hospital / Institution (2)							
Expired	Position **								
Archived	Coordinating Investigator's Delegation	Add							
All	Edit Email $\uparrow_{\downarrow}$ Title (7) $\uparrow_{\downarrow}$ Surname $\uparrow_{\downarrow}$ First name $\uparrow_{\downarrow}$	Position (?) T <sub>↓</sub> Cluster T <sub>↓</sub> Hospital / T <sub>↓</sub> Departn							
🚯 Post Approval Document 🗸 🗸		Institution							
Useful Information/User Manual	No Data								
FN Version: v0.936	4	•							
BN: v0.468 build at 20220426 14:45	Information of Site PI(s) 🕅 Add								
	Edit Email $\hat{\uparrow}_{\downarrow}$ Title $(?)$ $\hat{\uparrow}_{\downarrow}$ Surname $\hat{\uparrow}_{\downarrow}$ First name $\hat{\uparrow}_{\downarrow}$	Cluster $\uparrow_{\downarrow}$ Hospital / $\uparrow_{\downarrow}$ Department $\uparrow_{\downarrow}$							
	🛕 No Data								
	4								

Figure 5.2.2.1 Team Member Form

- 2. Fill in the Scientific Title;
- 3. Provide information for Coordinating Investigator\*;
- 4. Under Cl's Delegation, press **Add** button to add info for Cl's delegate(s) (Maximum: 3) in the pop-up form, if any;
- Under Information of Site PI(s), press Add button to add info for Site PI(s) (Minimum: 1) in pop-up form;
  - No. of Site PI(s) filled in = No. of site info tab
  - CI can be one of the Site PI
- 6. Press **Create** button to create a draft application;
- 7. Submission No. will be generated;
- 8. Application can be viewed as Draft status in "Draft" Application List;

- 9. CI, Site PIs and delegates will receive the notification in Portal and by email regarding the Initial Application creation
  - Change of Team members: <Coordinating Investigator/Coordinating Investigator's Delegate/ Site PI (XXX)> is changed for "<Submission No.>".

#### \*Remarks:

- 1. Tooltips (?): When hovering the pointer over "(?)" without clicking it, a text box will pop up and reveals additional information on the field ending with (?).
- 2. **Load Profile** button: Contact Number, Surname, First Name and Title can be auto-filled in for the registered user after the applicant email is input and clicking Load Profile button.
- 3. Any changes in the team member form after submission are required to go through the Request for Return (Initial Application submitted) / Application Amendment (Initial Application approved), except CI/Site PI change their delegation(s)

= 🍈 HA Clinical Resear	rch Ethics Review Portal	Taiman Chan Last Login: 2022-04-08 12:01	Applicant 👻 🧏 Loge	out
A Dashboard	Home > Initial Application > Create			
Q Search	Create			Î
O Profile	Team Member Form			1
Initial Applications	Applying IRB / REC			
New	Central IRE: For all eligible HA staff applying approval in			
Draft	Joint (1) IHK-ATTEC COPEC: For all elimitule (1) IHK and/or			
Sent	HA NTEC staff/students applying approval in CUHK/HA			
Returned	Load P	Contact Number		
Approved	HICU/HIA HICW HIEL FOR all eligible HICU and /or HIA HICWC staff/students applying approval in HICU and/or	Eine Manuel		
Completed	HA HKWC sites	Fist Name		
Acknowledged	Position 🕅 Department Cluster	▼ Hospital / Institu	tion (7) 👻	
Expired				
Archived	Coordinating Investigator's Delegation (7)		Add	
All	Edit Email †     Title (7) †     Surname †     First name †	Position (7) †	luster † Hospital / †	
nost Approval Document 🗸			in subsection 1	
Help	No Data			1
FN Version: v0.927	4		•	
BN: v0.458 build at 20220329 08:45	Information of Site $Pl(s)$ $^{(?)}$		Add	
	Edit Email $\hat{\tau}_{\pm}$ Title $^{(7)}$ $\hat{\tau}_{\pm}$ Surname $\hat{\tau}_{\pm}$ First name	↑↓ Cluster ↑↓ Ho	spital / † Department	
	A No Déta			1
	4		•	

Figure 5.2.2.2 Tooltips and Load Profile button



## 5.2.3 Fill in Study Info of Application Form (by Coordinating Investigator/Delegate(s))

As a CI, after creating an Initial Application, you will be directed to the Study Info of Application form. Both CI and assigned Delegate(s) are able to fill in the Study Info of the Initial Application.

As CI/Delegate(s), you can access the Initial Application as below:

- 1. Go to [Initial Application] in left menu bar;
- 2. Click Draft to the Initial Application list in draft status;
- 3. The Initial Application with **Pending signal "!"** means that you need to handle the application;
- 4. Click Scientific Title to open the Initial Application.

= 🌵 HA Clinical Resea	arch Ethics	Review	Portal			Taiman Ch Last Login: 20	an Applicar 122-04-11 00:09	nt 👻 🔎	Logout
A Dashboard	<u>Home</u> >	Initial A	oplications >	Draft					
Q, Search	Applicati	on List							
Profile	Hide/Sho	ow Colum	Coll	apse All Expand Al	Download Applic	cation Refresh			
Initial Applications						Filter key	word	Page Size:	10 *
New Draft			Pending	CRER Application	IRB/REC Reference †	Submission No. $\uparrow_{\downarrow}$	Scientific Title	† <sub>4</sub> s	itatus
Sent	+		()			20220208-002-000	Test123		Draft
Returned	+		0			20220328-005-000	Test123	C	Draft
Completed	+		()			20220322-001-000	Testing	C	þraft
Acknowledged	+		0		-	20220204-001-000	Sec Form	C	Draft
Expired	+		0			20220118-002-000	Testing	C	Draft
Archived	•								•
▲ Post Approval Document	Showing 1	to 5 of 5	entries					<	1
Help									
FN Version: v0.927 BN: v0.458 build at 20220329 08:45									

Figure 5.2.3.1 Application List in Draft Status

In the top toolbar of the Initial Application, there are several action buttons for Cl's operation: **Save**, **Print**, **Submit**, **Discard** and **Close**.

=	HA Clinical Research Ethics	s Review Portal		Taiman Chan Last Login: 2022-04-11 00:09	Applicant 👻	 Logout
ft.	<u>Home</u> > <u>Initial Application</u> > Initial A	pplication (20220208-002-000) (D	)raft)			
Q	B Save Print Submit	Discard				
0	Instruction		(0) 🖷	院管理局 OSPITAL		^
6	Team Member Form		AL AL	THORITY		
-	PART I: OUTLINE OF APPLICATION		Hospital Au	uthority		
0	PART IIA: STUDY DETAILS		Clinical Research Ethics Re	view Application Form		
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY		RB/ REC Reference No. (For Office Use)			
	PART III: ETHICAL IMPLICATIONS					
	PART IV: BUDGET, RESOURCES, INDEMNITY		Instructions to	applicant		

Figure 5.2.3.2 Action buttons for CI in Initial Application



Button	Description			
Save	To save the current change to the draft			
	"Application detail has been updated" message will be prompted			
Print	To download the saved Initial Application in PDF format for printing. (The unsaved changes will not be downloaded.)			
Submit	To submit the Initial Application to CCO/Secretary for further decision Refer to Submit Initial Application Form by CI/Delegate(s)			
Discard/ Withdraw	<ul> <li>Discard button is only available in the draft Initial Application         <ul> <li>"Application is discarded." message will pop up for confirmation</li> <li>Withdraw button is available after the Initial Application is submitted                 <ul></ul></li></ul></li></ul>			
Close	To exit the Initial Application Form and direct to the previous Application List Page			


### 5.2.3.1 Instructions

This section lists out the basic instructions to Applicants. You must go through the instructions and tick the checkbox of the acknowledgement for Instructions and Reminder after fully understanding the instructions.

IRB/REC Reference No. (For Office Use) above the instructions will be manually inputted by CCO/Central IRB/Secretary afterwards.



Figure 5.2.3.1.1 Instructions of Initial Application



## 5.2.3.2 Part I

Part I is mainly about outline of your application.

- 1. Fill in Textboxes for Q1. Name of Study;
- 2. Answer the Qs for Q2. Study Site(s);
  - If tick "Yes" in Q2.2, pls press **Add** button in Q2.3.2 to fill in the info of Collaborating site(s) in HA if applied
- 3. Q2.3.1 to be complete in Site info;
  - If tick "Yes" in Q2.3.3, pls press Add button to fill in info for Study Info which is Out-of-HA
- 4. Select the Answers for Q3. Clinical Research Ethics Review for Cross-cluster Study;
- 5. Select the Study Start/End Date, Report Submission date in Date-Pickers in Q4. Timetable;
  - Study Start Date should be later than current date
  - Study End Date should be later than Start Date and same/earlier than Tentative Final Report Submission Date
- 6. Input Brief Summary of Study in Q5.

≡	HA Clinical Research Ethic	s Review Portal	Taiman Chan Last Login: 2022-04-11 00:09	Applicant 👻	P Logout	1000
A	Home > Initial Application > Initial A	Application (20220411-001-000) (Draft)				
Q	Print Submit	Discard				
Θ	Instruction	1. Name of Study				*
B	Team Member Form	1.1. Scientific Title				
	PART I: OUTLINE OF APPLICATION					
•	PART IIA: STUDY DETAILS					
2	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	1.1.1. Short Title (for lay public / easy quote)				
	PART III: ETHICAL IMPLICATIONS					
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	1.1.2. Key Words (for search purpose, e.g. disease name, drug name, etc.)				
	CLINICAL STUDY CATEGORIZATION FORM					
	Document Upload	1.2. Research protocol number (7)				
		Study Site(s)     Study Site(s)     Study Site(s)     Study Site(s)     Study sites     Study sites     Study site(s) in HA ("To Complete in Site info)     Add     Study Site(s)	▼ nant 1. Het	nare plaasa enartifu	T. Dam	•

Figure 5.2.3.2.1 Part I: Outline of Application



#### 5.2.3.3 Part IIA

Part IIA is a section for study details.

- 1. Fill in textboxes for Q6. Scientific Basis & Q7. Study Subjects:
  - Q7.3.3
    - Tick "Yes", input the no. in Q7.3.3.1;
    - Tick "No", specify details in Q7.3.3.2
  - Q7.4 & 7.5 to be complete in Site info
- 2. Select the correct options in checkbox or from dropdown menus for Q8. Study Design;
- 3. Input the details for Q9. Methods of Data Analysis & Q10. Handling and Storage of Personal Data and Study Data.

≡	HA Clinical Research Ethic	s Review P	ortal	Taiman Chan Last Login: 2022-04-11 00:09	Applicant -	🧖 Logo	out
ŧ	Home > Initial Application > Initial A	opplication (2	0220411-001-000) (Draft)				
Q	Print Submit	Discard	Close				
Θ	Instruction	PART IIA	STUDY DETAILS				^
Ð	Team Member Form	6. Scie	entific Basis				
6	PART IIA: STUDY DETAILS	6.1. Ai	m of study				
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY						
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE CLINICAL STUDY CATEGORIZATION FORM	6.2. H	ypothesis 🕫				
	Document Upload	6.3. Outo 6.3.1.	ome measure(s) Primary outcome(s)				
		6.3.2.	Secondary outcome(s)				
		7. Stu	dy Subjects				
		7.1. In Study Info	Site (TWEH)				•

Figure 5.2.3.3.1 Part IIA: Study Details



## 5.2.3.4 Part IIB

Following by Part IIA, Part IIB is about study details for **prospective** study.

- 1. Select the correct options in checkboxes or from dropdown menus for Q11. Study Article and Arrangements:
  - If tick "Yes" in Q11.2.1 Study Article,
    - o Press Add button and fill in the pop-up form for Q11.2.2 Study Article Details
    - o Edit the pop-up form for Q11.2.3 Study Article License Registration
  - If tick "No" in Q11.2.4 Certificate for Clinical Trial ("CTC"),
    - Provide justification in Q11.2.4.1
  - Q11.3 & Q11.4 to be completed in Site Info
  - Input details on Q11.5 Biological Sample Storage for Future
- 2. Input all the details with selected checkboxes in Q12. Research Subject Protection.

≡	HA Clinical Research Ethic	Review Portal Taiman Chan Applicant - Applicant - S	Logout
♠	<u>Home</u> > <u>Initial Application</u> > Initial A	oplication (20220411-001-000) (Draft)	
Q	Submit:	Discard Close	
Θ	Instruction	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	<b>^</b>
B	Team Member Form	11. Study Article and Arrangements	
_	PART I: OUTLINE OF APPLICATION	11.1. How does the procedure/treatment differ from current treatment practice?	
•	PART IIA: STUDY DETAILS	×	
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Hothers, specify	
	PART III: ETHICAL IMPLICATIONS		_
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	11.1.2. Methods of assignment	
	CLINICAL STUDY CATEGORIZATION FORM	11.1.3. Degree of masking	
	Document Upload	11.1.4. Phase of study 🕅 👻	
		11.2. Study article 🕜	
		11.2.1. Is there any study article?	
		11.2.2. Study article details	
		Add	
		Edit Article / Control $\hat{T}_{\downarrow}$ Type $\hat{T}_{\downarrow}$ Name $\hat{T}_{\downarrow}$ Duration of $\hat{T}_{\downarrow}$ Dosage $\hat{T}_{\downarrow}$ Route of $\hat{T}_{\downarrow}$ administration	£
		🛕 No Data	-
		Study Info Site (TWEH)	

Figure 5.2.3.4.1 Part IIB: Study Details for Prospective Study



### 5.2.3.5 Part III

Part III is about ethical implications.

- 1. Input details with selected checkboxes/dropdown options in the following questions
  - Q13. Information and Consent
  - Q14. Data and Safety Monitoring
  - Q15. Major Ethical Issues
  - Q16. Preference on Review Channel
- 2. Answer all the questions with selected checkboxes or inputted details in Q17. Risk Assessment
  - If tick "Yes" in Q17.2, at least 1 option of Q17.2.1 should be selected and filled in.

≡	HA Clinical Research Ethic	Review Portal	Taiman Chan Last Login: 2022-04-11 00:09	Logout
A	Home > Initial Application > Initial A	oplication (20220411-001-000) (Draft)		
Q	B Save Print Submit	Discard		
Θ	Instruction	PART III: ETHICAL IMPLICATIONS		-
8	Team Member Form PART I: OUTLINE OF APPLICATION	13. Information and Consent (The informed consent should state < OIDB//ODEC/IDB > as one of	the sutherities in access the subjects' records related to the	study
	PART IIA: STUDY DETAILS	tor etnics review purpose.) Choose One		
12	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	13.1. Methodology of obtaining consent Oral		
	PART III: ETHICAL IMPLICATIONS	13.1.1. Written		
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	No (subject to wavier b	y CIRB/CREC/IRB)	
	CLINICAL STUDY CATEGORIZATION FORM	13.1.2. Justification for applying to waive the consent requirement		
	Document Upload	13.2. Who will carry out the informed consent process with the subject?         Principal Investigators       Other Investigators         13.3. Will an interpreter be available when required?       Yes         13.3.1.       If no justification         13.4. In obtaining informed consent from subjects, what is the minimal	(*To Complete in Site info) urch Assistant Others	2 09
		13.5. If subjects are incompetent in giving consent, what would be the	ne arrangement?	•
		Study Info Site (TWEH)		

Figure 5.2.3.5.1 Ethical Implications



### 5.2.3.6 Part IV

Part IV is mainly about budget, resources, indemnity and insurance.

≡	HA Clinical Research Ethic	cs Review Portal	Taiman Chan Applicant 👻 🚺 Logout
ŧ	Home > Initial Application > Initial >	Application (20220411-001-000) (Draft)	
Q	B Save Print Submit	Discard	
Θ	Instruction	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	*
6	Team Member Form	18. Source of Funding	
۵	PART I: OUTLINE OF APPLICATION PART IIA: STUDY DETAILS	18.1. Any source of funding? Yes No	
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Add	
	PART III: ETHICAL IMPLICATIONS	Edit Commercial / Non- †_ Type of funding †_ Name of organ	inization / party †_ Study data †_ Major Right an
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	commercial	Ownership organization /
	CLINICAL STUDY CATEGORIZATION FORM	A No Dat	ta
	Document Upload	4	Þ
		18.2. Any non-monetary support?	
		18.2.1. Specify the non-monetary support	
		400	
		Edit Commercial / Non- † Commercial Type of Support †	Name of organization / party $\uparrow_{\downarrow}$ . Study data Ownership
		A No Dat	ta
		4	Þ
		18.2.2. Please provide details arrangements of the non-monetary support	
		Study Info Site (TWEH)	

Figure 5.2.3.6.1 Part IV Budget, Resources, Indemnity and Insurance

- 1. Select the checkboxes in Q18. Source of Funding to answer all the Qs;
  - If tick "Yes" in Q18.1, press Add button and input details for Q18.1.1 in pop-up dialog
  - If tick "Yes" in Q18.2, press Add button and input details for Q18.2.1 in pop-up dialog and for Q18.2.2 in textbox
  - If tick "Yes" in Q18.3, Q18.3.1 will be enabled for selection
- 2. Q19. Resources Implication and Conflict of Interest to complete in Site Info;
- 3. Select the checkboxes in Q20. Financial Costs and Payment to Subjects to answer all the Qs;
- 4. Q21. Research Organization and Indemnity.
  - Press Add button to input Name of organization / individual in Q21.2
  - Q21.3.1.2
    - If tick "Yes", Q21.3.1.2 will be enabled for checkbox selection
      - o If tick "No", textbox of Q21.3.1.1 will be enabled to fill in details
  - If tick "Yes" in Q21.4, Q29 is mandatory for document upload.



## 5.2.3.7 Clinical Study Categorization Form

Complete the Clinical Study Categorization Form by ticking the checkboxes "Yes/No".

You can click "<u>here</u>" to go through the Notes for Completion before filling in the Clinical Study Categorization Form.

s Review Portal		Taiman Chan Last Login: 2022-04-11 00:09 -	Applicant 👻	L0			
Application (20220411-001-000) (Draft)							
Discard							
CLINICAL STUDY CATEGORIZATION	I FORM						
Note to Investigator: Please complete the following Clinical St Upon receipt of an application, the Secret Expedited Review or Full Review by Phase	udy Categoriza ariat will verify e 1 Panel.	tion Form and submit the Form together with each application for the information on the form and arrange for appropriate initial rev	r research ethics riew through Full	review. Review,			
Risk Group	No.	Risk Factors	Yes / No				
Human Subjects	1	Recruitment of human subjects	Ves [	] No			
Medical Products	2	Use of any medical product that is not needed or used for the Subjects' normal clinical care	Ves [	] No			
Medical Products	3	Each medical product used is registered or permitted to be marketed in Hong Kong	Ves [	] No			
Medical Products	4	Use of each medical product is within the labeled use in Hong Kong	Ves [	] No			
Medical Products	5	Any medical product used is a chemical or biological drug that is to be tested in humans for the first time	🗌 Yes [	] No			
Study Designs	6	The study is a phase 1 clinical trial on a chemical or biological drug as designated on its study protocol	🗆 Yes 🛛	] No			
Study Designs	7	The study only has human pharmacology, toxicity and/or safety (but not efficacy) of the chemical or biological drug as its primary objective(s) as specified on its study protocol	Ves [	] No			
Study Designs	8	involvement of placebo, impeding access to available treatment, or withdrawal of ongoing treatment driven by the study protocol	Ves [	] No			
Study Info Site (TWEH)							
		Subjects are assigned to different aligibal laterungian bu					
Subject Assignment Methods	11	randomization or other research specific methods (other than by the professional judgment of qualified medical professionals)	🗌 Yes 🗌	] No			
Subject Vulnerability	12	Involvement of vulnerable subjects	Yes [	] No			
4				Þ			
Channel A: Full review by Standard Panel (unless otherwise determined by the IRB/REC according to the IRB/REC's SOP)							
Channel B: Expedited review by Expedited Panel	(unless other principal inve	vise determined by the IRB/REC according to the IRB/REC's SOP stigator for a full review)	or requested by	the			
Channel C: Full review by Phase 1 Panel	(unless other	vise determined by the IRB/REC according to the IRB/REC's SOP)	)				
Clici here for Notes for Completion of the	Clinical Study	Dategorization Form					
	s Review Portal  pplication (20220411-001-000) (Draft)  Discard Close  CLINICAL STUDY CATEGORIZATION Note to Investigator: Please complete the following Clinical St Upon receipt of an application, the Secret Expedited Review or Full Review by Phase Risk Group Human Subjects Medical Products Medical Products Medical Products Medical Products Study Designs Channel A: Full review by Standard Pane Channel B: Expedited review by Panel Channel C: Full review by Phase 1 Panel Clic There for Notes for Completion of the Clic There for Notes for Co	s Review Portal  papelication (20220411-001-000) (Draft)  Discard Close  CLINICAL STUDY CATEGORIZATION FORM Note to Investigator: Please complete the following Clinical Study Categoriza Upon receipt of an application, the Secretariat will verify Expedited Review or Full Review by Phase 1 Panel.  Risk Group No.  Human Subjects 1  Medical Products 2  Medical Products 3  Medical Products 5  Study Designs 6  Study Designs 7  Study Designs 8  Study Info Site (TWEH)  Subject Assignment Methods 11  Subject Vulnerability 12  Channel A: Full review by Standard Panel (unless other Expedited Panel (unless other Channel B: Expedited review by Phase 1 Panel (unless other Channel C: Full review by Phase 1 Panel (unless other Clic There for Notes for Completion of the Clinical Study Cite Site (TWER)	Bit Review Portal       Taiman Chan Last Logn: 2022 doi:10.000         oplication (20220411-001-000) (Draft)         Observed       Iose         CLINICAL STUDY CARGORIZATION FORM         Note to Investigator:         Please complexe the following Clinical Study. Categorization Form and submit the Form together with each application for Upon receipt of an application, the Secretaria will verify the information on the form and arrange for appropriate initial re- Expected Review or Full Review by Phase 1 Panel.         Risk Group       No.         Human Subjects       1         Human Subjects       2         Medical Products       2         Medical Products       3         Medical Products       3         Medical Products       5         Any medical product used is registered or permitted to be marked in Humans for the first time         Study Designs       6       The study is a phase 1 clinical trial on chemical or biological drug as designated on its study protocol         Study Designs       8       timent or withoreand of modulut used is a chemical or biological drug as its primary elgetcire(i) as specified on its study protocol         Study Designs       8       timent merice or withorward of the chemical or biological drug as designated on its study protocol         Study Designs       8       timentme or withorward of qualified medical product so its study protocol	B Review Portal       Taiman Chan Lest Login 2020 411 0001 (Doth)       Applicant •         Decard       Close       Close       CLINICAL STUDY CATEGORIZATION FORM         Note to Investigator:       Plase complete the following Elina I Study Desegnation Form and submit the Form together with each application for research ethics Upon receipt of an application, the Secretarist will end the Inform and arrange for appropriate initial review through Full Exceeder Review or Full Review by Phase 1 Panel.       No.       Risk Review       Yes 0         Medical Products       1       Recruitment of human subjects       Yes 0         Medical Products       2       Use of new medical product that is not needed or used for the Subjects       Yes 0         Medical Products       3       Boh medical product sud is registered or permitted to be the Subject sud in the Subject sud in the Subject sud in a chemical or biological drug to the Subject sud in the Subject sud in the Subject sud in the Subject sud in a chemical or biological drug to the Subject sud in the Subject sud in the Subject sud in a chemical or biological drug to the Subject sud in the Subject sud in the Subject sud in a chemical or biological drug as the Subject involtance of the chemical or biological drug as the Subject involtance of the chemical or doubt in the subject and the subject and the subject sud in the subject sud in the subject and the subj			

Figure 5.2.3.7.1 Clinical Study Categorization Form



#### 5.2.3.8 Document Upload

In this section, you can upload the related documents in Study Info for your application.

