Hospital Authority CRER Portal

User Manual for Applicant

Date: 28 Sep, 2022

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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.

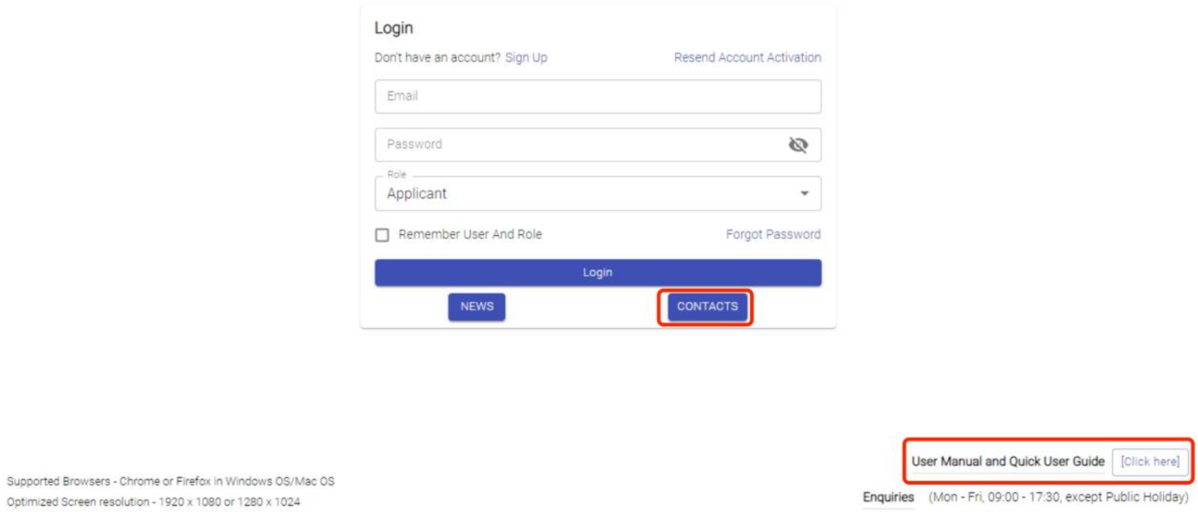
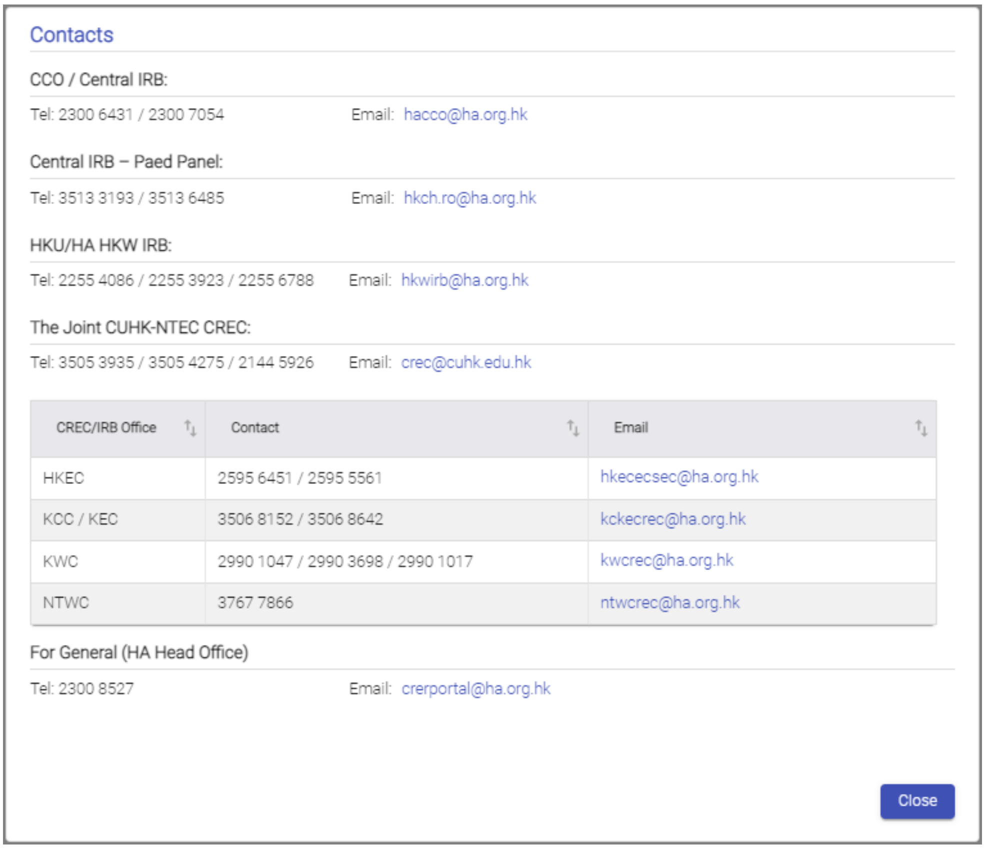


Figure 1.1 Action button for Contact Info and User Manual and Quick User Guide



Contacts

CCO / Central IRB:

Tel: 2300 6431 / 2300 7054 Email: hacco@ha.org.hk

Central IRB – Paed Panel:

Tel: 3513 3193 / 3513 6485 Email: hkch.ro@ha.org.hk

HKU/HA HKW IRB:

Tel: 2255 4086 / 2255 3923 / 2255 6788 Email: hkwirb@ha.org.hk

The Joint CUHK-NTEC CREC:

Tel: 3505 3935 / 3505 4275 / 2144 5926 Email: crec@cuhk.edu.hk

CREC/IRB Office	Contact	Email
HKEC	2595 6451 / 2595 5561	hkececsec@ha.org.hk
KCC / KEC	3506 8152 / 3506 8642	kckecrec@ha.org.hk
KWC	2990 1047 / 2990 3698 / 2990 1017	kwcrec@ha.org.hk
NTWC	3767 7866	ntwcrec@ha.org.hk

For General (HA Head Office)

Tel: 2300 8527 Email: crerportal@ha.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.

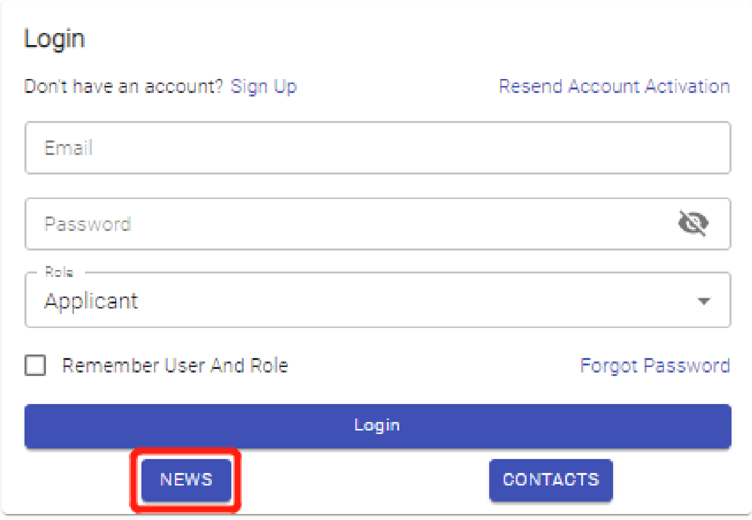


Figure 1.3 Action button for News