- Q27, 28, 34 will be completed in Site Info
- Q31 mandatory upload for student project in Study Info

≡	HA Clinical Research Ethic	s Review Portal	Taiman Chan Last Login: 2022-04	L11 17:50	Applicant -	🧖 Lo	gout			
<b>f</b>	Home > Initial Application > Initial A	Application (20220411-001-00	0) (Draft)							
Q	<b>Save</b> Print Submit	Discard								
Θ	Instruction	Document Upload								^
8	Team Member Form	22. Research Protocol (I	Mandatory)							
۵	PART IIA: STUDY DETAILS	Add								
2	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Upload Date	$\dagger_{\pm}$	Created By	$\tau_{\downarrow}$	File Name	† <sub>4</sub> Re	emove		
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE			A	No Data					
	CLINICAL STUDY CATEGORIZATION FORM	23. Subject Information	Sheet and Inf	ormed Consent Forr	n 🤭 (Supplem	entary)				
	Document Upload	Add								
		Upload Date	ήĻ	Created By	ή_4	File Name	† <sub>4</sub> Re	emove		
					No Data					
		<u></u>								

Figure 5.2.3.8.1 Document Upload

- Press Add button in the specific document upload table that you want to upload document. Multiple documents upload is feasible;
- 2. Dialog will be prompted for document upload as Figure 5.2.3.8.2;

Research Protocol									
Created By:	Taiman Chan								
File Name:	Upload								
	You haven't uploaded file anything yet!								



#### Figure 5.2.3.8.2 Pop-up Dialogs for document upload

- 3. Press Upload button to select the document from your local computer;
- 4. File Name will be same as the uploaded file;
- 5. Press **Add** button in the pop-up dialog for confirmation;
- 6. The record will be shown in the document upload table;
- 7. A hyperlink of File Name will be enabled for document checking once you "**Save**" the Initial Application;
- 8. Press Remove button you can delete the specific uploaded document.

# AUTOMATED ASL

## 5.2.4 Fill in Site Info of Application Form (by Site Principal Investigator/Delegate(s))

Message will be sent to Site PI(s) by notification in Portal and by email when Site Info(s) of application form is created as Figure 5.2.4.1.

• "Change of Team members: <Site PI (XXX)> is changed for "<Submission No.>"

As a Site PI(s), you can press **Notification Bell** button to check the notification for "Change of Team members". Click the notification message to direct to the Initial Application form as Figure 5.2.4.1.

=	HA Clinical Research Ethics	s Review Portal	site pi 5 Last Login: 2022-03-09 18:19 Applicant ✔ 📌 Logout
<b>A</b>	Home > Initial Application > Initial A	pplication (20220208-002-000) (Draft)	Notification Mark All Read
Q	Save Print Send to Coo	rdinating Investigator Close	From: Taiman Chan 2022-03-29 10:23 13 Change of Team members: SITE PI(TYH) is changed for 20220208-002-
Θ	Team Member Form	Team Member Form	000. Mark Read
8	Personal Particulars PART I: OUTLINE OF APPLICATION	Site Principal Investigator's Delegation	From: CRER System 2022-03-24 00:00 00 Overdue: IRB-2021-209 - Initial Submission is overdue. Please submit
0	PART IIA: STUDY DETAILS	Edit Email †, Title (?) †, Sur	afresh via the CRER Portal if needed. Mark Read
2	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE Document Upload Declaration And Endorsement	PERSONAL PARTICULARS OF PRINCIPAL INVESTIGATOR AND C Principal Investigator (Applicant) 1. Title (e.g. Mr. Mrs. Ms. Miss. Dr)	From: CRER System     2022-03-24 00:0000       Overdue: IRB-2021-209 - Initial Submission is overdue. Please submit afresh via the ORER Portal if needed.     Mark Read       From: CRER System     2022-03-23 00:0000       Overdue: NTEC-2021-070 - Initial Submission is overdue. Please submit afresh via the ORER Portal if needed.     Mark Read
		Surname         Name in Chinese (Optional)         2. Position of the Principal Investigator (PI)         2.1.       HA Staff (including HA Honorary staff)         2.11         Pesition         2.11         Study Info         Site (TYH)	First Name

Figure 5.2.4.1 Notification of Site Info Creation

Also, as Site PI(s)/Delegate(s), you can access the Initial Application as below:

- 1. Go to [Initial Application] in left menu bar;
- 2. Click Draft to the Initial Application list in Draft status as Figure 5.2.4.2;
- 3. The Initial Application with **Pending signal "!"** means that you need to handle the application;
- 4. Click Scientific Title to open the Initial Application;



= 🌵 HA Clinical Resea	rch Ethics	Review	Portal			Taiman Ch Last Login: 20	an Applican 22-04-11 00:09 —	<u>•-</u>	8 Logout
A Dashboard	<u>Home</u> >	Initial Ap	oplications >	Draft					
Q, Search	Applicati	on List							
e Profile	Hide/Sho	ow Column	Coll	apse All Expand Al	Download Applic	Refresh			
Initial Applications						Filter key	word	Page Siz	ze: 10 👻
New Draft			Pending	CRER Application †	IRB/REC Reference †	Submission No. $\ ^{\dagger }\downarrow$	Scientific Title	η,	Status
Sent	+		()			20220208-002-000	Test123		Draft
Returned	+		0	•		20220328-005-000	Test123		Draft
Completed	+		()	;		20220322-001-000	Testing		Draft
Acknowledged	+		0			20220204-001-000	Sec Form		Draft
Expired Archived	+		0		-	20220118-002-000	Testing		Draft
All	4								•
▲ Post Approval Document	Showing 1	to 5 of 5	entries					<	1 >
Help									
FN Version: v0.927									

BN: v0.458 build at 20220329 08:45 💌



- 5. Study Info will be view only when you enter the Initial Application as Figure 5.2.4.3;
- 6. Press Print button to download application form in PDF format to view the details if needed;
- 7. Select the right Site tab to fill in the details for Site Info.

								Last Login: 202	2-03-09 18:19	oplicant •		
Home > Initial Application > Initial	Application (2022	0208-002-000) (Draft)	)								_	
Save Print Close											Vi	
Instruction	Team Mem	ber Form										
Team Member Form	Applying IPR											
PART I: OUTLINE OF APPLICATION	Colocatilla titla	HKO/F										
PART IIA: STUDY DETAILS	Test123											
PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Coordinating	Investigator (7)										
PART III: ETHICAL IMPLICATIONS	Emal								Contact Number			
PART IV: BUDGET, RESOURCES, INDEMNITY	Taia (7)	nguesting.com			C		Lozo Prome	12345070				
AND INSURANCE	Testing				Chan		Taiman					
CUNICAL STUDY CATEGODIZATION FORM					- Department		Hospital / Institution (7)					
CEINICAL STODY CATEGORIZATION FORM	- Position (7) -											
Document Upload	Testing				Testing		OTHERS -	University o	r Hong Kong			
Document Upload	Coordinating	Investigator's Delegat	tion <sup>(7)</sup>		Testing		OTHERS +	University o	r Hong Kong		Add	
Lonione, S. Idor Edundzki für Ponar Document Upload	Coordinating	Investigator's Delegat Email	tion (7)	Title (?) † <sub>4</sub>	Testing Surname †	First name †	Position (7) †	Cluster †	Hospital / Institution	Depart	Add	
Lander, and Caready and Para	Coordinating	Investigator's Delegat Email simanchan@testing.co	tion (7) †_	Title (?) 1 <sub>2</sub> . Testing	Testing Sumame † <sub>4</sub> Chan	First name 14	Position (7) †	Cluster †	Hospital / Institution †	Depart	Add tment † <sub>3</sub> Re	
Londer, si dur careadina runar Document Upload	Coordinating	Investigator's Delegat Email simanchan@testing.co	tion <sup>(7)</sup> † <sub>2</sub> om	Title (?) 1 <sub>3</sub> . Testing	Testing Surname † <sub>4</sub> Chan	First name † <sub>4</sub> Taiman	Position (*) †4 Testing	Cluster †	Hospital / †4 Institution †4 SH	Depart Test	Add tment <sup>†</sup> å Re	
ument Upload	Coordinating	Investigator's Delegat Email simanchan@testing.co	tion <sup>(7)</sup> † <sub>8</sub> om	Title (?) † <sub>4</sub> Testing	Testing Sumame † <sub>4</sub> Chan	First name ${}^{\dagger}{}_{\delta}$ Taiman	Position (7) †	Cluster T <sub>4</sub> NTEC	Hospital / Institution	Depart Test	Add tment <sup>†</sup> 4 Re ting	
Londer, si dur caread	Coordinating Edit Information of Edit	Investigator's Delegat Email simanchan@testing.co f Site PI(s) (7) Email	ion (7) † 4 om	Title (?) T <sub>4</sub> Testing Title (?)	Testing Sumarne †, Chan †, Sumarne †,	First name 1/2 Taiman	Position (*) † <sub>4</sub> Testing	Cluster T <sub>\$</sub> NTEC	Hospital / T <sub>a</sub> Institution T <sub>a</sub> SH Department	Depart Test	Add tment 1 & Re ting Add	
Landa, shufi careanna ruan	Coordinating Coordinating Edit Information of Edit	Investigator's Delegat Email ismanchan@testing.cr f Site PI(s) (7) Email step15@ha.org.hi	tion (7) T <sub>4</sub> om T <sub>4</sub> k	Title (?) 1 <sub>8</sub> Testing Title (?) 1	Testing       Sumame       \$1_b       Chan       \$1_b       \$1_b       \$2_pi \$5\$	First name T <sub>a</sub> Taiman First name T <sub>i</sub> Site	Position (*) † <sub>4</sub> Testing	Cluster T <sub>\$</sub> NTEC Hospital / T <sub>\$</sub> Institution T <sub>\$</sub>	Hospital / T <sub>p</sub> Institution T <sub>p</sub> SH Department 123	Depart Test	Add tment † <sub>3</sub> Re ting Add End effective	

Figure 5.2.4.3 "View only" Study Info for Site PI(s)/Delegate(s)



In the top toolbar of the Site Info of Initial Application, there are several action buttons for Site PI(s)/Delegate(s)'s operation: **Save**, **Print**, **Send to Coordinating Investigator** and **Close**.

=	HA Clinical Research Ethic	s Review Portal	Į1				site pi 5 Last Login: 2022-0	A 13-29 10:24 —	pplicant 👻	102 Log	gout
ŧ	Home > Initial Application > Initial A	Application (2022020	08-002-000) (C	Draft)							
Q	B Save Print Send to Coo	ordinating Investigate	Close								
Θ	Team Member Form	2.3.3	.2.1.	,							^
R	Personal Particulars	2.4. Testing	ber								
	PART I: OUTLINE OF APPLICATION	- E-mail addr									
0	PART IIA: STUDY DETAILS	2.5. Testing									
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	2.6. Rm 979,	9/F, Building	19W, No. 19 Scie	ence Park Wes	Avenue, H					
	PART III: ETHICAL IMPLICATIONS	27 CV:	RER Testing	docx						×	1
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	2.1. 01.									J
	Document Upload	3. Co-invest	igators								
	Declaration And Endorsement	Any Co-inv	estigators Inve	olved in this stud	ty? 🔽 Yes	No No					
		(Please spe	ecify if there is	a Lead PI in this	s study in "Major	Responsibility*.)					
		bbA									
		Edit	Title $\uparrow_{\downarrow}$	Sumame $\uparrow_{\downarrow}$	First Name <sup>↑</sup> ↓	Email †	Department $\uparrow_{\downarrow}$	Position 1	Major Responsibilit	ty †j	
		1	Mr	Warren	Paau	111	Testing	Testing	Data/Samp Security	le	
		1	Ms	Warren	Paau	taimanchan@testing .com	123	Testing	Partners Coord	inator	
		4								•	
											-
		Study Info Site	(TYH)								

Figure 5.2.4.4 Action buttons for Site PI(s)/Delegate(S) in Initial Application

Below is the description of each button:

Button	Description
Save	<ul> <li>To save the current change to the draft</li> <li>"Application detail has been updated" message will be prompted</li> </ul>
Print	To download saved application in PDF format for printing
Send to Coordinating Investigator	<ul> <li>To submit the Site Info to CI</li> <li>"Coordinating investigator has been notified" message will pop up for confirmation and the button will be disabled after submission</li> <li>Application can still be viewed as draft status in "Draft" Application List</li> <li>Pending signal "!" will disappear and show "-" in Pending column</li> <li>Completion status of the specific Site Info will change from "X" to "√" after clicking the Indicator button</li> </ul>
	to "Ready to submit" if other Site Info(s) have been submitted to Cl
Close	To exit the Initial Application form and direct to the Application List Page



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## 5.2.4.1 Team Member Form

As a Site PI, you can add registered Delegate(s) (Maximum: 3) to assist completing Site Info if needed.

- 1. Press Add button under Site PI's Delegation of Team Member Form;
- 2. A pop-up dialog will be prompted;
- 3. Add info, including Email, Name, Title, Cluster, Hospital/Institution and Department, for Delegate in the pop-up dialog, if any\*;
- 4. Concerned Site PI(s) and Delegate(s) will receive the notification in Portal and by email regarding the updates on Delegation
  - Change of delegation: Delegation of <Site PI (XXX)> is changed for "<Submission No.>".

### \*Remarks:

1. **Load Profile** button in pop-up dialog: Contact Number, Surname, First Name and Title can be auto-filled in for the registered user after the applicant email is input and clicking Load Profile button.

≡	HA Clinical Research Ethic	Review Portal	site pi 5 Last Login: 2022-04-12 13:09 Applicant 👻 🖓 Logout
<b>A</b>	Home > Initial Application > Initial A	oplication (20220411-001-000) (Draft) rdinating Investigator Close	
8	Team Member Form Personal Particulars PART I: OUTLINE OF APPLICATION PART IIA: STUDY DETAILS PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Team Member Form       Site P       Adding site principal investigator's delegation       Enal       ran@ha.org.hk	Add X me T <sub>3</sub> Cluster T <sub>3</sub> Hospital / T <sub>3</sub> C
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE Document Upload Declaration And Endorsement	Sumame First Name Title (7)  PER: Cluster Hospital / Institution 1. Department	
		Cancel	rm _

Figure 5.2.4.1.1 Pop-Up dialogs for Adding Site PI's Delegate(s)



## 5.2.4.2 Personal Particulars

Personal Particulars is a section for Site PI to fill in personal information.

- 1. Fill in Title and Name of Site PI (Applicant) in Q1;
- 2. Provide info of Site PI's Position by selecting checkbox of Q2.1 2.3;
  - Multiple selection is allowed for Q2.1 2.3
  - Corresponding text area will be enabled and mandatory to fill in once the checkbox is selected
- 3. Provide Phone Number, Email Address and Mailing Address of Site PI in Q2.4 2.5;
- 4. Upload CV of PI by pressing **Upload** button in Q2.7;
- 5. Select "Yes/No" in checkbox of Q3 Co-investigators.
  - If "Yes" is selected, below **Add** button will be enabled to provide info for Coinvestigator in pop-up dialog.
  - More than 1 Co-investigator can be added.
  - Click Pencil button to edit filled data for the specific Co-investigator in pop-up dialog
  - Click Remove button to delete the selected Co-investigator

=	HA Clinical Research Ethic	s Review Portal	site pi 5 Last Login: 2022-04-12 13:09 Applicant ▼	Logout		
♠	Home > Initial Application > Initial A	pplication (20220411-001-000) (Draft)				
Q	Save Print Send to Coo	rdinating Investigator Close				
Θ	Team Member Form	PERSONAL PARTICULARS OF PRINCIPAL INVESTIGATOR AND CO-IN	VESTIGATOR	-		
6	Personal Particulars	Principal Investigator (Applicant)				
-	PART I: OUTLINE OF APPLICATION	1. Title (e.g. Mr, Mrs, Ms, Miss, Dr)				
0	PART IIA: STUDY DETAILS	Sumama	First Mamo			
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Summe	riist Norie			
	PART III: ETHICAL IMPLICATIONS	Name in Chinese (Optional)				
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	2. Position of the Principal Investigator (PI)				
	Document Upload	2.1. HA Staff (Including HA Honorary staff)				
	Declaration And Endorsement					
		2.1.1. Position				
		2.1.2. Department / Unit				
		2.1.3. Cluster -				
		2.1.4. Hospital 👻				
	2.1.4.1.					
		2.2. University Staff				
		2.2.1. Pesition		•		
		Study Info Site (TWEH)				

Figure 5.2.4.2.1 Personal Particulars



## 5.2.4.3 Part I

In Site Info, Part I is mainly for Site PI/Delegate(s) to fill in Study Site(s) details.

Click Add button to provide info for applying site(s) in pop-up dialog in Q2 Study Site(s)

- More than 1 applying site can be added
- Click **Pencil** button to edit the filled data for the specific applying site in pop-up dialog
- Click Remove button to delete the selected applying site

=	HA Clinical Research Ethics	Review Portal	site pi 5 Last Login: 2022-03-09 18:19	Applicant 👻 🙎	Logout
ŧ	Home > Initial Application > Initial A	pplication (20220208-002-000) (Draft)			
Q	Save Print Send to Coo	dinating Investigator Close			
Θ	Team Member Form	Eait Tibe 'J Sumame 'J Name 'J Email	·t Department ·t Position ·t	Responsibility	
6	Personal Particulars PART I: OUTLINE OF APPLICATION	🛕 No Da	ata		
?	PART IIA: STUDY DETAILS PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	•			<u> </u>
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE Document Upload Declaration And Endorsement	PART I: OUTLINE OF APPLICATION         2. Study Sites(s)         2.3. Study sites         2.3.1. Applying site(s) in HA (?)         Add			
		Edit Cluster T <sub>Å</sub> Hospital T <sub>Å</sub> De	partment $\dagger_{\hat{a}}$ If other Testing	rs, please specify † <sub>j</sub> No	Remov
		PART IIA: STUDY DETAILS         7. Study subjects         7.4. Number of subjects to be recruited locally in applying site(s) <sup>(7)</sup> 7.5. How will subject be identified and recruited         Study Info       Site (TYH)			

Figure 5.2.4.3.1 Part I: Outline of Application in Site Info



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## 5.2.4.4 Part IIA

Part IIA of Site Info is about study subjects' recruitment in the applying sites in Study Details.

- 1. Input the number of subjects to be recruited locally in applying site(s) in Q7.4;
- 2. Provide details on how subject to be identified and recruited in Q7.5

≡	HA Clinical Research Ethics	Review Portal	site pi 5 Last Login: 2022-03-09 18:19	Applicant 👻	99	Logout
ŧ	<u>Home</u> > <u>Initial Application</u> > Initial A	pplication (20220208-002-000) (Draft)				
Q	Save Print Send to Coo	dinating Investigator Close				
Θ	Team Member Form	NTWC POH	123	-		<b>^</b>
₽	Personal Particulars	•				•
۵	PART I: OUTLINE OF APPLICATION	PART IIA: STUDY DETAILS				
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	7. Study subjects				
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE Document Upload Declaration And Endorsement	7.4.     111       7.5.     Herry will subject to identified and recruited				
		PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY         11.       Study Article and Arrangements         11.3.       Number of extra visits / admission on top of usual care         11.4.       Will any of the study interventions / procedures be performed by persons of         Study Info       Site (TVH)	other than the investigators?			

Figure 5.2.4.4.1 Part IIA: Study Details in Site Info



## 5.2.4.5 Part IIB

Part IIB of Site Info is for Study Article and Arrangements in the applying site.

- 1. Input the number of extra visits / admissions on top of usual care in Q 11.3;
- 2. Select "Yes/No" in the checkbox of Q11.4 to answer the study interventions / procedures performed by person.
  - If "Yes" is selected, Q11.4.1 will be enabled to fill in;
  - If "No" is selected, Q11.4.1 will be dimmed

=	HA Clinical Research Ethica	s Review Portal	site pi 5 Last Login: 2022-03-09 18:19	Applicant 👻	. <mark>99</mark>	Logout
ŧ	Home > Initial Application > Initial A	pplication (20220208-002-000) (Draft)				
Q	Save Print Send to Coo	dinating Investigator Close				
Θ	Team Member Form					-
6	Personal Particulars PART I: OUTLINE OF APPLICATION PART IIA: STUDY DETAILS					
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	PART IIB: STI INV DETAILS FOR PROSPECTIVE STI INV				
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE Document Upload Declaration And Endorsement	11. Study Article and Arrangements         Number of extra visits / admission on top of usual care         11.3. 1         11.4. Will any of the study interventions / procedures be performed by persons other the Yes         Yes       No         11.4.1. If yes, by whom and where	nan the investigators?			
		PART III: ETHICAL IMPLICATIONS  13. Information and Consent  13.2. Who will carry out the informed consent process with the subject?  Principal Investigators Other Investigators Research Assistant  PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE  Study Info Site (TVH)	Others			

Figure 5.2.4.5.1 Part IIB: Study Details for Prospective Study in Site Info



## 5.2.4.6 Part III

Part III of Site Info is about who to carry out the informed consent process with the subjects in Ethical Implications.

- Select checkbox of "Principal Investigator / Other Investigator / Research Assistant / Others" to answer Q13.2;
- 2. If "Others" is selected, the text area will be enabled to fill in details.



Figure 5.2.4.6.1 Part III: Ethical Implications in Site Info



## 5.2.4.7 Part IV

Part IV of Site Info is about the impact on extra HA resources and additional reimbursement received by the applying site in Budget, Resource, Indemnity and Insurance.

- 1. Select "Yes/No" in checkbox of Q19.1;
  - If "Yes" is selected, Q19.1.1 & 19.1.2 will be enabled to fill in details;
  - If "No" is selected, Q19.1.1 & 19.1.2 will be dimmed
- 2. Select "Yes/No" in checkbox of Q19.2
  - If "Yes" is selected, Q19.2.1 will be enabled to fill in details;
  - If "No" is selected, Q19.2.2 will be enabled to fill in details

=	HA Clinical Research Ethic	Review Portal	site pi 5 Last Login: 2022-03-09 18:19	Applicant 👻	99	Logout	t
ŧ	Home > Initial Application > Initial A	pplication (20220208-002-000) (Draft)					
Q	B Save Print Send to Coo	dinating Investigator Close					
Θ	Team Member Form	Principal Investigators 🗌 Other Investigators 🗌 Research As	ssistant 🗌 Others				*
6	Personal Particulars PART I: OUTLINE OF APPLICATION PART IIA: STUDY DETAILS PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	PART IV. BUDGET, RESOURCES, INDEMNITY AND INSURANCE         19.1. Will this study consume extra HA resources?       ☑ Yes □ No         19.1.1.       □ <sup>H</sup> yes, provide setalls       □         19.1.2.       If extra HA resources is required, how will this affect the HA services	s of other patients with competing ner	eds?			
	Document Upload Declaration And Endorsement	Testing         19.2. Will the study site (hospital) receive reimbursement for the study?         19.2.1.         If yes, state the format of reimbursement         19.2.1.         If no, state the reason(s)         19.2.2.         If no, state the reason(s)         19.2.2.         Document Upload         23.       Subject Information Sheet and Informed Consent Form (7) (Supplemental Study Info	Yes No				Ŧ

Figure 5.2.4.7.1 Part IV: Budget, Resource, Indemnity and Insurance in Site Info



## 5.2.4.8 Document Upload

In this section, you can upload the related documents in Site Info for your application.

- Q27 & Q34 is mandatory to upload files
- Form for Q27 can be downloaded from "Useful Information/User Manual" via the navigation bar on the left.

≡	HA Clinical Research Ethics	s Review Portal				site pi 5 Last Logir	i 2022-04-12 13:0	Appli	cant 👻	98 Log	out
<b>n</b>	Home > Initial Application > Initial A	Application (20220411-001-000)	(Draft)								
Q	Save Print Send to Coor	ordinating Investigator	se								
θ	Team Member Form	Document Upload									1
6	Personal Particulars	23. Subject Information Sh	eet and In	formed Consent Forr	n <sup>(7)</sup> (S	Supplementary)					
۵	PART IIA: STUDY DETAILS	bbA									
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Upload Date	† <sub>1</sub>	Created By	t <sub>k</sub>	File Name	† <sub>1</sub>	Remove			
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE			<b>A</b>	No	Data					
	Document Upload	OF Weller information for									
	Declaration And Endorsement	Add	subject, s	uch as recruitment a	avertis	ement, etc 🥶 (Supplementary)					l
		Upload Date	τ,	Created By	$^{\dagger}$	File Name	† <sub>1</sub>	Remove			ľ
					No	Data					

Figure 5.2.4.8.1 Document Upload in Site Info

- Press Add button in the specific document upload table that you want to upload document. Multiple documents upload is feasible;
- 2. Dialog will be prompted for document upload as Figure 5.2.4.8.2;
- 3. Press Upload button to select the document from your local computer;
- 4. File Name will be same as the uploaded file;
- 5. Press Add button in the pop-up dialog for confirmation;
- 6. The record will be shown in the document upload table;
- 7. A hyperlink of File Name will be enabled for download once you "Save" the Initial Application;
- 8. Press **Remove** button you can delete the specific uploaded document.

Subject Info	rmation Sheet and Informed Consent Form
Created By:	site pi 5
File Name:	Upload
	You haven't uploaded file anything yet!
	Cancel Add

Figure 5.2.4.8.2 Pop-up Dialogs for Document Upload



### 5.2.4.9 Declaration and Endorsement

This part is about Declaration and Endorsement by Investigators as Figure 5.2.4.9.1.

There are 4 sections in this part:

- Section A. Declaration by Principal Investigator and other Investigator(s)
- Section B. Endorsement by COS or Authorised Representative<sup>3</sup> of HA
- Section C. Endorsement by Head of Department<sup>4</sup> of the Universities
- Section D. Endorsement by COS(s) or Head(s) of the Collaborating Department(s) in HA or in Universities.



Figure 5.2.4.9.1 Declaration and Endorsement in Site Info

- 1. In Section A:
  - For PI and Co-Investigator, Role, Title and Name will be auto-filled based on the initial filled data of PI and Co-Investigator in Personal Particulars. If you have made any changes after initial, please check this part and update before further proceeding.
    - Press Pencil button to revise the pre-filled data or input Position, Responsibility for clinical oversight and Date for PI and Co-investigators if needed
  - For Student Project, if checkbox of Q2.3 Student is selected with data inputted, Role and Name of Academic Supervisor and Site Supervisor in Q2.3.2 and Q2.3.3 will be auto-filled in Student Project table.
    - Press Pencil button to input Title, Position, Responsibility for clinical oversight and Date for completeness



- Both Academic Supervisor and Site Supervisor can be removed in the table if their signature is not needed.
- 2. Either Section B. or Section C. is mandatory for data input:
  - Press Add button in corresponding table(s) to input data in the pop-up dialogs if needed
- 3. Section D. is not mandatory for data input:
  - Press Add button in the table to input data in the pop-up dialogs if needed
- 4. Press Print button to download Initial Application for signature in current Site Info;
- 5. Upload the signed document in Q34. Signed Application Form Declaration and Endorsement (Mandatory).



# 5.2.5 Site PI/Delegate(s) to Submit the Site Info to CI/Delegate(s)

After completing all the mandatory field and uploading the signed Declaration and Endorsement form of Site Info, Site PI/Delegate(s) can submit the Site Info to CI.

- 1. Press Send to Coordinating Investigator button to submit the Site Info to CI;
- 2. Indicator will be shown in the pop-up dialog for incomplete field if applicable;

≡	HA Clinical Research Ethics	Review Portal	site pi 5 Applicant	Logout
ŧ	Home > Initial Application > Initial Application			
Q	Save Print Send to Coor	dinating Investigator Close		
Θ	Team Member Form	28. Indemnity Agreement (Mandatory for sponsored trial)		-
6	Personal Particulars	Add		
-	PART I: OUTLINE OF APPLICATION			
0	PART IIA: STUDY DETAILS	Upload Date $\uparrow_{\downarrow}$ Created By $\uparrow_{\downarrow}$	File Name <sup>†</sup> Remove	
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	2022-03-29 site pi 5	CRER Testing.docx	
	PART III: ETHICAL IMPLICATIONS	2022-03-29 site pi 5	CRER Testing.docx	
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	30. Other Documents - Site Information (Supplementary)		
	Document Upload	Add		
	Declaration And Endorsement	Upload Date $\uparrow_{\downarrow}$ Created By $\uparrow_{\downarrow}$	File Name $$\hat{\uparrow}_{\downarrow}$$ Remove	
		2022-03-29 site pi 5	CRER Testing.docx	
		2022-03-29 site pi 5	CRER Testing.docx	
		34. Signed DECLARATION AND ENDORSEMENT (Mandatory)		
		Upload Date $\ensuremath{\uparrow_{\downarrow}}$ Created By $\ensuremath{\uparrow_{\downarrow}}$	File Name <sup>†</sup> ↓ Remove	
		2022-03-29 site pi 5	CRER Testing.docx	

Figure 5.2.5.1 Screen of "Send to Coordinating Investigator" button in Site Info

3. A dialog as Figure 5.2.5.2 will be prompted before submitting the Site Info to CI;



Figure 5.2.5.2 Pop-up dialogs of Reminder for Unsaved Changes in Site Info before submission

- 4. Press Confirm button to proceed the submission;
- 5. A dialog with "Coordinating investigator has been notified" will be prompted for confirmation as Figure 5.2.5.3;





Figure 5.2.5.3 Pop-up dialogs for Confirmation for Site Info Submission

- 6. The related application can still be viewed as Draft status in "Draft" Application List as Figure 5.2.5.4;
  - Pending signal "!" will disappear and show "-" in Pending column
  - Completion status of the specific Site Info will change from "X" to "√" after clicking the Info button
- 7. Overall Site Info status in Site Info column will change from "Incomplete" to "Ready to submit" when all Site Info(s) have been submitted to CI;

≡	Ф н	A Clinic	al Research	n Ethics Review Port	al		5 L	site pi 5 ast Login: 2022	04-12 19:11	Applicant 🗸		Logout
♠	Home >	Initial Ap	oplications >	Draft								
Q	Applicati	on List										
θ	Hide/Shi	ow Columr	Colla	apse All Expand Al	Download Appli	Refresh						
6								Filter keywo	rd		Page Size:	10 -
۵			Pending	CRER Application	IRB/REC Reference	Submission No. 1	Scientific Title	t.	Status	Site Infr		Last Modifi
?			renariy	No. +	No. +		Generative The	+	Giarda	Crite His		Last mount
	+					20220208-002-000	Test123		Draft	Ready to submit	0 2	022-04-12
	+		()		-	20220411-001-000	Testing - 0411		Draft	Incompiete	H V	022-04-12

Figure 5.2.5.4 Changes on Application List after Site Info is submitted

8. Draft (a/b) previously shown in Application List will change to Draft (a-1/b) after Site Info submitted to CI as Figure 5.2.5.5.

= 🍈 HA Clinical Resear	ch Ethics Review Portal	site pi 5 Last Login: 2022-1	04-12 23:05 Applicant 👻	P Logout	
A Dashboard	Home				
Q Search	Dashboard				
Profile	Applications				
Initial Applications	Draft 3 / 4	Returned			
🚯 Post Approval Document 🗸 🗸					
Useful Information/User Manual		Expire in < 30 days <u>JQ</u>			
FN Version: v0.931 BN: v0.458 build at 20220329 08:45					

Figure 5.2.5.5 Changes on Dashboard for Application after Site Info is submitted



# 5.2.6 CI/Delegate(s) Return the Site Info to Site PI/Delegate(s)

After receiving the notification that the Site Info is submitted from Site PI/Delegate(s), as a CI/Delegate(s), you can click the notification message to access to the relevant Initial Application as Figure 5.2.6.1.

• Site Info Submission: Site Info"(hospital)" has been submitted to you "<CRER Application No.>".



Figure 5.2.6.1 Screen of Initial Application after clicking notification of Site Info Submission

You can return the specific Site Info to the relevant Site PI/Delegate(s) as below.

- Click the Site Info tab to switch to the "View-only" Site Info as Figure 5.2.6.2;
- Press the **Return to Site** button to return the Site Info to the concerned Site PI/Delegate(s);
- A dialog "Are you sure to return to study site?" will be prompted as Figure 5.2.6.3;
- Click **Confirm** button in pop-up dialog to proceed;
- Pop-up dialog "Application is Returned to Study Site." will be shown as Figure 5.2.6.4;
- Concerned Site PI/Delegate(s) will receive a notification in Portal and by email when the Site Info is returned
  - Site Info for Modification: Site Info"(hospital)" has been returned to you for modification <Submission No>. Please click "Send to Coordinating Investigator" after modified.
- Concerned Site PI/Delegate(s) can re-submit the Site Info after modification. Refer to <u>Re-submit the Site Info by Site PI/Delegate(s)</u>.



## Hospital Authority CRER Portal User Manual for Applicant

≡	HA Clinical Research Ethic	s Review Portal	Taiman Chan Applicant 👻 🤔 Logout Last Login: 2022-04-12 23:36	
ŧ	Home > Initial Application > Initial	Application (20220208-002-000) (Draft)		
Q	Save Print Submit	Discard Return to Site Close	View On	у
Θ	Team Member Form	Team Member Form		•
6	Personal Particulars PART I: OUTLINE OF APPLICATION	Site Principal Investigator's Delegation	Add	
0	PART IIA: STUDY DETAILS	Edit Email $\uparrow_{\downarrow}$ Title $^{(7)}$ $\uparrow_{\downarrow}$ Surname $\uparrow_{\downarrow}$	$\begin{array}{ccc} \mbox{First name} & \hat{\tau}_{\downarrow} & \mbox{Cluster} & \hat{\tau}_{\downarrow} & \mbox{Hospital}  / & \\ \mbox{Institution} & \hat{\tau}_{\downarrow} & \mbox{D} \end{array}$	
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	✓ sitepi5@ha.org.hk 1 pi 5	site KWC PMH	
	PART III: ETHICAL IMPLICATIONS	4	•	
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	PERSONAL PARTICULARS OF PRINCIPAL INVESTIGATOR AND CO-INVESTIG	GATOR	
	Document Upload	Principal Investigator (Applicant)		
	Declaration And Endorsement	Title (a.g. Mr; Mrs, Ms, Miss, Dr)		
		Sumame First Na	ime	
		Chan Tèi Mi	an	
		2. Position of the Principal Investigator (PI)		
		2.1. 🛛 HA Staff (Including HA Honorary staff)		
		2.1.1. Position		
		2.1.2. 11		
		2.1.3. HKWC *		
		Study Info Site (TYH)		

Figure 5.2.6.2 Screen of "View-only" Site Info of Initial Application

Are you sure to return to study site?		
	Cancel	Confirm

Figure 5.2.6.3 Popup dialog before returning Site Info to Study Site



Figure 5.2.6.4 Popup dialog after returning Site Info to Study Site



# 5.2.7 Re-submit the Site Info by Site PI/Delegate(s)

As a Site PI/Delegate(s), you will receive a notification in Portal and by email when the Site Info is returned by CI/Delegate(s) as Figure 5.2.7.1.

• Site Info for Modification: Site Info"(hospital)" has been returned to you for modification <Submission No>. Please click "Send to Coordinating Investigator" after modified.

= 💠 HA Clinical Resear	ch Ethics Review Portal			Site pi 5 Applicant ▾ 🦉 Log	out
A Dashboard	Home			Notification Mark All Re	ad
Q Search	Dashboard			From: Taiman Chan 2022-04-12 23-04-57 Site info for Modification: Site info"(TVH)" has been returned to you for modification 2022/02/9-002-000. Please click "Send to Coordinating Investigations" after modified	
Initial Applications  Post Approval Document	Draft 3/3		Returned	From: Taiman Chan 2022-04-12 19:10:20 Change of Team members: SITE PI(TWEH) is changed for 20220411-001-	
Useful Information/User Manual		Expire in ≥ 30 days	<u>.(Q).</u>	000. Mark Read	
FN Version: v0.932 BN: v0.458 build at 20220329 08:45	Post Approval Documents	Expire in < 30 days	101	From: CRER System 2022-04-12 00:00:00 Overdue: IRB-2022-002 - Initial Submission is overdue: Please submit afresh via the CRER Portal if needed. Mark Read	
	Draft Z./.Z	Expire in ≥ 30 days	Returned <u>0 / 0</u> ( <u>0)</u>	From: CRER System 2022-04-11 00:00:01 Overdue: IRB-2022-002 - Initial Submission is overdue. Please submit afresh via the CRER Portal if needed. Mark Read	•
		Expire in < 30 days	<u>(Q)</u>		

Figure 5.2.7.1 Notification of Site Info returned for modification

- 1. Click the notification to access to the Site Info;
- 2. Amend the Site Info directly;
- 3. Re-submit the Site Info after modification. Refer to <u>Site PI/Delegate(s) to Submit the Site Info</u> to <u>CI/Delegate(s)</u>



# 5.2.8 Submit Initial Application Form by CI/Delegate(s)

As a Cl/Delegate(s), you can submit the Initial Application form if the following items are ready:

1. Overall Site Info status in Site Info column will change from "Incomplete" to "Ready to submit" as Figure 5.2.8.1;

2. Complete all the mandatory fields in Study info.

= 🔷 HA Clinical Researc	ch Ethics Revi	iew Portal			Taiman Chan Last Login: 2022-04-13 00:4	5 Applicant	<u> </u>	gout
A Dashboard	<u>Home</u> > <u>Init</u>	ial <u>Applications</u> > Drafi	t.					
Q, Search	Application Li	st						
O Profile	Hide/Show Co	lumns Collapse Al	Expand All	Download Application	Refresh			
Initial Applications					Filter keyword		Page Size: 1	10 -
New Draft	Pending	$\begin{array}{c} \text{CRER Application} \\ \text{No.} \end{array} \uparrow_{\downarrow}$	IRB/REC Reference $\uparrow_{\downarrow}$ No.	Submission No. $\uparrow_{\downarrow}$	Scientific Title	† <sub>↓</sub> Status	Site Info	•
Sent	()			20220208-002-000	Test123	Draft	Ready to submit	0
Returned	0			20220411-001-000	Testing - 0411	Draft	Incomplete	0
Completed	()	•	۰.	20220328-005-000	Testing	Draft	Incomplete	0
Acknowledged	()			20220322-001-000	Testing	Draft	Incomplete	0
Expired	()			20220204-001-000	Sec Form	Draft	Incomplete	0
All	()	-	2	20220118-002-000	Testing	Draft	Incomplete	0
Post Approval Document	4							•
Useful Information/User Manual	Showing 1 to 6	of 6 entries					< 1	>
FN Version: v0.931 BN: v0.458 build at 20220329 08:45								

Figure 5.2.8.1 Screen of "Ready to Submit" Site Info status in Application List



CI/Delegate(s) can submit the Initial Application form by following steps:

- 1. Click Scientific Title to access to the Initial Application;
- 2. Press **Submit** button to submit the Initial Application form as Figure 5.2.8.2.
- 3. Indicator will be shown in the pop-up dialog for incomplete field in Study Info if applicable

=	HA Clinical Research Ethic:	Review Portal	Taiman Chan Last Login: 2022-04-13 00:45	Applicant 👻	<b>64</b>	Logout			
A	Home > Initial Application > Initial A	pplication (20220208-002-000) (Draft)							
Q	B Save Print Submit	Discard Close							
Θ	Instruction					-			
6	Team Member Form		局						
6	PART I: OUTLINE OF APPLICATION	AUTHORIT	r v						
?	PART HIS STUDY DETAILS PART HIS STUDY DETAILS FOR PROSPECTIVE STUDY	Hospital Authority Clinical Research Ethics Review Applica	tion Form						
	PART III: ETHICAL IMPLICATIONS PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE CLINICAL STUDY CATEGORIZATION FORM	IRB: REC Reference No. (For Office Use)							
Document Upload         1. Central Institutional Review Board / Oluster Research Ethics Committee/Institutional Review Board ("CIRB/CREC/IRB") is dedicated to oversee conducted by Hospital Authority ("HA")/University personnel in the Oluster with the aim of protecting the rights, safety and well-being of the resorted for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, being of subjects recruited from the Cluster.									
		<ol> <li>Please submit the application via online system, enter all internation required and upload reliance of the submit o</li></ol>	evant application dossier files jects must be uniquely ident	to the required fields. ified, for example, by	Applicat	tion			
		4. For information on research ethics and methodology, please visit HA Research Ethics Intrane	et Website ( <u>http://cetm.home/c</u>	es/re/Home.aspx)					
		<ol> <li>The handling and storage for data containing personal identity must comply with HA Oli university policies if applicable.</li> </ol>	inical Data Policy Manual and	d other prevailing HA	policies i	and			
		6. Selected information will be passed to the HA's and University's Central Register of Clinical Re	esearch for the purpose of cen	tral record and risk m	anagemer	nt.			
		7. Information will be passed to corresponding Central IRB / CREC/IRB for the purpose of resea	irch ethics review.						
		Reminder							
		<ol> <li>Hospital Authority as a Research Institution         The HA is a body corporate established under the Hospital Authority Ordinance (Chapter responsibilities of establishing, managing, controlling and developing the public hospital systematic policies and strategies, the HA also has the responsibility to promote assist and     </li> </ol>	er 113 of the laws of Hong stem in Hong Kong and advisi d take part in research relating	Kong). In addition to ing the Hong Kong go to hospital services (	the prim vernment Chapter 1	nary ton 113. ▼			
		Study Info Site (TYH)							

Figure 5.2.8.2 Screen of Submit button in Study Info of Initial Application

4. A dialog as Figure 5.2.8.3 will be prompted for confirmation;



Figure 5.2.8.3 Pop-up dialog of Reminder for Unsaved Changes in Study Info before submission

- 5. Press Confirm button to proceed;
- 6. A dialog of "Submitted successfully." will be prompted for confirmation as Figure 5.2.8.4;
- 7. You will be direct to the Dashboard Page after submission;





Figure 5.2.8.4 Pop-up dialogs after the Submission of Initial Application

8. The status of the Initial Application will change from "Draft" to "Submitted" Status and can be found in "Sent" Application List as Figure 5.2.8.5.

- Pending signal "!" will disappear and show "-" in Pending column
- Overall Site Info status will change from "Ready to Submit" to **Info** icon in Site Info Column
- CRER Application No. will be auto-generated by system and shown in the related column

= 📫 HA Clinical Resear	rch Ethics Review	/ Portal		1	site pi 1 Last Login	2022-06-30 12:36	Applicant	<b></b>	Logout
f Dashboard	Home > Initial A	Applications > Sent							
Q Search	Application List								
Profile	Hide/Show Colum	Collapse All	Expand All	Download Application	fresh				
Initial Applications					Filter	keyword		Page Size:	10 -
New									
Draft	$\begin{array}{c} \text{RER Application} \\ \text{No.} \end{array} \uparrow_{\downarrow}$	IRB/REC Reference T <sub>↓</sub>	Submission No. $\uparrow_{\downarrow}$	Scientific Title	↑Ļ	Status	Site Info	Last	Modified Da
Sent	TEC-2022-007	-	20220628-003-000	User Manual		Requested for Return	0	2022-0	6-28 16:3
Returned	RB-2022-042		20220627-006-000	DISTRIBUTE STATUS		Submitted	θ	2022-0	6-27 16:5
Completed	RB-2022-041	1234	20220627-005-000	TEST		Confirmed	0	2022-0	6-27 16:1
Acknowledged	RB-2022-040		20220627-004-000	TEST		Submitted	θ	2022-0	6-27 16:0

Figure 5.2.8.5 Changes on Application List after Initial Application is submitted

4. Draft (a/b) previously shown in "Application" on Dashboard will change to Draft (a-1/b-1) as Figure 5.2.8.6, after Initial Application is submitted.

= 🍈 HA Clinical Researc	ch Ethics Review Portal		Taiman Cha Last Login: 202	in Applicant -	🧖 Logout
A Dashboard	Home				
Q, Search	Dashboard				
Profile	Applications				
Initial Applications	Draft 5 / 5	Returned			
Post Approval Document ~	( <u> </u>				
Useful Information/User Manual		Expire in 2 30 days			
FN Version: v0.932 BN: v0.458 build at 20220329 08:45		Expire in < 30 days (0)			

Figure 5.2.8.6 Changes on Dashboard for Application after Initial Application is submitted



## 5.2.8.1 Submitted Initial Application

After the Initial Application is submitted, it will be shown in "Sent" Application List.

To review the application details, you follow the below steps as Figure 5.2.8.1.1:

- 1. Tick the checkbox of the specific Initial Application;
- 2. Download Application button will be enabled for further action;
- 3. Press Download Application button;
- 4. Initial Application named <Submission No><Scientific Title> will be downloaded in zip file;
- 5. The zip file includes the application form in PDF format and all uploaded documents.

= 🍈 HA Clinical Researc	ch Ethics	Review I	Portal			Taiman Last Logi	Chan Applican 2022-04-13 00:45	nt 👻 📮	Logout
A Dashboard	Home >	Initial Ap	plications >	> Sent					
Q Search	Applicat	on List							
Profile	Hide/Sh	ow Column	s Coll	apse All Expand A	I Download Appli	cation Refresh			
Initial Applications						Filter	keyword	Page Size	e: 10 +
New		-		CRER Application	IRB/REC Reference				
Draft			Pending	No.	No.	Submission No. 1	Scientific Title	τ <sub>4</sub>	Status
Sent	+			HKWC-2022-053	1 <b>a</b> 2	20220208-002-000	Test123	SU	ubmitted
Returned	4								Þ
Approved									
Completed	Showing	to 1 of 1 e	ntries					<	
Acknowledged									
Expired									
Archived									
All									
Post Approval Document									
Useful Information/User Manual									
FN Version: v0.932 BN: v0.458 build at 20220329 08:45									
	/								
20220208-002-000zip	^							Show	all X

Figure 5.2.8.1.1 Download Initial Application



Also, you can click the **Scientific Title** to access to the Initial Application to review the details of the Initial Application, both Study Info and Site Info will be view-only as Figure 5.2.8.1.2.

You can also find the CRER Application No. in the top right corner of Study Info.

=	HA Clinical Research Ethic	s Review Portal Taiman Chan Applicant - 49 Logout
ŧ	Home > Initial Application > Initial A	pplication (20220208-002-000) (Submitted)
Q	Print Close	View Only
Θ	Instruction	CRER Application No: HKWC-2022-053
R	Team Member Form	<b>醫院管理局</b>
	PART I: OUTLINE OF APPLICATION	HOSPITAL
0	PART IIA: STUDY DETAILS	Hospital Authority
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Clinical Research Ethics Review Application Form
	PART III: ETHICAL IMPLICATIONS	IRB/ REC Reference No. (For Office Use)
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	
	CLINICAL STUDY CATEGORIZATION FORM	Instructions to applicant
	Document Upload	<ol> <li>Central Institutional Review Board / Cluster Research Ethics Committee/Institutional Review Board ("CIRB/OREO/RB") is dedicated to oversee clinical studies conducted by Hospital Authority (HA)/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.</li> </ol>
		2. Please submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
		<ol> <li>Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.</li> </ol>
2		Study Info Site (TYH) Comment Sheet

Figure 5.2.8.1.2 View-only mode for submitted Initial Application

Comment Sheet will be shown and allows you to review the comment history after switching to the Comment Sheet tab as Figure 5.2.8.1.3.

≡	(The clinical Rest	search Ethics Re	eview Portal			Taiman Chan Last Login: 2022-04-13 00:45	Applicant 👻	67 Logout
A	Home > Initial Applicat	on > Initial Applie	cation (20220208-002	-000) (Submitted)				
Q	Back to study info							
Θ	Comment History							
Ð	Date î	From	†_ То	η	Comment	$\hat{\tau}_{\downarrow}$ Attachment $\hat{\tau}_{\downarrow}$		
0								
?				No Data				
	Study Info Site (TYH)	Comment Sheet						

5.2.8.1.3 Comment Sheet of the Initial Application



If you would like to make changes to the Initial Application after submission, you can use "**Request for Return**". If you would like to add / update the Delegation(s), you can use "**Change Delegation**".

- CI Delegate(s) can only be added/edited by CI
- Site PI Delegate(s) can only be added/edited by the relevant Site PI.

These 2 options can be found by clicking More Button in Action Menu in "Sent" Application List as Figure 5.2.8.1.4.

= 🔹 HA Clinical Resea	rch Ethics Re	view Portal			Taima Last Log	n Chan in: 2022-04-13 09:21	Applicant 👻	57 Logout
A Dashboard	Home > In	nitial Applications > Sent						
Q, Search	Application	List						
O Profile	Hide/Show (	Columns Collapse All	Expand All	Download Appli	Refresh			
Initial Applications					Filte	r keyword	Pa	ge Size: 10 🔻
New								
Draft	o. †j.	Scientific Title $$^{\uparrow}_{\downarrow}$$	Status	Site Info	Last Modified Date	Expiry Date $\uparrow_{\downarrow}$	Coordinating Investigator (CI)	↑ <sub>↓</sub> Action
Sent	-000	Test123	Submitted		2022-04-13 17:28:31		Taiman Chan	
Returned	4						Char	nge Delegation
Approved		122					Requ	uest for Return
Completed	Showing 1 to	1 of 1 entries					Clon	e to draft
Acknowledged							Over	view
Expired							_	
Archived								
All								

Figure 5.2.8.1.4 Screen of "Change Delegation" & "Request for Return" button in Application List

Refer to <u>Request for Return of Initial Application</u> and <u>Change Delegation</u> for more information.



## 5.2.9 Returned Initial Application and Re-submit Initial Application

You may receive a notification in Portal and by email from CCO/Cluster Admin/Secretary if Study Info or Site Info of an application is returned to you as Figure 5.2.9.1.

• Return: <Action Role> returned "<CRER Application No.>" - <Document Name>. Please check the "Comment Sheet" tab for suggested comments.

Dashboard Home Q Search Dashbo	pard			Notification Mar	k All Read
Q Search Dashbo	pard				_
				From: Taiman Chan 2022-04-13/2 Desum: SEORETARY returned HK/WO 2022-053, Joint Scheduling	3:07:37
9 Profile Applicat	tions			Please check the "Comment Sheet" tab for suggested comments. Mar	k Read
Initial Applications V	Draft	1	Returned	From: Taiman Chan 2022-04-13 1	7:28:38
▶ Post Approval Document ∨	5/5		1/1	Submission: Received a new submission HKWC-2022-053 - Initial Application.	
2 Liseful Information/Liser Manual		Expire in ≥ 30 days	. <u>(0)</u>	Mar	k Read
oserui mornation/oser Manuar		Expire in < 30 days	(1)	From: site pi 1 2022-04-13 1	7:26:08
Version: v0.932				Request: Received a request for return IRB-2022-085 - Amendment Application.	
N: v0.458 build at 20220329 08:45 Post Ap	proval Documents			Mar	k Read
1	Draft	1	Returned	From: site pi 1 2022-04-13 1	7:25:30
1	2/2	1	0/0	Submission: Received a new submission IRB-2022-085 - Amendme Application.	nt
		Expire in ≥ 30 days	<u>(Q)</u>	Mar	k Read
		Expire in < 30 days	<u>(0)</u>		

Figure 5.2.9.1 Notification for Returned Initial Application

The status of the Initial Application will change from "Submitted" to "Returned". Also, the figures on your Dashboard will be changed when an Initial Application is returned as Figure 5.2.9.2.

= 🌵 HA Clinical Resear	ch Ethics Review Portal			Taiman Chan Last Login: 2022-04-13 23:42	Applicant 👻	68 Logou	ť
A Dashboard	Home						
Q Search	Dashboard						
Profile	Applications						
♣ Initial Applications ∨		575	Returned				
Post Approval Document     V     Useful Information/User Manual		Expire in ≥ 30 da	ys <u>(0)</u>				
FN Version: v0.932 BN: v0.458 build at 20220329 08:45	Dest to see the	Expire in < 30 da	ys <u>(1)</u>				
	Post Approval Documents						
	2	0raft 2/2	Returned				
		Expire in ≥ 30 da	ys <u>(Q)</u>				
		Expire in < 30 da	ys <u>(Q)</u>				

Figure 5.2.9.2 Changes on Dashboard for Returned Initial Application



Application Status	Dashboard of CI/Delegate(s)	Dashboard of Site PI/Delegate(s)	
Submitted	Returned (c/d)	Returned (c/d)	
Only Study Info Returned	Returned (c+1/d+1)	Returned (c/d+1)	
Only Site Info Returned	Returned (c+1/d+1)	Returned (c+1/d+1)	
Both Study Info and Site Info Returned	Returned (c+1/d+1)	Returned (c+1/d+1)	

Below is summary of Dashboard changes of CI/Site PI/Delegate(s) when Initial Application returned.

You can access the returned Initial Application by the following methods to check the comment, amend and re-submit the application:

- 1. Click the notification for returned Initial Application directly as Figure 5.2.9.1; or
- 2. Click the No. in Returned box of Applications on Dashboard as Figure 5.2.9.2; or

3. Go to the "Returned" Application List and click the Scientific Title of the specific Initial Application as Figure 5.2.9.3.

If Site Info(s) or both Study Info and Site Info(s) has been returned, the column of Site Info will be shown as "Incomplete" instead of **Info** icon. Both the Study Info and Site Info(s) are editable by the concerned CI/Site PI/Delegate(s) respectively.

If only Study Info has been returned, the column of Site Info will be "Ready to submit". Only the returned Study Info is editable by the CI/Delegate(s), others Site Info(s) will be view-only.

= 🌵 HA Clinical Resear	rch Ethics	Review	Portal				Taiman Chan Last Login: 2022-04-13 23:42	Applicant 👻	75	Logout
A Dashboard	<u>Home</u> >	Initial Ag	oplications :	Returned						
Q Search	Applicati	on List								
Profile	Hide/Sho	ow Columr	Col	apse All Expand Al	Download Appli	Refres	h			
Initial Applications							Filter keyword	F	Page Size:	10 -
New										
Draft			Pending	CRER Application 1	IRB/REC Reference T <sub>↓</sub>	Submission No.	† <sub>4</sub> Scientific 1	Title †	Statu	JS
Sent	+		()	HKWC-2022-053		20220208-002-00	0 Test12	3	Return	ned
Returned	4									•
Approved										_
Completed	Showing 1	to 1 of 1	entries						<	1 >
Acknowledged										
Expired										
Archived										
All										
▲ Post Approval Document										
Useful Information/User Man										
FN Version: v0.932										





Comment from CCO/Cluster Admin/Secretary can be seen in "Comment tab" of Initial Application as Figure 5.2.9.4. You can click the **View** button to download the attachment uploaded by CCO/Cluster Admin/Secretary in the pop-up dialog if available.

=	THA Clinical Res	earch Ethics Re	view Portal		Taiman Chan Last Login: 2022-04-13 23:42	Applicant - Logout
<b>f</b>	Home > Initial Applicati	on > Initial Applic	ation (20220208-002-000) (Ret	:urned)		
Q	Back to study info					
Θ	Comment History					
6	Date †	From <sup>†</sup>	1 To <sup>†</sup> 1	Comment	$\hat{\tau}_{\downarrow}$ Attachment $\hat{\tau}_{\downarrow}$	
0	2022-04-13 23:07:36	Secretary	Applicant (CI)	Return the Study Info to CI	View	
2						
	Study Info Site (TYH)	Comment Sheet				

Figure 5.2.9.4 Comment tab of the Initial Application

After modification, you can re-submit the application as following steps:

- If you are a Site PI/Delegate(s), you need to re-submit the returned Site Info to CI/Delegate(s) for their further re-submission. Refer to <u>Site PI/Delegate(s) to Submit the Site Info to</u> <u>CI/Delegate(s)</u>
- If you are a CI/Delegate(s), you need to re-submit the returned Initial Application after the returned Site Info(s) and/or Study Info are ready with the following steps:



1. Press **Re-submit** button as Figure 5.2.9.5;

Figure 5.2.9.5 Screen of Re-Submit button in Returned Initial Application



2. "Are you sure to re-submit?" dialog will be prompted for you to leave your message if any;

Leave your message (if any)	
	_

Figure 5.2.9.6 Pop-up dialog when resubmission

- 3. Press Confirm button to proceed the re-submission;
- 4. "Re-submit successfully." message will be popped up for confirmation.

Re-submit successfully.	
	Confirm

Figure 5.2.9.7 Pop-up dialog after resubmission

After re-submission, the status of the specific application will be "Re-submitted" and can be found in "Sent" Application List. Refer to <u>Re-submitted Initial Application</u>.

The "Return and Re-submit" process may happen more than once until CCO/Secretary confirms the application.

If the returned Initial Application has not yet been re-submitted, the number of the boxes "Expire  $\geq$  30 days" and "Expire < 30 days" will be updated accordingly based on the expiry date of returned Initial Application in Figure 5.2.9.2.

You will receive notifications as following for returned Initial application that is not yet re-submitted:

- 1. Reminder of re-submitting the returned application 30 days before expiry date
- 2. Notification of Application is overdue

When the returned Initial Application is overdue, it will change to "Expired" status and can be seen in the "Expired" Application List.


### 5.2.9.1 Re-submitted Initial Application

To view the re-submitted Initial Application, you can go to the "Sent" Application List as below and click the **Scientific Title** to open the Initial Application.

= 👘 HA Clinical Resear	rch Ethics F	Review Port	tal			site pi 5 Last Login: 2022-04-13 23:38	Applica	ant 👻 🧏 🧏	Logout
A Dashboard	Home >	Initial Applica	itions > Sent						
Q Search	Applicatio	n List							
e Profile	Hide/Shov	v Columns	Collapse All	xpand All	ad Application Ref	esh			
Initial Applications						Filter keyword		Page Size:	10 *
New		-	CRER Application	IRB/REC Reference					
Draft		Pending	No. T <sub>1</sub>	No. T <sub>4</sub>	Submission No. T <sub>4</sub>	Scientific Title	ψ	Status	Site In
Sent		0.00	IRB-2022-009		20220111-007-000	Test Case 1		Submitted	
Returned			NTEC-2021-072		20211224-003-000	Test Case 2		Confirmed	
Approved	U		11120-2021-072		20211224-003-000	1651 0656 2		Commined	
Completed		127	HKWC-2022-053	-	20220208-002-000	Testing 123	- 1	Re- Submitted	
Acknowledged	4								×
Expired	Showing 1	o 3 of 3 antria							1
Archived	Showing I	o o or o entrie							
All									
▲ Post Approval Document									
Useful Information/User Man									
FN Version: v0.932	6								

Figure 5.2.9.1.1 "Re-submitted" Initial Application in "Sent" Application List



## 5.2.10 Confirmed Initial Application

You may receive a confirmation notification in Portal and by email once CCO/Secretary has confirmed the Initial Application.

• Confirmation: Your application "<CRER Application No.>" - <Document Name> is confirmed and will be arranged for review.

Status of the Initial Application will change from "Submitted" / "Re-submitted" to "Confirmed".

= 🍈 HA Clinical Resea	rch Ethics	s Review	Portal			site pi 5 Last Login: 2022-04-13 23:38	Applicant - Logout
A Dashboard	Home :	> Initial Ap	oplications >	Sent		Notificat	tion Mark All Read
Q, Search	Applicat	tion List				Secretary(HKWC) Confirmation: Your application HKWC-20 confirmed and will be arranged for review	2022-01-18 11:04:15 022-053 - Initial Submission is v.
e Profile	Hide/Sh	how Column	Colla	apse All Expand Al	Download Applica		Mark Read
Initial Applications						From: site pi 3	2022-01-18 11:01:54
New						Change of delegation: Delegation of Site 20220118-001-000.	PI(NDH) is changed for
Draft			Pending	CRER Application	IRB/REC Reference		Mark Read
Sent	+			IRB-2022-009		From: site pi 1	2022-01-17 10:52:09
Returned		_				Withdrawal: IRB-2022-002 - Amendment	Application is withdrawn.
Approved	+		•	NTEC-2021-072	•		Магк неао
Completed	+			HKWC-2022-053		From: qa1- cco	2022-01-14 13:47:40
Acknowledged	4					Confirmation: Your application IRB-2022- confirmed and will be arranged for review	-009 - Initial Submission is v.
Expired	Showing	1 to 3 of 3	entries				Mark Read
Archived	onowing	1 10 0 01 01 01	entree :			From: ga1- cco	2022-01-14 13:46:23 👻
All							

Figure 5.2.10.1 Notification of Confirmed Initial Application

To view a confirmed application, you can refer to the below steps:

- 1. Click the notification for confirmed Initial Application directly as Figure 5.2.10.1; or
- 2. Go to the "Sent" Application List and click the **Scientific Title** of the specific Initial Application in "Confirmed" status as Figure 5.2.10.2.

= 🍈 HA Clinical Resear	rch Ethics	Review	Portal			sil La	te pi 5 st Login: 2022-04-13 23:38	Applicant 👻	200 Logout
A Dashboard	Home >	Initial Ac	oplications >	Sent					
Q, Search	Applicati	ion List							
Profile	Hide/Sh	ow Column	Coll	apse All Expand Al	Download Apple	cation Refresh			
Initial Applications							Filter keyword	Pa	age Size: 10 👻
New									
Draft			Pending	No.	IRB/REC Reference	Submission No. 1	Scientific T	itle †	Status
Sent	+			IRB-2022-009		20220111-007-000	Test Case	E1	Submitted
Returned	+			NTEC-2021-072		20211224-003-000	Test Case	-2	Confirmed
Approved		0							
Completed	+			HKWC-2022-053		20220208-002-000	Testing 1	23	Re- Submitted
Acknowledged	•								Þ
Expired	Showing 1	1 to 3 of 3 (	entries						< 1 >

Figure 5.2.10.2 Confirmed Initial Application in "Sent" Application List



## 5.2.11 For Review Initial Application

After an Initial Application being confirmed, Central IRB / Secretary can arrange review meeting for the Initial Application:

• Once the review meeting is arranged for the confirmed Initial Application, its status will change from "Confirmed" to "For Review". You can find it in "Sent" Application List as Figure 5.2.11.1

= 📫 HA Clinical Researc	ch Ethics Review Port	al		Lucky L Last Login	ee : 2022-07-12	14:51 Applicant	- <sup>80</sup>	Logout
A Dashboard	Home > Initial Applica	<u>tions</u> > Sent						
Q Search	Application List							
Profile	Hide/Show Columns	Collapse All	Expand All Downlo	Refresh				
Initial Applications					Filter key	word		Page Size – 10 –
New	CREP Application	IDR/DEC Deference				Coordinating		
Draft	No.	No.	Submission No. $\uparrow_{\downarrow}$	Scientific Title	†↓	Investigator (CI)	Status	S
Sent	IRB-2022-230	-	20220704-002-000	Test		Lucky Lee	Submitte	d
Returned	IRB-2022-169	irb flow`~~	20220601-005-000	QAQAQA		Lucky Lee	For Review	N
Completed	IRB-2022-236	irb flow`~~	20220707-001-000	Test		Lucky Lee	For Review	N
Acknowledged	IRB-2022-235	irb flow`~~	20220706-003-000	Test		Lucky Lee	For Review	N
Expired	IRB-2022-234	irb flow`~~	20220706-002-000	Test		Lucky Lee	For Review	N
All	IRB-2022-226	-	20220629-003-000	Test		Lucky Lee	Submitte	d
🚯 Post Approval Document 🗸 🗸	IRB-2022-215	irb flow`~~	20220622-001-000	Test		Lucky Lee	For Review	N
Useful Information/User Manual	IRB-2022-170	irb flow`~~	20220601-006-000	QAQAQA		Lucky Lee	For Review	N
EN Version: v0.977	IRB-2022-206	irb flow`~~	20220621-002-000	Test		Lucky Lee	For Review	N
BN Version: v0.520	NTEC-2022-088	1	20220621-011-000	Test		site pi 1	For Review	N
	•							Þ
	Showing 1 to 10 of 70 ent	ries			< 1	2 3 4	5 6	7

Figure 5.2.11.1 For Review Initial Applications in "Sent" Application List



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## 5.2.12 Approved/Disapproved Initial Application

You will receive the corresponding notification in Portal and by email once the "For Review" Initial Application is approved or disapproved by Central IRB or Secretary as Figure 5.2.11.1.

- Application approved: Approval: "<CRER Application No.>" <Document Name> is approved.
- Application disapproved: Disapproval: "<CRER Application No.>" <Document Name> is disapproved.

= 🍈 HA Clinical Resear	rch Ethics Review Portal		site pi 5 Applicant 👻 🥵 Logout
A Dashboard	Home		Notification Mark All Read
Q Search	Dashboard		From: Central IRB 2022-03-08 14:42:47 Approval: IRB-2022-055 - Initial Application is approved
Profile	Applications		Mark Read
Initial Applications	Draft <u>3/3</u>	Returned	From: qa- all-roles-(none KCC) 2022-03-08 1441:55 Confirmation: Your application IRB-2022-055 - Amendment Application is confirmed and will be arranged for review.
Draft		Expire in ≥ 30 days (0)	Mark Read
Sent Returned		Expire in < 30 days ( <u>1</u> )	From: site pi4 2022-03-08141110 Site Info Submission: Site Info"(DKCH)" has been submitted to you 20220121-001-001 Mark Read
Completed	Post Approval Documents		From: site ni 1 2022-03-08 13 54:25
Acknowledged	Draft	Returned	Change of Team members: SITE PI(DKCH) is changed for 20220121-001- 001.
Expired	<u>6/6</u>	0/0	Mark Read
Archived		Expire in $\geq$ 30 days (0)	From: site pi 1 2022-03-08 13:51:45 🔻
All		Expire in < 30 days (0)	

Figure 5.2.12.1 Notification of Approved Initial Application

Status of the Initial Application will change from "Confirmed" to "Approved" or "Disapproved" based on the decision consolidated by Central IRB/Secretary.

To view the "Approved" or "Disapproved" Initial Application:

- 1. Click the notification for the approved or disapproved Initial Application as Figure 5.2.12.1; or
- 2. Go to "Approved" Application List and click the **Scientific Title** of the specific Initial Application in "Approved" status as Figure 5.2.12.2;
- 3. Go to "Archived" Application List to view the application in "Disapproved" Status.

= 🍈 HA Clinical Resea	rch Ethics	Review	Portal			S L	ite pi 5 ast Login: 2022-04-13 23:38	Applicant 🗸		Logout
A Dashboard	Home >	Initial Ap	plications >	Approved						
Q, Search	Applicati	on List								
Profile	Hide/Sh	ow Column	s	apse All Expand All	Download Apple	Refresh				
Initial Applications							Filter keyword	F	age Size:	10 -
New										
Draft			Pending	CRER Application	IRB/REC Reference T <sub>1</sub> No.	Submission No.	f↓ Scientific 1	Title T <sub>4</sub>	State	25
Sent	+			IRB-2021-197	1	20211217-002-000	Testing 1	23	Appro	ved
Returned	-			IDR-2021-154	901	20211202-002-000	Tert Ca		Anner	und
Approved	T	U		180-2021-134	521	20211203-002-000	Test Ga	20	Appro	veu
Completed	4									,
Acknowledged	Showing '	11 to 12 of	12 entries					<	] ]	2 >

Figure 5.2.12.2 Approved Initial Application in "Approved" Application List



# 5.3 Overview of Initial Application

You can view the application history of the Initial Application by pressing **Overview** button in Action Menu of Application List in all statuses as Figure 5.3.1.

= 🔷 HA Clinical Resear	rch Ethics I	Review Portal			site pi <sub>Last Log</sub>	5 in: 2022-04-13 23:38	Applicant 👻	. 🤒	Logout
A Dashboard	<u>Home</u> >	Initial Applications > Draft							
Q Search	Applicatio	n List							
e Profile	Hide/Sho	w Columns Collapse All	Expand All	Download Applic	Refresh				
Initial Applications					Filte	r keyword	5	Page Size:	10 *
Draft	o. † <sub>4</sub>	Scientific Title †	Status	Site Info	Last Modified Date	Expiry Date 1,	Coordinating Investigator (C	10 <sup>†</sup> 1	Action
Sent	-000	Testing - 0411	Draft	Incomplete	2022-04-12 19:10:09		Taiman Cha	n	:
Returned	-000	Testing	Draft	Incomplete 🚯	2022-02-07 09:16:30	-	site pi 1	Clone to	o draft
Completed	-000	Demo	Draft	Incomplete	2022-01-18 11:13:14		site pi 5	Overvie	w
Acknowledged	4								÷
Expired	Showing 1	to 3 of 3 entries							1
Archived									
All									

### Figure 5.3.1 Screen of "Overview" button in Application List

In Overview, you can view the summary about General information, CTC/CTI Expiry Date, Progress Report Submission History, Status History, Approval History and Document Log as Figure 5.3.2.

= 🍈 HA Clinical Resea	ch Ethics Review Portal		Taiman Chan Last Login: 2022-03-23 22:58	Applicant -	Logout
A Dashboard	Home > Initial Application > Initial application overview				
Q Search	Back				
Profile	Application History				
Initial Applications	General Information				
New Draft	Central IRB/CREC/IRB Reference No.: TEST-123456				
Sent Returned	Application Submission Date: 2022-01-12 15:51     Application Confirmed Date: 2022-01-21 16:51				
Approved	5. Type of sponsored study: Commercial				
Completed Acknowledged	6. Review Board: Central IRB (Paed)     7. Type of Review: -				
Expired	8. Review Decision for the study: Approved				
All	9. Approval Expiry Date: 2022-01-21 10. Decision Date (Study): 2022-01-21				
Draft	11. Is CTC required: No				
Sent	13. Is CTA required: Yes, With HA				
Approved	14. Final Report Submission Date: -				
Completed Acknowledged	CTC Expiry Date				
Expired	No. $\hat{\tau}_{\downarrow}$ Certificate No. $\hat{\tau}_{\downarrow}$	Expiry Date $\uparrow_{\downarrow}$	Uploaded by $$^{\uparrow_{\downarrow}}$$	Upload Date	τĻ
Archived		No Data			

Figure 5.3.2 Screen of "Overview" Page of Initial Application

Press **Back** button to return to previous Application List page.



# 5.4 Clone to Draft

You can use the "**Clone to Draft**" function to copy an existing application form data to a new one in order to speed up the data filling time.

- Application Submission Flow, Scientific title, CI/Site PI(s)/Delegations are required to fill-in again as a new Team Member Form;
- Original Study Info (Part 1 Document Upload) will be kept;
- Original Site Info(s) will be cleared.

To clone an existing application, you can follow the below steps:

= 👘 HA Clinical Resea	rch Ethics Review Port	al			Tain Last L	nan Chan ogin: 2022-09-23 10:44	Applicant 👻	Logout
A Dashboard	Home > Initial Applica	<u>tions</u> > Draft						
Q Search	Application List							
e Profile	Hide/Show Columns	Collapse All Expand			Refresh			
Initial Applications						Filter keyword	1	Page Size
New								
Draft	Submission No. 1	Scientific Title	↑Ļ	Coordinating Investigator (CI)	Status	Site Info	Last Modified Date	Action
Sent	20220725-001-000	Testing		Taiman Chan	Draft	Incomplete 🕕	2022-07-25 10:19:12	:
Returned	4	-					Olar	a ta draft
Approved							Clor	le to drait
Completed	Showing 1 to 1 of 1 entrie	S					Over	rview
Acknowledged								
Expired								

1. Press **Clone to draft** button in Action Menu in Application List;

Figure 5.4.1 Screen of Clone to draft button in Application List

2. You will be directed to Team Member Form in the new application draft as Figure 5.4.2;

3. Select the new Submission Flow for the new draft and fill in Scientific Title, new CI/Delegation's info and new Site PI(s)'s info in Team Member Form;

4. Press Clone button to confirm to clone the selected application form to a new draft;

5. "Draft application is created" message will pop up as Figure 5.4.3 and direct to the "All" Application List page;

Draft application is created.	
	Confirm

Figure 5.4.3 Popup message after Initial Application is cloned

- 6. Notification will be sent to new CI/Site PI(s)/Delegate(s) in Portal and by email.
  - Change of Team members: <Coordinating Investigator /Coordinating Investigator's Delegate/ Site PI (XXX)> is changed for "<Submission No.>".



$\equiv$ $$ HA Clinical Researce	ch Ethics Review Portal	site pi 5 Last Login: 2022-04-13 23:38 Applicant 👻 👭 Logi	out
1 Dashboard	Home > Initial Application > Clone		
Q, Search	Clone		Î
Profile	Team Member Form		
Initial Applications	Applying IRB / REC (7):		
New	Scientific title		I
Sent	Coordinating Investigator (7)		I
Returned	Email Load Pro	Contact Number	
Approved Completed	Title 🤭	First Name	I
Acknowledged	Position (7) Department Cluster	▼ Hospital / Institution (7) ▼	I
Expired	Coordinating Investigator's Delegation (7)	Add	
All	Eda Emol î Tilo (7) î Surome î Eisteore î	Position (7) 1. Cluster 1. Hospital / 1.	
Post Approval Document	EDIT FILIAII -1 LINE		
Useful Information/User Manual	No Data		I
FN Version: v0.932	•	•	
BN: v0.458 build at 20220329 08:45	Information of Site PI(s) (7)	Add	I
	Edit Email $\hat{\uparrow}_{\downarrow}$ Title $(?)$ $\hat{\uparrow}_{\downarrow}$ Surname $\hat{\uparrow}_{\downarrow}$ First name $\hat{\uparrow}$	Cluster $\uparrow_{\downarrow}$ Hospital / $\uparrow_{\downarrow}$ Department	I
	🔥 No Data		I
	4	•	•

Figure 5.4.2 Team Member Form when "Cloning" Application



# 5.5 Change of Initial Application

# 5.5.1 Request for Return of Initial Application

You are allowed to make a request to CCO/Secretary for returning an application before it is confirmed. You can modify the returned Initial Application and then re-submit it to them.

Initial Application with the following statuses could be requested for a return:

- Submitted
- Re-submitted

However, once the Initial Application is distributed to Cluster Admin or verified by Cluster Admin although the application status is still "Submitted" or "Re-submitted", you may not be able to "Request for Return" the distributed or verified Initial Application. The **Request for Return** button will not be shown in this case.

To make a request for returning an Initial Application, you can follow the below steps:

= 🔹 HA Clinical Resea	arch Ethics	Review Portal				Taimar Last Logi	n Chan in: 2022-04-13 23:42	Applicant	- 🇖	Logout
A Dashboard	<u>Home</u> >	Initial Applications > S	ent							
Q, Search	Applicati	ion List								
e Profile	Hide/Sh	ow Columns Collapse	all a	Expand All	Download Ap	Refresh				
Initial Applications						Filter	r keyword		Page Size	10 -
New										
Draft	η.	Scientific Title	η,	Status	Site Info	Last Modified Date $\downarrow_A^z$	Expiry Date $~~^{\dagger}_{\downarrow}$	Coordinat Investigator	ng † <sub>↓</sub>	Action
Sent	20	Test123		Re- Submitted		2022-04-14 10:30:55		Taiman C	han	
Returned	4								Change Del	egation
Approved								ſ	Request for	Return
Completed	Showing 1	1 to 1 of 1 entries						L	Clone to dra	
Acknowledged									Overview	
Expired									Preimen	_
Archived										
All										
Post Approval Document										
Useful Information/User Manu										
FN Version: v0.932	-									
4 F										

1. Press **Request for Return** button in Action Menu of "Sent" Application List as Figure 5.5.1.1;

Figure 5.5.1.1 Screen of "Request for Return" button in "Sent" Application List

2. A popup dialog "Are you sure to request for return?" will be prompted for you to state the reason as Figure 5.5.1.2;



Please state the reason(s).	

Figure 5.5.1.2 Pop-up dialog to proceed "Request for Return"

- 3. Press Confirm button to proceed;
- 4. A dialog of "Request for return has been sent." will be prompted as Figure 5.5.1.3;



Figure 5.5.1.3 Pop-up dialog after "Request for Return"

5. The status of the Initial Application will change to "Requested for Return" in "Sent" Application List as Figure 5.5.1.4;

= 🍈 HA Clinical Resea	rch Ethics Review Porta	al			Taiman Cha Last Login: 202	n 2-04-13 23:48	Applicant 👻	78	Logout
A Dashboard	Home > Initial Applicat	ions > Sent							
Q Search	Application List								
Profile	Hide/Show Columns	Collapse All	Expand All	sed Application Refre	sh				
Initial Applications					Filter keyw	ord	Pa	ge Size:	10 -
New									
Draft	CRER Application	IRB/REC Reference †	Submission No. $~^{\dagger}_{\downarrow}$	Scientific Title	τ <sub>4</sub>	Status	Site Info		Last Modifi
Sent	HKWC-2022-053		20220208-002-000	Test123	[	Requested for Return	] -	20	022-04-14
Returned	4						-		) F
Approved									
Completed	Showing 1 to 1 of 1 entries	5						<	1 >

Figure 5.5.1.4 "Requested for Return" Status of the Initial Application

CCO/Secretary can make two decisions on the "Request for Return"

- Confirm Request for Return
- Reject Request for Return



If the decision is "Confirm Request for Return", the status of the Initial Application will be "Returned". And the Initial Application will be shown in "Returned" Application List. Refer to <u>Returned Initial</u> <u>Application and Re-submit Initial Application</u>

If the decision is "Reject Request for Return", the status of the application will change back to the original status, Submitted or Re-submitted.

You can view the application status by the following ways:

1. In "Sent" Application List, as Figure 5.5.1.5; or

=   HA Clinical Resear	HA Clinical Research Ethics Review Portal							<b>78</b>	Logout
A Dashboard	Home > Initial Applica	tions > Sent							
Q, Search	Application List								
Profile	Hide/Show Columns	Collapse All	Expand All	load Application Refr	esh				
Initial Applications					Filter keyv	/ord		Page Size:	10 -
New									
Draft	CRER Application †	IRB/REC Reference †	Submission No. $\ ^{\dagger} \! _{\downarrow}$	Scientific Title	$\tau_{\downarrow}$	Status	Site Info		Last Modifie
Sent	HKWC-2022-053		20220208-002-000	Test123		Re- Submitted	] .	20	22-04-14
Returned	4				_		<b>,</b>		•
Approved	Chausian 1 an 1 af 1 annia								
Completed	anowing i to i of i entrie	0						<u></u>	· /

Figure 5.5.1.5 Screen of "Reject Request for Return" Initial Application in Sent Application List

2. In the "Status History" of the Overview of the Initial Application as Figure 5.5.1.6.

= 🍈 HA Clinical Resea	rch Ethics Review Portal			Taiman Ch Last Login: 20	nan 022-04-13 23:48	Applicant 🗸 🥂 🧖	Logout
A Dashboard	Home > Initial Application >	Initial application overview					
Q, Search	Status History						^
O Profile	Date †	Document Type 7	User †	From †	To †	Original Submission No.	$\hat{\tau}_{j_{\rm c}}$
Initial Applications	2022-02-08 14:28:12	Initial Application	Taiman Chan	N/A	Draft	20220208-001-000	
New	2022-04-13 17:28:32	Initial Application	Taiman Chan	Draft	Submitted	20220208-001-000	
Draft	2022-04-13 23:07:36	Initial Application	Taiman Chan	Submitted	Returned	20220208-001-000	
Sent	2022-04-14 10:30:55	Initial Application	Taiman Chan	Returned	Re-submitted	20220208-001-000	
Returned	2022-04-14 12:52:14	Initial Application	Taiman Chan	Re-submitted	Requested for return	20220208-001-000	٦.
Completed	2022-04-14 13:27:13	Initial Application	Taiman Chan	Requested for return	Re-submitted	20220208-001-000	
Acknowledged							_

Figure 5.5.1.6 View the Status changes in Status History of Initial Application Overview



Regarding the Rejection Comment from CCO/Secretary, you can view it in "Comment Sheet" tab inside the Initial Application as Figure 5.5.1.7. You can click the **View** button, which will be enabled if there is an attachment uploaded by CCO/Secretary, to download the attachment in the pop-up dialog.

≡	HA Clinical Res	search Ethics Revi	ew Portal			Taima Last Lo	an Chan gin: 2022-04-13 23:48	Applicant 👻	<b>78</b>	Logout
<b>f</b>	Home > Initial Applicati	on > Initial Applicat	ion (20220208-002-00	0) (Re-Su	ubmitted)					
Q	Back to study info									
Θ	Comment History									
8	Date †	From †	То	ti.	Comment	$\tau_{\rm L}$	Attachment †			
0	2022-04-14 13:27:13	Secretary	Applicant		Reason to reject the return request		View			
2	2022-04-14 12:52:14	Applicant (CI)	Secretary		Would like to request for return		-	1		
	2022-04-14 10:30:55	Applicant (CI)	Secretary		Re-submit the amended form					
	2022-04-13 23:07:36	Secretary	Applicant (CI)		Return the Study Info to CI		View			

Figure 5.5.1.7 Comment tab of the Initial Application



## 5.5.2 Change Delegation

You can use "**Change Delegation**" to add Delegation(s) or update info of Delegation(s) directly without "Request for Return"/ "Amendment Application" after Initial Application is submitted/approved.

- CI Delegate(s) can only be added/edited by CI;
- Site PI Delegate(s) can only be added/edited by the relevant Site PI.

Dashboard Home > Initial Applications > Sent	
Q Search Application List	
Profile     Hide/Show Columns     Collapse All     Expand All     Download Application     Refresh	
Initial Applications     Filter keyword     Page	Size: 10 👻
New	
Draft T <sub>1</sub> Scientific Title T <sub>1</sub> Status Site Info Last Modified Date 1 Expiry Date T <sub>1</sub> Coordinating T Investigator (C)	Action
Sent         D0         Test123         Re- Submitted         -         2022-04-14 13:27:13         -         Taiman Chan	:
Returned 4 Change	Delegation
Approved	for Return
Completed Clone tr	draft
Acknowledged Overvie	N
Expired	
Archived	
All III	
Post Approval Document	

Figure 5.5.2.1 Screen of "Change Delegation" button in Application List

You can add delegation or change the info of delegation with below processes:

- 1. Press Change Delegation button in the Action Menu of Application List;
- 2. Cl's Delegation/Site PI's Delegation Table will be shown based on your role in the application
  - CI Delegate(s) can only be added/edited by CI;
  - Site PI Delegate(s) can only be added/edited by the relevant Site PI.

= 🔹 HA Clinical Resear	rch Ethics F	Review Portal		3		ň.		L	Taiman Chan ast Login: 2022-04-	14 12:48	Applicar	nt 👻 🙎	9 L	.ogout
A Dashboard	Home >	Initial Application > Ch	ange D	elegation										
Q, Search	Submit	Back												
Profile	Coordinat	ting Investigator delega	ions											Add
Initial Applications												Hospital /		
New	Edit	Email	ų.	Title (9)	.a.	Sumame	4	First name	Position 1	Clus	ter 11	Institution	.î <sup>†</sup>	
Draft	1	taimanchan@testing.co	m	Testing		Chan		Taiman	Testing	NTE	5C	SH		
Sent	4													+
Returned														
Approved														
Completed														

Figure 5.5.2.2 Page of "Change Delegation"



3. Press **Pencil** button to edit info for CI's (& Site PI's) delegation in pop-up dialog as Figure 5.5.2.3;

taimanchan@testing.com			Load Profi
Surname		- First Name	
Chan		Taiman	
Title (7)			- Position (7)
Testing			Testing
Cluster		- Hospital / Institution	· · · · · · · · · · · · · · · · · · ·
NTEC	•	SH	
Department			
Testing			

Figure 5.5.2.3 Pop-up Dialog for Editing Cl's delegation

4. Press Add button add Cl's (& Site Pl's) delegation in pop-up dialog as Figure 5.5.2.4;

Adding coordinating investigator's	delegation X
Email	Load Profile
Surname	First Name
Title 🧭	Position (?)
Cluster 👻	Hospital / Institution
Department	
	Cancel Confirm

Figure 5.5.2.4 Pop-up Dialog for Adding Cl's delegation

5. Press **Submit** button to update the changes on delegation in Study Info (& Site Info) in Initial Application form;

6. "Delegation updated" message will pop up for confirmation as Figure 5.5.2.5;

Delegation updated	
	Confirm

Figure 5.5.2.5 Pop-up dialog of "Delegation Updated"

7. Notification will be sent to the concerned Delegate(s) of CI (& Site PI) in Portal and by email.



# 5.6 Download Approval Letter

After the Initial Application is approved, you may download the approval letter by the following ways:

- Click the hyperlink of Approval Letter in the Overview of the approved Initial Application as Figure 5.6.1; or
- Click the Download Approval Letter button in Action Menu of "Approved" Application List

$\equiv$ $$ HA Clinical Researce	h Ethics Review Portal										Taiman Chan Last Login: 2022-0	4-27 12:04	Applicant 👻	93 Logoi	ut
A Dashboard	Home > Initial Application	> Initial	application overview												
Q Search	CTI Expiry Date														^
Profile	No.	No. 1 Policy No.				↑_ Expiry Date ↑_ Uploade					by †	Upload Date	Ťμ		
Initial Applications							🛕 No Da	ata							
New															
Draft	Progress Report Submission														
Sent		-					December 7 me			÷.		Octorization	0.11	*.	
Returned		NG. 12 Document type 12 Submission use										Ψ			
Approved		A 10 0mm													
Completed							A NO De	110							
Acknowledged															
Expired	Status History														
Archived	Date	ŤĻ.	Docur	ment Type	τĻ		User	ŤĻ	From	τĻ	То	t <sub>1</sub>	Original Submission No	$\tau_{\downarrow}$	
All	2022.01.04.17.47.42		Initial /	Application			Applicant		Droft		Submitted				
🚯 Post Approval Document 🗸 🗸	2022-01-04 17:47:42		telblat /	Application			oppicant		Cohereitand		Confirmed				
Useful Information/User Manual	2022-01-04 17:48:40		Initial A	Application			000		Submitted		Confirmed		-		
	2022-01-04 17:49:25		Initial A	Application			Central IRB		Confirmed		Approved		-		
FN Version: v0.938 BN: v0.468 build at 20220426 14:45	Approval History														
	Document type $\uparrow_{\downarrow}$	Rev	iew type $\uparrow_{\downarrow}$	Decision	† <sub>4</sub>	Decision Date	$\tau_{\downarrow}$	Decision	n Reason 1		Approval Letter	† <sub>4</sub>	Upload date of approval	letter †	
	Initial Application	Initial Application - Approved 2022-						22-01-04 Approved Approved			Approval Letter.pdf 2022-01-04 17:49			9	

Figure 5.6.1 Approval Letter in Overview of Initial Application

To download approval letter with **Download Approval Letter** button, you can follow the below steps:

1. Go to the "Approved" Application List and click the **Download Approval Letter** button in Action menu as Figure 5.6.2;

= 👘 HA Clinical Resear	rch Ethics Review Portal				Taiman Chan Last Login: 2022-04-27 12:04	Applicant -	23 Logout
A Dashboard	Home > Initial Applications > Appro	oved					
Q, Search	Application List						Î
e Profile	Hide/Show Columns Collapse All	Expand All		cation Re	fresh		
Initial Applications					Filter keyword	Page Si	ze: 10 🕶
New							
Draft	Scientific Title $$^{\dagger}_{\downarrow}$$	Coordinating T <sub>1</sub> Investigator (CI)	Status	Site Info	Last Modified Date	Expiry Date $\uparrow_{\downarrow}$	Action
Sent	<b>Re-submission</b>	Mark-1 Zhu-1111	Approved	-	2022-04-28 00:22:25		:
Returned	Text	Made 1 7hu 1111	Approvad		0000 00 00 14 40 07	Application A	mendment
Approved	Test	Mark-1 Zriu-1111	Approved		2022-03-00 14.42.37	Change Deleg	ation
Completed	Demo	site pi 1	Approved	-	2022-01-18 11:53:20	Clone to draft	auon
Acknowledged	Testing 1	site pi 6	Approved		2022-01-04 17:48:46	Overview	
Expired	Testing 2	Mark1 Zhu1111	Approved		2021-12-23 10:20:26	Download Ap	proval Letter

Figure 5.6.2 Screen of "Download Approval Letter" in Action Menu



2. A dialog of "Download Approval Letter" will be prompted as Figure 5.6.3;

Download Approval Letter	
Approval Expiry date 2022-01-21	
Click <u>here</u> to download Approval letter	
	Close

Figure 5.6.3 Popup dialog of "Download Approval Letter"

- 3. You can view the Approval Expiry Date as Figure 5.6.3. As Approval Expiry Date is optional, so there may not be an Approval Expiry Date.
- 4. Click "<u>here</u>" to download the Approval Letter.



# 5.7 Suspension of Study Site in Initial Application

You may receive a suspension notification in Portal and by email once Central IRB/Secretary has suspended study site of Initial Application.

• Suspension: "<CRER Application No.>" - <Site> is suspended due to <Reason>.

= 📫 HA Clinical Researc	Review	site pi 1 Last Logi	l Applic n: 2022-06-29 11:51 —	ant 👻 🤔 Logout						
A Dashboard	<u>Home</u> >	Initial A	pplications	> All		Notification Mark All As				
Q Search	Applicati	on List				From: Taiman Chan Suspension: IRB-2022-0	)38 - NLTH is suspended due	2022-06-30 10:44:55 to Suspend the NLTH		
Profile	Hide/Sho	ow Colum	ns Ci	ollapse All Expand	Download Ap	Site.		Mark As Read		
Initial Applications						From: qa -all roles		2022-06-29 18:01:05		
New						Return: SECRETARY ret Please check the "Com	urned NTEC-2022-006 - Ame ment Sheet" tab for suggeste	endment Application .		
Draft			Pending	CRER Application No.	IRB/REC Reference 1			Mark As Read		
Sent	+		()	-		From: qa -all roles		2022-06-29 16:49:05		
Returned	+			NTEC-2022-006	1	Approval: NTEC-2022-0	06 - Amendment Application	is approved. Mark As Read		
Approved		_		NTEO 0000 000	NTEO Remi					
Completed	+			NTEC-2022-008	NTEC NOW ~~	From: qa -all roles	08 - Amendment Application	2022-06-29 16:47:15		
Acknowledged	+		-	IRB-2022-044	1	Approval: NTEC-2022-006 - Amendment Application is approved. Mark As Read				
Expired	+		-	IRB-2022-038	irb flow`~~	From: ga -all roles		2022-06-29 16:46:41		
Archived	+		()	-	-	20220629-002-000 ann	Request for return	Mark1 Zhu1		
Post Approval Document	+		•	IRB-2022-043	irb flow`~~	20220629-001-000	Request for return	Mark1 Zhu1		
Useful Information/User Manual	+		()			20220627-002-000	ddd	site pi 1		
EN Version: v0 971	+		-	NTEC-2022-007	-	20220628-003-000	User Manual	site pi 1		
BN Version: v0.485	+		-	IRB-2022-042	-	20220627-006-000	DISTRIBUTE STATUS	Mark1 Zhu1		
	4							•		
	Showing 1	to 10 of i	35 entries				< 1 2 3 4	¥ 5 9 >		

Figure 5.7.1 Notification of Suspending Study Site

To view suspension comment of study site:

- 1. Click Info icon in "Site Info" column;
- 2. Mouse over **Clock** icon in corresponding suspended study site as Figure 5.7.2.

Applic	ation List							
Hide/	Show Columns	Collapse All Expand All			Refresh			
					Filter	keyword	Page Size:	10 🕶
nce <sub>†↓</sub>	Submission No. $\ \uparrow_{\downarrow}$	Scientific Title	†↓	Status	Site Info	Last Modified Date	Expiry Date $\ \ ^{\uparrow }\downarrow$	Version No.
	20220624-010-000	USER MANUAL		Approved		2022-06-30 10:44:55	-	1
	20220628-001-000	Test Major drop down		Draft	Incomplete Suspend the NLTH si	2022-06-29 17:44:23 te	-	1
	20220628-002-000	User Manual - amend		Approved	0	2022-06-29 16:49:04	-	2

Figure 5.7.2 Tooltips of Suspension



3. Or click notification of suspension as Figure 5.7.1;

4. Click **Comment Sheet** in Initial Application page and view the suspension comment as Figure 5.7.3.

Q	Back to study info						
Θ	Comment History						
÷	Date $\uparrow_{\downarrow}$	From †	To <sup>†</sup> ↓	Comment	†↓	Attachment	$\uparrow_{\downarrow}$
0	2022-06-30 10:44:55	IRB	Applicant	Suspend the NLTH site		-	
?	2022-06-29 15:54:12	IRB	Applicant	Suspend the NLTH site		-	
	2022-06-28 14:32:12	IRB	Applicant	Suspend again		-	
	2022-06-28 12:22:06	IRB	Applicant	Suspend the NLTH site		-	
	2022-06-27 17:22:43	IRB	Applicant	Demo suspension		-	
	2022-06-27 17:03:44	IRB	Applicant	Demo for suspension		View	
	2022-06-27 09:36:46	IRB	Applicant	First time suspend		-	
	2022-06-24 17:22:26	CCO	Applicant	-		View	

### Figure 5.7.3 Suspension comment in Comment Sheet



# 6. Manage an Application (Post-Approval)

Once the Initial Application is approved, if any Post Approval Activity is required, CI/Delegate(s) or Site PI/Delegate(s) can submit Post Approval Document for Study Info or Site Info. The Post Approval Document will follow the workflow of the Initial Application to be passed to CCO/Cluster Admin/Central IRB or Secretary for review.

Study/Site Base	Form/Report	CI/Delegate(s)	Site PI/Delegate(s)		
	SUSAR Report				
	Miscellaneous Report				
Study Base (Study Info)	Amendment Application	Create, Edit and Submit	View only		
	Final Report				
	CTC/CTI Submission				
	Progress Report				
	Local SAE Report				
Site Base (Site Info)	Miscellaneous Report	View only	Create, Edit and Submit		
(Site info)	Protocol Deviation Report				
	Amendment Application				

Below is the table of Action/View Right of Post Approval Activities for Cl/Site Pl/Delegate(s):

Table 6.1 Action/View Right of Post Approval Activities for CI/Site PI/Delegate(s)



# 6.1 Creation of Post Approval Activities for Approved Initial Application

# 6.1.1 Create Post Approval Document

The following table displays the rules for different Post Approval Document creations for the Approved Initial Application.

Allow Multiple Creation	SUSAR Report, Miscellaneous Report, CTI/CTC submission, Local SAE Report, Protocol Deviation
Only 1 form is allowed before consolidation	Final Report, Progress Report, Amendment Application Form

## 6.1.1.1 Create Post Approval Document (except Amendment Application)

To create a Post Approval Document, except Amendment Application, please follow the below steps:

- 1. Go to "Approved" Application List as Figure 6.1.1.1.1;
- 2. Click the specific **Post Approval Document** button under Action Menu to create the corresponding form under Action Menu. (List of Post Approval Activities for creation under Action Menu will be different based on your role, please refer to Table 6.1 for details);

Taiman Chan Last Login: 2022-08-22 15:41								Applicant 🗸 💄 Logout
A Dashboard	<u>Home</u> >	Initial Applications >	Approved					
Q, Search	Applicati	on List						
Profile	Hide/Sh	ow Columns Collaps	e All Expand All		d Application	efresh		
Initial Applications							Filter keyword	Page Size
New Draft	erence $_{\uparrow_\downarrow}$	Submission No. $\uparrow_{\downarrow}$	Scientific Title	τţ	Coordinating Investigator (CI)	Status	Site Info	Last Modified Date $\downarrow_A^Z$ Action
Sent	~~	20220519-001-000	Test		Lucky Lee	Approved	0	2022-05-19 10:39:11
Approved	~~	20220518-003-000	Test		Lucky Lee	Approved	0	2 Change Delegation
Completed	~~	20220517-014-000	Test		Lucky Lee	Approved	0	Clone to draft
Acknowledged	w	20220516-022-000	Demo		Lucky Lee	Approved	0	Overview
Expired	~~	20220516-003-000	Demo 2		Lucky Lee	Approved	0	Download Approval Letter
Archived	4							Post-approval activities
All Document	Showing 4	11 to 45 of 45 entries					<	Application Amendment
								Progress Report
? Useful Information/User Manual								Final Report
FN Version: v1.006								Protocol Deviation Form
BN Version: v0.530								SAE Report
								Missellenseus Depart
								Miscellaneous Report
								CTC/CTI submission

Figure 6.1.1.1.1 Post Approval Activities buttons of "Approved" Application List



 If you are assigned as CI/Delegate(s) only, the Document Type button displayed under Action Menu in Approved Application List will only include Study Base Post Approval Activities as Figure 6.1.1.1.2;



Figure 6.1.1.1.2 Post Approval Document Type button displayed for CI/Delegate(s)

4. After you press the specific **Document Type** button, it will direct to report form page. Take SUSAR Report as an example as Figure 6.1.1.1.3;

= 💠 HA Clinical Researc	h Ethics Review Portal	Lucky Lee Last Login: 2022-07-07 17:20	Applicant 👻	Logout
1 Dashboard	Home > SUSAR Report			
Q Search	Print Upload signed document Save Submit Close			
Profile	Overseas Suspected Unexpected Serious Adverse React	tion (SUSAR) Report Form		<u>^</u>
Initial Applications	1. Basic Information			
New Draft Sent Returned Approved Completed Acknowledged Expired Archived	Scientific Title:       Test         IRB/REC Ref. No:       1       Protocol No.:         Coordinating Investigator:       Lucky Lee       Anticipated Stud         Actual Study Start Date:       Date       Image: Constraint of the start	1 fy End Date: 2022-08-31 of this SUSAR (total)		
All  Post Approval Document  Useful Information/User Manual  KN Version: v0.975 BN Version: v0.520	Total No. of Reports Submitted:       Total No. of Reports Submitted       Download SUSAR re         3. Follow-up Actions       3.1 Any alteration of protocol required?       No         9. Yes (please submit Protocol Amendment Application)       No       No         3.2 Any recommendation from the Data Monitoring Committee?       Yes (please attach relevant document)       No         Upload Supplementary Document       Add       Form       Form	eport template		

Figure 6.1.1.1.3 Report page of Study Base Post Approval Document

5. <u>If you are assigned as Site PI/Delegate(s) only, the Document Type button displayed under</u> Action Menu in Approved Application List will only include Site Base Post Approval Activities as Figure 6.1.1.1.4.





Figure 6.1.1.1.4 Post Approval Document Type button displayed for Site PI/Delegate(s)

6. After you press the specific **Document Type** button, a dialog will be prompted for you to choose the site for creating the Post Approval Document form from the drop-down menu. Take Progress Report as an example as Figure 6.1.1.1.5;

Please select the site for	creating Pr	rogress Rep	ort
Choose one			•
		Cancel	Confirm

Figure 6.1.1.1.5 Dialog for choosing Site of Site Base Post Approval Document

7. Press **Confirm** button to proceed the creation of the Post Approval Document and you will be direct to the report form page. Take Progress Report as an example as Figure 6.1.1.1.6.



Figure 6.1.1.1.6 Report page of Site Base Post Approval Document



8. <u>If you are assigned as both CI/Site PI and Delegate(s) of Site PI/CI</u>, the Document Type button displayed under Action Menu in Approval Application List will include both Study Base and Site Base Post Approval Activities as Figure 6.1.1.1.7.

	Post-approval activities
	Application Amendment
_	Progress Report
	Final Report
	Protocol Deviation Form
	SAE Report
	SUSAR Report
	Miscellaneous Report
	CTC/CTI submission

### Figure 6.1.1.1.7 Post Approval Document Type button for both CI/Site PI and Delegate(s) of Site PI/CI

 If the Miscellaneous Report is selected, a dialog will be prompted for you to choose if you want to create for the Study Info or Site Info from the drop-down menu as Figure 6.1.1.1.8. After selection, you can press **Confirm** button to proceed the creation of Miscellaneous Report;

	 	-	
Choose One			
AHNH - Study Info			
CUHK - Site Info			

### Figure 6.1.1.1.8 Dialog for choosing Site of Miscellaneous for both CI/Site PI and Delegate(s) of Site PI/CI

- 10. If other Study-based or Site-based reports are selected, it will follow the behaviour of Step 3 Step 4 or Step 5 Step 7 above for the form creation.
- 11. Only when a new Post Approval Document is saved by CI/Site PI/Delegate(s), a "Draft" Post Approval Document will be created and shown in the "Draft" Post Approval List.
  - If CI/Site PI/Delegate(s) closes the Post Approval Document Page without pressing **Save** button, the data will be lost and the form will not be created and saved in Portal.
- 12. When a new Post Approval Document is submitted by CI/Site PI/Delegate(s), a "Submitted" Post Approval Document will be shown in the "Submitted" Post Approval List.



### 6.1.1.2 Create the Application Amendment Form

To create an Application Amendment, please follow the below steps:

- 1. Go to "Approved" Application List as Figure 6.1.1.2.1;
- 2. Press Application Amendment button in the Action Menu;
  - List of Post Approval Activities for creation under Action Menu will be different based on your role, please refer to Table 6.1 for details.

= 🍈 HA Clinical Resea	arch Ethic	s Review Portal				Taim Last Lo	an Chan ogin: 2022-07-20 10:23	Applicant 👻	Logout
A Dashboard	Home	> Initial Applications >	> Approved						
Q, Search	Applica	tion List							
Profile	Hide/S	how Columns Colla	epse All Expand All		oad Application	efresh			
Initial Applications							Filter keyword		Page Size
New	rence <sub>†1</sub>	Submission No.	Scientific Title	Ť_L	Coordinating	Status	Site Info	Last Modified Date	Z Action
Sent		20220516-011-000	Test		Site PI	Approved	0	2022-06-29 10:20:09	:
Returned	~~	20220516-012-000	Test		site pi1	Approved	0	Change Delegat	ion
Completed	~~	20220516-016-000	Test		site pi1	Approved	0	Clone to draft	
Acknowledged	~~	20220516-014-000	Test		site pi1	Approved	θ	Download Appro	oval Letter
Expired	~~	20220516-013-000	Test		site pi1	Approved	0	Post-approval activ	vities
All	~	20220516-010-000	Test		Lucky Lee	Approved	0	Application Ame	endment
Post Approval Document	~	20220516-009-000	Test		Lucky Lee	Approved	0	Progress Report	t
Draft	~	20220516-008-000	Test		Lucky Lee	Approved	0	Final Report	
Sent	~	20220516-007-000	Test		Lucky Lee	Approved	0	Protocol Deviati	on Form
Approved	4							SAE Report	
Completed	Showing	1 to 9 of 9 entries						SUSAR Report	
Acknowledged								Miscellaneous F	Report
Expired	_							CTC/CTI submis	ssion
•	•								

Figure 6.1.1.2.1 Application Amendment button of "Approved" Application List

3. A dialog will be prompted for you to choose to amend the Study Info or Site Info of the "Approved" Initial Application from the drop-down menu as Figure 6.1.1.2.2;

would like to an	nend?
	Ŧ
Cancel	Confirm
	would like to an Cancel

Figure 6.1.1.2.2 Pop-up dialog of choosing which part to amend

- 4. Press Confirm button to proceed the selection of Study Info or Site Info Amendment;
- 5. A dialog of "Are you sure to create the application amendment form before amendment?" will be prompted as Figure 6.1.1.2.3;





Figure 6.1.1.2.3 Pop-up dialog of confirming the creation of Application Amendment Form

- 6. Press **Confirm** button to proceed the Application Amendment creation;
- 7. You will be directed to the related Study Info or Site Info tab and revise all necessary content that you need as Figure 6.1.1.2.4. Other tab(s) will be view-only;

≡	HA Clinical Research Ethics	Review Portal	Taiman Chan Last Login: 2022-05-16 11:07 Applicant 👻	Logout					
A	Home > Post Approval Document > Application amendment (20220516-016-001) (Draft)								
Q	Print Save Compare char	ge Discard Close							
Θ	Team Member Form	Team Member Form		1 Alianti di					
÷	Personal Particulars	Site Principal Investigator's Delegation		Add					
6	PART IIA: STUDY DETAILS	Edit Email 1 Title (7) 1 Surname 1 First name	e † Cluster † Hospital / †	Department					
i)	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY PART III: ETHICAL IMPLICATIONS	No Data	n Stration						
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	4		4					
	Document Upload Declaration And Endorsement	PERSONAL PARTICULARS OF PRINCIPAL INVESTIGATOR AND CO-INVESTIGATOR         Principal Investigator (Applicant)         1.       32         Summe       312         Name in Ohinese (Optional)       312         2.       Position of the Principal Investigator (PI)         2.       Constitution of the Principal Investigator (PI)							

Figure 6.1.1.2.4 Editable tab of Application Amendment Form

- 8. Click Save button to save the changes made on Application Amendment Form;
- 9. "Update successfully." dialog will be popped up for changes confirmation as Figure 6.1.1.2.5;

Update successfully.	
	Confirm

Figure 6.1.1.2.5 Popup dialog after Application Amendment Form is saved

10. Press **Compare change** button in the top toolbar to direct to the Amendments and Changes Application Form as Figure 6.1.1.2.6;



(You are advised to complete all changes in the Application Amendment Form before pressing **Compare change** button to avoid duplicated input on the value in the re-generated Amendments and Changes Application Form. Please refer to next section and Figure 6.1.1.2.9 for details.)

	HA Clinical Research Eth	ics Review Portal	site ; Last L	Di 5 ogin: 2022-04-13 23:47	Applicant 👻	Logout
н	ome > Post Approval Document	> Application amendment (20220223-001-005) (Draft)				
L	Back Save Submit	Download amendment form Upload signed document				
A	mendments and Changes Applic	ation Form				
1	Background information					
	Re-submission - test cluster distribu	ition				
	IRB/REC Ref. No		Actual Study Start Date			ā
1	Protocol no. 321 modify		Anticipated Study End Date 2022-03-26			
	Coordinating Investigator sitepi1@ha.org.hk Proposed Amendments (Annend per	w document with track changes)				
2	riopooca ranchamento (rependite					
2	1. Study Info/Site Info	Site Info				
2	1. Study Info/Site Info Field Name/Document Name	Site Info 1. Title (e.g. Mr, Mrs, Ms, Miss, Dr)				
2	1. Study Info/Site Info Field Name/Document Name Current condition	Site Info 1. Title (e.g. Mr, Mrs, Ms, Miss, Dr)	Amendment			
2	1. Study Info/Site Info Field Name/Document Name Current condition	Site Info 1. Title (e.g. Mr. Mrs. Ms. Miss, Dr)	Amendment 1 - Amendment			
2	Study Info/Site Info     Field Name/Document Name     Current condition     1     Proposed by	Site Info  1. Title (e.g. Mr, Mrs, Ms, Miss, Dr)	Amendment 1 - Amendment Will change increase risk to participants?	Ves 1	No	

Figure 6.1.1.2.6 Amendments and Changes Application Form

- 11. After confirming the content that you revised in the Amendments and Changes Application Form, you need to select the Actual Study Start Date in the Date-time Picker;
  - Actual Study Start Date should not be earlier than current date.
- 12. Click "<u>Compare</u>" next to "Amendment" of 2. Proposed Amendments table to view changes in pop-up dialog as Figure 6.1.1.2.7 if needed;

×.,	Study Info/Site Info	Site Info				
	Field Name/Document Name	2.2.3 Universit				
	Current condition			Amendment		
				нки		
	Proposed by	Tester	Compare changes	×	🗋 Yes 🕑 No	
	Reason for change	Testing	21 - Amendment Testing			
6.	Study info/Site info	Site Info		Confirm		
	Field Name/Document Name	7.5 How will s	ubject be identified and recruited			
	Current condition			Amendment (Compare)		
	21			21 - Amendment Testing		
	Proposed by	Tester		Will change increase risk to participants?	🗆 Yes 🕑 No	
	Reason for change	Testing				

Figure 6.1.1.2.7 Pop-up dialogs of "Compare Changes"

Input the Proposed Person in "Proposed by" and Reason in "Reason for change" in the textbox;
 Tick "Yes/No" checkbox to confirm if the change will increase risk to participants;



15. Press Save button to save the draft of Amendments and Changes Application Form;
(You are advised to press Save button before press Back button to exit the Amendments and Changes Application Form. Otherwise, the changes in the form will be discarded)
16. "Save successfully." dialog will be prompted for confirmation as Figure 6.1.1.2.8.

Save successfully.	
	Confirm

6.1.1.2.8 Pop-up message after saving the Amendments and Changes Application Form

If you want to pause the submission and make further changes in draft of the saved Application Amendment Form, please follow the steps below:

- 1. Switch back to the Study Info or Site tab you want to make further changes in the current Application Amendment Form; or
- 2. Click the Amendment Form for the specific Study Info or Site Info in the "Draft" Post Approval List to direct to the Application Amendment Form if you have exited the form;
- 3. Revise the contents of the Application Amendment form last saved;
- 4. After you confirm the revised content in the draft of Study Info or Site Info Application Amendment form, you can click **Compare Change** button again;
- 5. A pop-up dialog will be shown as a confirmation of regenerating the Amendments and Changes Application Form as Figure 6.1.1.2.9;



Figure 6.1.1.2.9 Dialog of regenerating the Amendment Application Form

- 6. The original value, such as reason for change, proposed by, the option of whether the changes will increase risk to participants and Actual Study Start Date will be cleared and need to input again in the new Amendment Application Form;
- 7. Press **Confirm** button to direct to the new Amendments and Changes Application Form to input the value for submission.



## 6.1.2 Discard Post Approval Document

If you want to discard the draft of Post Approval Document, you can follow the below steps:

1. Press **Discard** button in the top toolbar of the Post Approval Document as Figure 6.1.2.1;

= 💠 HA Clinical Resea	rch Ethics Review Portal		Taiman Chan Last Login: 2022-08-23 10:47	Applicant 🗸	Logout	
f Dashboard	Home > Progress Report (2	0220516-013-001) (Draft)				
Q Search	Print Upload signed d	locument Save Submi	t Discard Close			
Profile		F	Research Progress Report Form			Â
Initial Applications	1. Research Identification					
	Scientific Title:	Test				
New	100 (050 D-6 No.	BE0.000	O	-1414		
Draft	IRB/REU Ref. No	REC-003	Coordinating Investigator:	site pri		
Sent	Protocol No.:	2	Study Site of this progress report:	Study Site of this progress	s report	
Returned						
Approved	Anticipated Study End Date:	2025-05-09	Site Principal Investigator of the above study site(s):	312 321		
Completed	2. Progress Report					
Acknowledged	Pepart sequence no :	1	Report Pariod (From) + (to):	Doto 🗎 to	Data	-
Expired	Report sequence no	I	Report Period (FIGH) F (to).	Date	Date	
Archived	Actual Study Start Date:	Date 🛅	Not yet started			
All						
Post Approval Document	Planned Sample Size (site):	321	No. of Completed:	No. of Completed		•
· · · · · · · · · · · · · · · · · · ·	Form					

Figure 6.1.2.1 Discard button in the Draft Post Approval Document

2. A dialog of "Are you sure to discard the application?" will pop up as Figure 6.1.2.2;

Are you sure to discard the application?		
	Cancel	Confirm

Figure 6.1.2.2 Popup dialog before discarding Post Approval Document

- 3. Press Confirm button to proceed the discard confirmation;
- 4. A dialog of "Application is discarded." will be prompted as Figure 6.1.2.3;

Application is discarded.	
	Confirm

Figure 6.1.2.3 Popup dialog after Post Approval Document is discarded

5. The Post Approval Document will be "Withdrawn" status and can be found in "Archived" Post Approval List.



### 6.1.3 Submit Post Approval Document

6.1.3.1 Submit Post Approval Document (except Amendment Application)

If you want to proceed the submission of Post Approval Document, except Amendment Application, please follow the steps below:

1. Press **Print** button in the top toolbar to download the report in PDF format for signature as Figure 6.1.3.1.1;

= 📫 HA Clinical Resear	ch Ethics Review Portal				Taiman Chan Last Login: 2022-09-14 09:26	Applicant 👻	385	Logout
♠ Dashboard	Home > Progress Report (2	0220516-013-001) (Draft)						
Q, Search	Print Upload signed d	ocument Save	Submit	Discard Close				
Profile			F	Research Progress Report Form				Î
► Initial Applications ∨	1. Research Identification Scientific Title:	Test						
Post Approval Document	IRB/REC Ref. No.:	REC-2022-010		Coordinating Investigator:	site pi1			
Draft	Protocol No.:	2		Study Site of this progress report:	Study Site of this progress report HKWC			
Returned	Anticipated Study End Date:	2025-05-09		Site Principal Investigator of the above study site(s):	312 321			
Completed	2. Progress Report							
Acknowledged	Report sequence no.:	1		Report Period (From) + (to):	2022-08-24 💼 to	Date 2022-08-10  🛅	I	
Expired	Actual Study Start Date:	Date		Not yet started				•
	Form							
PROGRESS_REPORpdf							Show al	×

Figure 6.1.3.1.1 Download report in PDF format for signature

2. Press **Upload signed document** button to upload the signed form from your local computer. The uploaded file will be shown in the toolbar. You can download the uploaded file by pressing the hyperlink as Figure 6.1.3.1.2;

$\equiv \Phi$ HA Clinical Research	Taiman Chan Last Login: 2022-09-14 09:26	Applicant 👻	Logout				
A Dashboard	Home > Progress Report (2	0220516-013-001) (Draft	)				
Q Search	Print Upload signed d	ocument	Submit	Discard Close Signed	Document: <u>Signed Progress Rep</u>	<u>ort.pdf</u>	
e Profile				Research Progress Report Form			A
Initial Applications 🗸 🗸	1. Research Identification Scientific Title:	Test					
Post Approval Document	IRB/REC Ref. No.:	REC-2022-010		Coordinating Investigator:	site pi1		
Draft Sent	Protocol No.:	2		Study Site of this progress report:	Study Site of this progress report HKWC		
Returned	Anticipated Study End Date:	2025-05-09		Site Principal Investigator of the above study site(s):	312 321		
Approved	2. Progress Report				Data	Data	
Acknowledged	Report sequence no.:	1		Report Period (From) + (to):	2022-08-24 <b>t</b>	2022-08-10	
Expired		Date					
Archived	Actual Study Start Date:	2022-08-17		Not yet started			
All	Planned Sample Size (site):	321		No. of Completed:	No. of Completed		
👔 Useful Information/User Manu 🗸							<b>v</b>
× •	Form						

Figure 6.1.3.1.2 Screen of the uploaded signed file



3. Press **Submit** button for submission and a dialog of "Are you sure to submit?" will be prompted as Figure 6.1.3.1.3;



Figure 6.1.3.1.3 Dialog of confirming before submission

- 4. Press **Confirm** button in pop-up dialog to confirm the submission for further approval;
- 5. A dialog of "Submitted successfully." will be prompted as confirmation as Figure 6.1.3.2.4;



Figure 6.1.3.2.4 Dialog after Post Approval Document is submitted

6. The Post Approval Document will change to "Submitted" status and will be shown in the "Sent" Post Approval List.

You are not allowed to create more than one Progress Report / Final Report for the Study Info or Site Info at a time.

 If a Progress Report / Final Report was created for the selected Study Info or Site Info and has not yet been approved by Central IRB or Secretary, a dialog will be prompted as Figure 6.1.3.2.5;



Figure 6.1.3.2.5 Pop-up dialog of redirecting to the existing report

- 2. Click Confirm button to direct to the submitted Progress Report / Final Report;
- 3. Report will be view-only as Figure 6.1.3.2.6 and not allowed to make changes on it;

= 💠 HA Clinical Researc	h Ethics Review Portal			Taiman Chan Last Login: 2022-08-23 10:47	Applicant 👻	Logout
Profile	Home > Progress Report (2	0220516-012-001) (For Review)				
Initial Applications	Close Signed Document	t: <u>Signed Progress Report.docx</u>				View Only
Draft		F	Research Progress Report Form			<b>^</b>
Sent	1. Research Identification					
Returned	Scientific Title:	Test				
Approved	IRB/REC Ref. No.:	REC-003	Coordinating Investigator:	site pi1		
Completed	Protocol No.:	2	Study Site of this progress report:	Study Site of this progress report - 11		
Acknowledged						
Expired	Anticipated Study End Date:	2025-05-09	Site Principal Investigator of the above study site(s):	312 321		
Archived	2. Progress Report					
All				Date	_ Date	_
Post Approval Document	Report sequence no.:	1	Report Period (From) + (to):	2022-05-10 💼 to	2022-05-10	
Draft	Actual Study Start Date:	2022-05-11	<ul> <li>Not yet started</li> </ul>			
Sent				- No. of Completed		
Returned	Planned Sample Size (site):	321	No. of Completed:	11		•
Anneniud F	Form Comment Sheet					

Figure 6.1.3.2.6 View-only mode of the submitted report

- 4. You can view the comment in the "Comment Sheet" tab inside the Post Approval Document if any;
- 5. If you want to amend the submitted Post Approval Document, you can use "Request for Return". Refer to <u>Request for Return of Post Approval Document</u>.



### 6.1.3.2 Submit Amendment Application Form

If you want to proceed the submission of Amendment Application Form, please follow the steps below:

1. Press **Download amendment form** button in the top toolbar to download the Amendment Form in PDF format for signature as Figure 6.1.3.2.1;

≡		HA Clinical Research Ethi	cs Review Portal	Taiman ( Last Login:	Chan 2022-09-14 09:26	Applicant 👻	385 Lo	gout				
♠	Home > Post Approval Document > Application amendment (20220516-010-002) (Draft)											
Q	Back to study info Save Submit Download amendment form Upload signed document											
Θ	Ame	endments and Changes Applica	ation Form					Î				
	1. Ba	ackground information										
0	Te											
?	CI	8/REC Ref. No. RB-2022-020-5		Actual Study Start Date 2022-09-30			Ē					
	Pro 2	otacol no		Anticipated Study End Date 2025-05-09								
	tai	ordinating Investigator imanchan@testing.com oposed Amendments (Append new	document with track changes)									
	1.	Study Info/Site Info	Site Info					1				
		Field Name/Document Name	7.4 No. of subjects to be recruited in the site(s) stated in Q.2.3.1	3.1 above.								
		Current condition		Amendment								
		66	1	100								
		Proposed by	Taiman Chan	Will change increase risk to participants?	🗌 Yes 🔽 M	٩٥						
			Increased the recruitment					•				
	Study	Info Site (NLTH) Amendmen	nt application									
P	Amendments_andpdf											

Figure 6.1.3.2.1 Screen of downloading Amendment form in PDF format

2. Press **Upload signed document** button to upload the signed form from your local computer as Figure 6.1.3.2.2;

≡		HA Clinical Research Ethi	cs Review Portal	Taiman Last Login:	Chan 2022-09-14 09:26	Applicant 👻	Logout			
A	<u>Home</u>	e > <u>Post Approval Document</u> :	> Application amendment (20220516-010-002) (Draft)							
Q	Back	k to study info	bmit Download amendment form Upload signed docu	ment Signed Document: Signed Amendment App	olication.pdf 🗴	]				
Θ	Amendments and Changes Application Form									
B	1. Ba	ackground information								
	Te	idy Title								
•		1/050 D-6 N-		Annual Divide Dente Data						
?	CIF	RB-2022-020-5		2022-09-30						
	- Pro	stocol no		Anticipated Study End Date						
	2			2025-05-09						
	Coc	ordinating Investigator								
	tai	manchan@testing.com								
	2. Pro	oposed Amendments (Append new	document with track changes)							
	1.	Study Info/Site Info	Site Info							
		Field Name/Document Name	7.4 No. of subjects to be recruited in the site(s) stated in Q.2.3.	3.1 above.						
		Current condition		Amendment						
		66		100						
		Proposed by	Taiman Chan	Will change increase risk to participants?						
		Reason for change	Increased the recruitment	·						
	Study	y Info Site (NLTH) Amendmen	t application				•			

Figure 6.1.3.2.2 Screen of uploading Amendment form before pressing Save button



• You can download the uploaded file by pressing the hyperlink after clicking **Save** button as Figure 6.1.3.2.3;

≡	Ф	HA Clinical Research Ethi	cs Review Portal	Taima Last Log	n Chan in: 2022-09-14 09:26	Applicant 👻	Logout
♠	Home	e > Post Approval Document	> Application amendment (20220516-010-002) (Draft)				
۹	Bac	k to study info	bmit Download amendment form Upload signed docur	nent Signed Document Signed Amendment A	pplication.pdf 😣	]	
Θ	Ame	endments and Changes Applica	ation Form				A
	1. Ba	ackground information					
63	Stu	udy Title					
0	Te	51					
?	CI	8/REC Ref. No RB-2022-020-5		Actual Study Start Date 2022-09-30			
-	- Pro	stocol no.		- Anticipated Study End Date			
	2			2025-05-09			
	tai 2. Pr	ordinating Investigator imanchan@testing.com oposed Amendments (Append new	r document with track changes)				
	1.	Study Info/Site Info	Site Info				
		Field Name/Document Name	7.4 No. of subjects to be recruited in the site(s) stated in Q.2.3.1	above.			
		Current condition	·	Amendment			
		66		100			
		Proposed by	Taiman Chan	Will change increase risk to participants?	🗌 Yes 🛛	No	- 11
		Reason for change	Increased the recruitment				
	Stude	(Info Site (NITH) Amendmen	and application				•

### Figure 6.1.3.2.3 Hyperlink to download the Signed form after pressing Save button

- 3. Submit button will be enabled once the signed Amendment Form has been uploaded;
  - Indicator will be shown in the pop-up dialog for incomplete field if applicable
- 4. Press **Submit** button for submission and a dialog of "Are you sure to submit the amendment application form?" will be prompted as Figure 6.1.3.2.4;



Figure 6.1.3.2.4 Dialog of confirming Application Amendment before submission

- 5. Press Confirm button in pop-up dialog to confirm the submission for further approval;
- 6. A dialog of "Amendment Application Form has been submitted." will be prompted as confirmation as Figure 6.1.3.2.5;



Figure 6.1.3.2.5 Dialog after Application Amendment is submitted

7. The Amendment Form will change to "Submitted" status and will be shown in the "Sent" Post Approval List.



You are not allowed to create more than one amendment form for the Study Info or Site Info at a time.

1. If an Amendment Form was created for the selected Study Info or Site Info and has not yet been approved by Central IRB or Secretary, a dialog will be prompted as Figure 6.1.3.2.6;



Figure 6.1.3.2.6 Pop-up dialog of redirecting to the existing amendment form

- 2. Click Confirm button to direct to the submitted Application Amendment Form;
- 3. Study Info, Site Info and the Amendment Application Form will be view-only as Figure 6.1.3.2.7 and not allowed to make changes on it;

≡	HA Clinical Research Ethics	Review Portal	Tairnan Chan Last Logir: 2022-04-17 18:42 Applicant 🛫 🧖 Log	out
ŧ	Home > Post Approval Document >	Application amendment (20220107-003-002) (Submitted)		
Q	Print Compare change Clos	e	View	Only
Θ	Instruction	Team Member Form		-
B	Tearn Member Form	Applying IRB / REC (7): Central IRB 👻		
	PART I: OUTLINE OF APPLICATION	Scientific title		
0	PART IIA: STUDY DETAILS	Testing		
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	Coordinating Investigator (7)	Contact Number	
	PART III: ETHICAL IMPLICATIONS	taimanchan@testing.com	12343070	
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	Title (7) Testing	Sumana FistNama Chan Taiman	
	CLINICAL STUDY CATEGORIZATION FORM	Position (*) Tester	Department         Cluster         Hespital / Institution (0)           Testing         HKWC +         FYKH +	
	Document Upload	Coordinating Investigator's Delegation (7)	Add	
		Edit Email 1, Title (7)	$ \hat{\uparrow}_{\hat{\delta}} \qquad \text{Sumame}  \hat{\uparrow}_{\hat{\delta}} \qquad \text{First name}  \hat{\uparrow}_{\hat{\delta}} \qquad \text{Position}  (?)  \hat{\uparrow}_{\hat{\delta}} \qquad \text{Cluster}  \hat{\uparrow}_{\hat{\delta}} \qquad \text{Hospital} /  \hat{\uparrow}_{\hat{\delta}} \qquad \text{Institution}  \hat{\uparrow}_{\hat{\delta}} \qquad \text{Institution}  \hat{\uparrow}_{\hat{\delta}} = 1 $	
		/ taimanchan@abc.com Tester	CHAN TAI MAN Tester HKWC DKCH	
		4	· · · · · · · · · · · · · · · · · · ·	
		Information of Site $PI(s)$ $(7)$	bb4	
		Edit Email † Title (7)	$ \label{eq:constraint} \hat{\gamma}_{\pm} \qquad \text{Surname}  \hat{\gamma}_{\pm} \qquad \text{First name}  \hat{\gamma}_{\pm} \qquad \text{Cluster}  \hat{\gamma}_{\pm} \qquad \text{Hospital } f  \hat{\gamma}_{\pm} \qquad \text{Department} $	
		/ taimanchan@testing.com Testing	Chan Taiman NTEC SCH Test	-
		Study Info Site (SCH) Amendment application Com	mment Sheet	

Figure 6.1.3.2.7 View-only mode of the Application Amendment

- 4. You can view the comment in the "Comment Sheet" tab inside the Application Amendment Form if any;
- 5. If you want to amend the submitted the Application Amendment Form, you can use "Request for Return". Refer to <u>Request for Return of Application Amendment</u>.



## 6.1.4 Returned Post Approval Document

You may receive a notification in Portal and by email from CCO/ Cluster Admin/ Secretary if Post Approval Document for Study Info or Site Info is returned as Figure 6.1.4.1.

• Return: <Action Role> returned "<CRER Application No.>" - <Document Name>. Please check the "Comment Sheet" tab for suggested comments.

= 🍈 HA Clinical Resear	ch Ethics Review Portal		site pi 5 Last Login: 2022-04-18 11:44 Applicant 👻 👭 Logout
A Dashboard	Home		Notification Mark All Read
Q, Search	Dashboard Applications		From: CCO 2022-04-18 11/42-43 Return: CCO returned IRB-2022-072 - Amendment Application - Please check the 'Comment Sheet' tab for suggested comments. Mark Read
initial Applications  Not Approval Document  Subseful Information/User Manual  FN Version: v0.932 BN: v0.460 build at 20220329 08-45	Draft <u>3/3</u>	Returned       Q/Q       Expire in ≥ 30 days       Expire in < 30 days	From: CRER System         2022-04-18:00:000           Overdue: IRB-2022-002 - Initial Submission is overdue. Please submit afresn via the CRER Portal if needed.         Mark. Read           From: CRER System         2022-04-18:00:000           Overdue: IRB-2022-002 - Initial Submission is overdue. Please submit afresn via the CRER Portal if needed.         Mark. Read
	Post Approval Documents Draft <u>675</u>	Returned           1/1           Expire in ≥ 30 days         (1)           Expire in < 30 days	From: CRER System 2022-04-15 00 00 02 Overdue: IRB-2022-002 - Initial Submission is overdue. Please submit afresh via the CRER Portal if needed, Mark Read

Figure 6.1.4.1 Notification for Returned Post Approval Document

The status of the Post Approval Document will change from "Submitted" to "Returned". Also, the figures on your Dashboard will be changed when a Post Approval Document is returned as Figure 6.1.4.2.

= 🍈 HA Clinical Resear	ch Ethics Review Portal				site pi 5 Last Login: 2022-04-18 11:44	Applicant 👻	94	Logout
A Dashboard	Home							
Q, Search	Dashboard							
e Profile	Applications							
<ul> <li>Initial Applications</li> <li>Post Approval Document</li> <li>Useful Information/User Manual</li> <li>FN Version: v0.932</li> <li>BN: v0.460 build at 20220329 08:45</li> </ul>	Port Assessed Decuments	Draft <u>3/3</u>	Expire in ≥ 30 days Expire in < 30 days	Returned <u>0/0</u> <u>(0)</u> <u>(0)</u>				
		Draft <u>676</u>	Expire in ≥ 30 days Expire in < 30 days	Returned 1/1 (1) (0)				

Figure 6.1.4.2 Changes on Dashboard for Returned Post Approval Document



Below is summary of Dashboard changes of CI/Site PI/Delegate(s) when a Post Approval Document is returned.

Post Approval Document Status	Dashboard of CI/Delegate(s)	Dashboard of Site PI/Delegate(s)
Submitted	Returned (c/d)	Returned (c/d)
Post Approval Document of Study Base Returned	Returned (c+1/d+1)	Returned (c/d)
Post Approval Document of Site Base Returned	Returned (c/d)	Returned (c+1/d+1)

You can access the returned Post Approval Document by the following methods to check the comment, amend and re-submit the application:

- 1. Click the notification for returned Post Approval Document directly as Figure 6.1.4.1; or
- 2. Click the No. in Returned box of Post Approval Documents on Dashboard as Figure 6.1.4.2; or
- 3. Go to the "Returned" Post Approval List and click the Document Type of the specific Post Approval Document as Figure 6.1.4.3.

Concerned CI/Site PI/Delegate(s) can edit the returned Post Approval Document after directing to the form page.

= 🍈 HA Clinical Resear	h Ethics Review Portal				aiman Chan 1st Login: 2022-04-17 18:42	Applicant 👻	101	Logout
A Dashboard	Home > Post Approval Document	> Returned						
Q, Search	Post Approval List							
e Profile	Hide/Show Columns Refresh							
Initial Applications					Filter keyword	P	age Size:	10 -
Post Approval Document								
Draft	Submission No.	Scientific Title	Document Type	Status	Last Modified Date	1 <sub>Å</sub> Exp	oiry Date	34 - A
Sent	20220107-003-002	Testing	Amendment Form (Study Info)	Returned	2022-04-18 15:45:2	29 202	2-07-17	I.
Returned	4							•
Approved	Showing 1 to 1 of 1 entries						< 1	1 >
Completed								
Acknowledged								

Figure 6.1.4.3 Returned Post Approval Document in "Returned" Post Approval List



Comment from CCO/Secretary can be seen in "Comment tab" of Post Approval Document. You can click **View** button, which will be enabled if there is an attachment uploaded by CCO/Secretary, to download the attachment in the pop-up dialog.

≡	Ф на	Clinical Re	search Ethics	Revi	iew Portal				Taiman Chan Last Login: 2022-0	9-19 13:49	Applicant 👻	506	Logout
ŧ	. Home > Post Approval Document > Application amendment (20220728-003-002) (Returned)												
Q	Withdraw	Back to :	study info										
Θ	Comment H	<u>listory</u>											
÷	Dat	e î <sub>↓</sub>	From	↑Ļ	То	↑ <sub>↓</sub>	Comment	$\uparrow_{\downarrow}$	Attachment $\uparrow_{\downarrow}$				
6	2022-09-20	16:31:04	CCO		Applicant (CI)		Return for modification		View				
?	2022-09-20	16:30:03	Applicant (Cl	)	CCO		Re-submit Application Amendment form		-				
	2022-07-29	11:18:40	CCO		Applicant (CI)		Requested for Return		-				
	Study Info	Site (NLTH)	Site (HHH)	Ame	endment application	Con	ment Sheet						

Figure 6.1.4.4 Comment tab of Post Approval Document

If the returned Post Approval Document has not yet been re-submitted, the number of the boxes "Expire  $\geq$  30 days" and "Expire < 30 days" will be updated accordingly based on the expiry date of returned Post Approval Document as Figure 6.1.4.2.

You will also receive notifications as following for returned Post Approval Document form that is not yet re-submitted:

1. Reminder of re-submitting the returned Post Approval Document – 90/30 days before expiry date

2. Notification of Post Approval Document is overdue

When the Returned Post Approval Document is overdue, the Post Approval Document will change to "Expired" status and can be seen in the "Expired" Post Approval List.


# 6.1.5 Re-submit / Withdraw Returned Post Approval Document

Regarding the returned Post Approval Document, you can review the comments from CCO/Cluster Admin or Secretary in the Comment Sheet tab as Figure 6.1.4.4, re-submit it after modification or withdraw it if applicable.

#### 6.1.5.1 Re-submit / Withdraw Returned Post Approval Document (except Amendment Application)

To re-submit Post Approval Document, except Amendment Application, please follow the below steps:

- 1. Amend all necessary content in the Form tab;
- 2. Press Print button to download the amended form for signature;
- 3. Upload the signed document by pressing Upload signed document button;
- 4. Click Re-Submit button after the signed document is uploaded;

5. "Are you sure to re-submit the application amendment?" dialog will be prompted for you to leave your message if any as Figure 6.1.5.1.1;

Are you sure to re-submit?		
	Cancel	Confirm

Figure 6.1.5.1.1 Pop-up dialog before re-submission

- 6. Press **Confirm** button to confirm the re-submission;
- 7. "Submitted successfully." message will be popped up for confirmation.



Figure 6.1.5.1.2 Pop-up dialog after re-submission

The "Return and Re-submit" process may happen more than once until CCO/Secretary confirms the Post Approval Document.



To withdraw the returned Post Approval Document, you can follow the below steps:

1. Click Withdraw button in the Post Approval Document;

Ξ	E 🌵 HA Clinical Researce	ch Ethics Review Portal				Lucky Lee Last Login: 2022-07-08 15:22	Applicant 👻	793	Logout
1	Dashboard	Home > Progress Report (2	0220516-005-003) (Retu	rned)					
Q	Search	Print Upload signed d	ocument Save	Re-sub	withdraw Close	Signed Document: Progres	<u>s.txt</u>		
e	Profile			Re	esearch Progress Report Form				<b>^</b>
÷	Initial Applications 🗸	1. Research Identification Scientific Title:	⊤est						
G	Post Approval Document	IRB/REC Ref. No.:	irb flow`~~		Coordinating Investigator:	Lucky Lee			- 1
	Draft	Protocol No.:	2		Study Site of this progress report:	Study Site of this progress report	t		
	Sent		0005.05.00		Other Designational Instructional Activity				
	Approved	Anticipated Study End Date:	2025-05-09		site Principal Investigator of the above study site(s):	циску Lee			
	Completed	2. Progress Report							
	Acknowledged	Report sequence no.:	1		Report Period (From) + (to):	 2022-05-16 <b>1</b> to	o 2022-05-16		
	Expired				1				
	Archived	Actual Study Start Date:	Date		Not yet started				
	All	Planned Sample Size (site):	66		No. of Completed:	No. of Completed			
?	Useful Information/User Manual	No. of Recruited^:	No. of Recruited						
FN	Version: v0.975								
BN	version: VU.520	Any withdrawal?:	⊙ Yes ○ No		No. of Withdrawn after recruited^:	21			
		Withdrawal reasons:	Withdrawal reasons 111						
		^Please submit Protocol Ame	endment Application if the	e no. of n	ecruited will exceed the planned sar	mple size.			_
		Form Comment Sheet							

Figure 6.1.5.1.3 Screen of Withdraw button in Post Approval Document

2. A dialog of "Are you sure to withdraw?" will be prompted for you to provide the withdrawn reason as Figure 6.1.5.1.4;





3. Press **Confirm** button to proceed and a dialog of "Application is Withdrawn" will be prompted for confirmation.





Figure 6.1.5.1.5 Pop-up dialog of "Withdraw successfully."

4. The Post Approval Document will be in "Withdrawn" status and can be found in "Archived" Post Approval List.



#### 6.1.5.2 Re-submit / Withdraw Returned Amendment Application Form

To re-submit Application Amendment, please follow the below steps:

- 1. Amend all necessary content in the Study Info or Site Info tab;
- 2. Click Compare change button in the related Study Info or Site Info tab;
- 3. A dialog will be prompted as a confirmation of regenerating the Amendment Application form
- as Figure 6.1.5.2.1;



Figure 6.1.5.2.1 Dialog of regenerating the Amendment Application Form

4. The fields, such as Reason for Change, Proposed person, the option of whether the changes will increase risk to participants and Actual Study Start Date, in original Amendment Application Forms will be cleared and need to input again in the new Amendment Application Form;

5. Press **Confirm** button to direct to the new Amendments and Changes Application Form for re-submission;

6. After inputting the value of Actual Study Start Date, Reason for Change, Proposed person and select the option of whether the changes will increase risk to participants, you can download the Amendment Form for signature;

- 7. Press Download amendment form button to download the Amendment Form for signature;
- 8. Upload the signed document by pressing Upload signed document button;
- 9. Click Re-Submit button after the signed document is uploaded;

10. "Are you sure to re-submit the application amendment?" dialog will be prompted for you to leave your message if any as Figure 6.1.5.2.2;



Leave your com	ments (if any)	

Figure 6.1.5.2.2 Pop-up dialog before re-submission

- 11. Press Confirm button to confirm the re-submission;
- 12. "Application amendment has been re-submitted" message will be popped up for confirmation.

Amendment Application Form has been re-submitted.	
	Confirm

Figure 6.1.5.2.3 Pop-up dialog after re-submission

The "Return and Re-submit" process may happen more than once until CCO/Secretary confirms the Application Amendment.



To withdraw the returned Application Amendment, you can follow the below steps:

1. Click Withdraw button in the Application Amendment as Figure 6.1.5.2.4;

≡	HA Clinical Research Ethics	Review Portal	site pi 5 Last Login: 2022-04-18 11:44	Applicant 👻	94 Logout
A	Home > Post Approval Document >	Application amendment (20220223-001-005) (Returned)			
Q	Print Save Compare char	ge Withdraw Close			
Θ	Team Member Form	Team Member Form			<u>^</u>
Ð	Personal Particulars	Site Principal Investigator's Delegation			Add
0	PART I: OUTLINE OF APPLICATION PART IIA: STUDY DETAILS	Edit Email 1, Title (7) 1, Sumarne 1, H	First name †_ Cluster †_	Hospital /	Depar
?	PART IIB: STUDY DETAILS FOR PROSPECTIVE STUDY	No Data		Institution	
	PART III: ETHICAL IMPLICATIONS	Ho bita			
	PART IV: BUDGET, RESOURCES, INDEMNITY AND INSURANCE	4			•
	Document Upload	PERSONAL PARTICULARS OF PRINCIPAL INVESTIGATOR AND CO-INVESTIGAT	TOR		
	Declaration And Endorsement	Principal Investigator (Applicant) Tee (e.g. Mr, Mrs, Mrs, Mrs, 20)  1. Tee (e.g. Mr, Mrs, Mrs, Mrs, 20)  1. Start and an analysis of the set o	mment Sheet		

Figure 6.1.5.2.4 Screen of Withdraw button in Application amendment

2. A dialog of "Are you sure to withdraw the application?" will be prompted for you to provide the withdrawn reason as Figure 6.1.5.2.5;



Figure 6.1.5.2.5 Pop-up dialog of Reason Statement when withdrawing the Amendment Form

3. Press **Confirm** button to proceed and a dialog of "Application is Withdrawn" will be prompted for confirmation.





Figure 6.1.5.2.6 Pop-up dialog of "Application is Withdrawn."

4. The Amendment Application will be in "Withdrawn" status and can be found in "Archived" Post Approval List.



### 6.1.6 Confirmed Post Approval Document

The submitted Post Approval Document will be reviewed by CCO/Cluster Admin or Secretary based on the workflow of the Initial Application. They will confirm the Post Approval Document when the information and documents are ready.

Once the Post Approval Document is confirmed, you will receive a notification in Portal and by email:

• Confirmation: Your application "<CRER Application No.>" - <Document Name> is confirmed and will be arranged for review.

= 啦 HA Clinical Resear	ch Ethics Review Portal			Taiman Chan Last Login: 2022-04-17 18:42	Applicant - Logout
A Dashboard	Home			Notificatio	n Mark All Read
Q, Search	Dashboard			From: Taiman Chan Confirmation: Your application IRB-2022-01	2022-02-14 00:08:43
O Profile	Applications			confirmed and will be arranged for review.	
Initial Applications	Draft <u>5/5</u>		Returned	From: Taiman Chan Submission: Received a new submission IF Application.	2022-02-13 23:58:08 RB-2022-011 - Amendment
Draft Sent		Expire in ≥ 30 days Expire in < 30 days	( <u>Q)</u> ( <u>Q)</u>	From: Taiman Chan Withdrawal: IRB-2022-062 - Initial Submiss	2022-02-13 23:03:01 ion is withdrawn.
Returned Approved	Post Approval Documents			From: CRER System Expired: 68706134-7b07-4ee1-8737-5f64e 2022-02-12. Please submit the renewed do	2022-02-13 00:00:00 4ea3a7f - CTI is expired on ocument(s) accordingly.
Completed Acknowledged Expired	Draft 2/2		Returned	From: CRER System Expired: be9b0fa3-2790-4556-b1df-c18cc4	2022-02-13 00:00:00
Archived		Expire in ≥ 30 days	(0)	2022-02-12. Please Submit the renewed do	voument(s) accordingly.
All		Expire in < 30 days	<u>(0)</u>		
Useful Information/User Manual					

Figure 6.1.6.1 Notification of Confirmed Post Approval Document

To view the confirmed Post Approval Document, you can:

- 1. Click the notification message directly to the Post Approval Document as Figure 6.1.6.1; or
- Visit the "Sent" Post Approval List. The confirmed Post Approval Document will be in "Confirmed" status;
- 3. Click **Document Type** to access to the Post Approval Document as Figure 6.1.6.2.

≡ <b>(</b> ) H⁄	A Clinical Res	earch Ethics Review Porta	F.			Taiman Chan Last Login: 2022-0	Applicant	<sup>108</sup>	Logout
A Dashboard		Home > Post Approval D	<u>Document</u> > Sent						
Q Search		Post Approval List							
Profile		Hide/Show Columns	Refresh						
Initial Applica	ations	<i>y</i>				Filter keywor	d	Page Size:	10 -
Draft	al Document	Submission No. †	Scientific Title	$^{\dagger}$	Document Type †	Status	Last Modified Date	Expl	ry Date
Sent		20220107-003-002	Testing		Amendment Form (Study Info)	Submitted	2022-04-18 17:06:49		
Returned		20220107-003-003	Testing		Amendment Form (SCH)	Confirmed	2022-02-14 00:08:42		•
Approved		20220107-001-002	Test234		Amendment Form (Study Info)	Submitted	2022-01-20 18:48:23		•
Completed		4							) þ
Acknowledged		Showing 1 to 3 of 3 entries						< 1	
Expired		-						النار	
Archived									

Figure 6.1.6.2 Confirmed Status of Post Approval Document



### 6.1.7 For Review Post Approval Document

After a Post Approval Document is confirmed, Central IRB / Secretary can arrange review meeting for the Post Approval Document:

• Once the review meeting is arranged for the confirmed Post Approval Document, its status will change from "Confirmed" to "For Review". You can find it in Sent Post Approval List as Figure 6.1.7.1

= 📫 HA Clinical Resear	ch Ethics	Review Portal			Taiman Chan Last Login: 2022-09	Applicant 👻	Logout
A Dashboard	<u>Home</u> >	Post Approval Document	> Sent				
Q, Search	Post App	roval List					
Profile	Hide/Sho	ow Columns Refresh					
♣ Initial Applications ∨					Filter	keyword	Page Size
Post Approval Document ^ Draft		Submission No. $\uparrow_{\downarrow}$	Scientific Title $\uparrow_\downarrow$	Document Type $\uparrow_{\downarrow}$	Status	Last Modified Date $\downarrow_A^Z$	Action
Sent		20220516-012-001	Test	Progress Report (CUHK)	For Review	2022-09-27 14:24:16	-
Returned		20220516-010-001	Test	Amendment Form (Study Info)	For Review	2022-08-31 15:42:14	-
Approved		20220516-011-010	Test	Amendment Form (Study Info)	Re-Submitted	2022-07-18 16:10:55	:
Acknowledged		20220516-011-006	Case 2	Miscellaneous Report (Study Info)	Submitted	2022-07-18 16:08:07	:
Expired		20220516-011-014	Case 5	SUSAR Report (Study Info)	Submitted	2022-06-29 12:33:35	:
Archived		20220516-011-013	Demo	SUSAR Report (Study Info)	Submitted	2022-06-29 10:16:35	:
2 Useful Information/User Manual		20220516-011-012	Case 4	SUSAR Report (Study Info)	Submitted	2022-06-29 10:14:29	:
		20220516-012-002	Test	SUSAR Report (Study Info)	Confirmed	2022-06-28 17:24:42	-
FN Version: v1.011 BN Version: v0.530		20220516-011-003	Demo for testing	Final Report (Study Info)	Submitted	2022-06-22 15:47:35	:
		20220516-011-004	Demo	Protocol Deviation Report (NLTH)	Submitted	2022-06-16 16:47:37	:
	Showing 1	to 10 of 11 entries				<	1 2 >

Figure 6.1.7.1 For Review Post Approval Documents in "Sent" Post Approval List



### 6.1.8 Approved/Acknowledged/Disapproved Post Approval Document

You will receive the corresponding notification in Portal and by email once the "For Review" Post Approval Document is approved, acknowledged or disapproved by Central IRB or Secretary as Figure 6.1.8.1.

- Post Approval Document approved: Approval: "<CRER Application No.>" <Document Name> is approved.
- Post Approval Document acknowledged: Acknowledgement: "<CRER Application No.>" <Document Name> is acknowledged.
- Post Approval Document disapproved: Disapproval: "<CRER Application No.>" <Document Name> is disapproved.

= 🔹 HA Clinical Resea	arch Ethics Review Portal			site pi 5 Last Login: 2022-04-18 11:44	Applicant 👻 🙎 Logout
A Dashboard	Home			Notification	Mark All Read
Q Search	Dashboard			From: Central IRB Approval: IRB-2022-072 - Amendment Applica	2022-03-17 10:00:36 *
O Profile	Applications				Mark Read
Initial Applications	Draft <u>3/3</u>	1	Returned	From: CCO Confirmation: Your application IR8-2022-072 confirmed and will be arranged for review.	2022-03-17 10:00:20 - Amendment Application is
Draft		Expire in ≥ 30 days	(0)		Mark Read
Sent		Expire in < 30 days	<u>(0)</u>	From: CRER System Reminder: Please re-submit IRB-2022-002 - Ir	2022-03-15 00:00:00
Returned				expired in 30 days.	Mark Read
Completed	Post Approval Documents			From: CRER System	2022-03-14 00:00:00
Acknowledged Expired	Draft <u>6 / 6</u>		Returned	Reminder: Please re-submit IRB-2022-002 - In expired in 30 days.	itial Submission. It will be Mark Read
Archived		Expire in ≥ 30 days	<u>(0)</u>	From: CRER System	2022-03-14 00:00:00 🔻
All Post Approval Documents		Expire in < 30 days	(0)		
Draft					
Sent					
Returned					
Approved					
Completed					
•					

Figure 6.1.8.1 Notification of Approved Post Approval Document

Status of the Post Approval Document will change to "Approved", "Acknowledged" or "Disapproved" based on the decision consolidated by Central IRB/Secretary.

To view an Approved/Acknowledged/Disapproved Post Approval Document:

1. Click the notification for Approved/Acknowledged/Disapproved Post Approval Document directly as Figure 6.1.8.1; or

2. Go to "Approved" Post Approval List to view the Post Approval Document in "Approved" status as Figure 6.1.8.2; or

3. Go to "Acknowledged" Post Approval List to view the Post Approval Document in "Acknowledged" status; or

4. Go to "Archived" Post Approval List to view Post Approval Document in "Disapproved" status;

5. Click the **Document Type** of the Post Approval Document to view the details.



= 🌵 HA Clinical Rese	earch Ethics Review Portal			site pi 5 Last Login: 2022-04-1	811:44 Applicant	- 🧖	Logout
A Dashboard	Home > Post Approval D	locument > Approved					
Q Search	Post Approval List						
Profile	Hide/Show Columns	Refresh					
Initial Applications				Filter keyword		Page Size:	10 -
Post Approval Document	Submission No. 1	Scientific Title †	Document Type †	Status	Last Modified Date	Exp	iry Date
Draft Sent	20220223-001-003	Testing 1	Amendment Form (Study Info)	Approved	2022-03-17 10:00:33		•
Returned	20220121-001-004	Testing 2	Amendment Form (NLTH)	Approved	2022-03-08 15:41:57		
Approved	20220121-001-001	Testing 1234	Amendment Form (Study Info)	Approved	2022-03-08 14:42:37		•
Completed	20220118-001-005	Scientific Title	Amendment Form (NDH)	Approved	2022-01-18 12:00:31		•

Figure 6.1.8.2 Approved Post Approval Document in "Approved" Post Approval List



# 6.2 Change of Post Approval Document

# 6.2.1 Request for Return of Post Approval Document

You are allowed to make a request to CCO/Secretary for returning a Post Approval Document. You can modify the returned Post Approval Document and then re-submit it to CCO/Secretary.

Post Approval Document with the following statuses could be requested for a return:

- Submitted
- Re-submitted

However, once the Post Approval Document is distributed to Cluster Admin or verified by Cluster Admin although its status is still show "Submitted" or "Re-submitted", you may not be able to "Request for Return" the distributed or verified Post Approval Document. The **Request for Return** button will not be shown in this case.

To make a request for returning a Post Approval Document, you can make follow the steps:

#### 1. Press Request for Return button in Action Menu of "Sent" Post Approval List as Figure 6.2.1.1;

= 🍈 HA Clinical Resear	rch Ethics Review Po	ortal					Taiman Chan Last Login: 2022-04-17 18:42	Applicant	- 🧖	Logout
A Dashboard	Home > Post Appro	wal Document > Sent								
Q Search	Post Approval List									
e Profile	Hide/Show Columns	Refresh								
Initial Applications							Filter keyword		Page Size	10 -
New										
Draft	tission No. $\uparrow_{\downarrow}$	Scientific Title	$^{\dagger}$	Document Type	T <sub>2</sub>	Status	Last Modified Date	Expiry Date	ή, γ	Action
Sent	07-003-003	Testing		Amendment Form (SCH)		Confirmed	2022-02-14 00:08:42			
Returned	07-003-002	Testing		Amendment Form (Study Info)	1	Submitted	2022-01-21 17:49:46			+
Approved	07-001-002	Test234		Amendment Form (Study Info)	1	Submitted	2022-01-20 18:48:23		Request for	Return
Completed	4									
Acknowledged										
Expired	Showing 1 to 3 of 3 ent	ries							<	1 >

Figure 6.2.1.1 Screen of "Request for Return" button in "Sent" Post Approval List

2. A popup dialog "Are you sure to request for return?" will be prompted for you to state the request reason as Figure 6.2.1.2;

rn?	
Cancel	Confirm
	rn? Cancel

Figure 6.2.1.2 Pop-up dialog to confirm Request for Return



- 3. Press Confirm button to proceed the request;
- 4. A dialog of "Request for return has been sent." will be prompted as Figure 6.2.1.3;



Figure 6.2.1.3 Pop-up dialog after "Request for Return"

5. The status of the Post Approval Document will change to "Requested for Return" in "Sent" Post Approval List as Figure 6.2.1.4.

= 🌵 HA Clinical Resear	Tain Last L	nan Chan ja ogin: 2022-04-17 18:42 _	oplicant 🗸 📫	Logout			
A Dashboard	Home > Post Approval Doct	ument > Sent					
Q Search	Post Approval List						
Profile	Hide/Show Columns	Refresh					
Initial Applications				Fi	ter keyword	Page Size:	10 -
Post Approval Document     A	Colorization Mar. 1	Colonida Tala 1.	Descent Tax	Clature	Lost Madfied Pote	Z Evolution Desta	
Draft	Submission No. 1	Scientific Title '1	Document type '1	Status	Last Modified Date	A Expry Date	.7
Sent	20220107-003-002	Testing	Amendment Form (Study Info)	Requested for Return	2022-04-18 15:27:04	a l	
Returned	20220107-003-003	Testing	Amendment Form (SCH)	Confirmed	2022-02-14 00:08:42		
Approved	20220107-001-002	Test234	Amendment Form (Study Info)	Submitted	2022-01-20 18:48:23		
Completed	4						•
Acknowledged							
Expired	snowing 1 to 3 of 3 entries						

Figure 6.2.1.4 "Requested for Return" Status of the Application Amendment

CCO/Secretary can make two decisions on the "Request for Return"

- Confirm Request for Return
- Reject Request for Return

If the decision is "Confirm Request for Return", the Post Approval Document will be in "Returned" status and will be shown in "Returned" Post Approval List. Refer to <u>Returned Application Amendment</u>

If the decision is "Reject Request for Return", the Post Approval Document will be back to "Submitted" or "Re-submitted" status in "Sent" Post Approval List.



# 7. Completion of Initial Application

After the Final Report under an Initial Application being Approved/Acknowledge, status of the Initial Application will change from "Approved" to "Completed", you can find "Completed" Initial Application in "Completed" folder as Figure 7.1.

$\equiv$ $\mathbf{\Phi}$ HA Clinical Research Ethics Review Portal						Taiman Cha Last Login: 202	Taiman Chan Last Login: 2022-09-23 10:44		Logout	
A Dashboard	<u>Home</u> >	Initial A	pplications	> Completed						
Q Search	Application List									
e Profile	Hide/Sh	ow Colum	ns	ollapse All Expand	All Download Ap	plication Refresh				
Initial Applications							Filt	er keyword		Page Size
Draft			Pending	CRER Application T <sub>↓</sub>	IRB/REC Reference $_{\rm ref}$ No.	Submission No. $\hat{\ }\uparrow _{\downarrow }$	Scientific Title	↑ <sub>↓</sub>	Coordinating 1 Investigator (CI)	Status
Sent	+		-	NTEC-2022-062	NTEC-003	20220516-012-000	Test		Lucky Lee	Completed
Returned	+		-	IRB-2022-189	IRB-0609	20220609-002-000	UAT Briefing		Taiman Chan	Completed
Completed	•									•
Acknowledged	Showing	1 to 2 of 2	entries							< 1 →
Expired										
Archived										
All										
🚯 Post Approval Document 🗸 🗸										
Useful Information/User Manual										
FN Version: v1.011 BN Version: v0.530										
L										

Figure 7.1 Completed Initial Application in "Completed" Folder

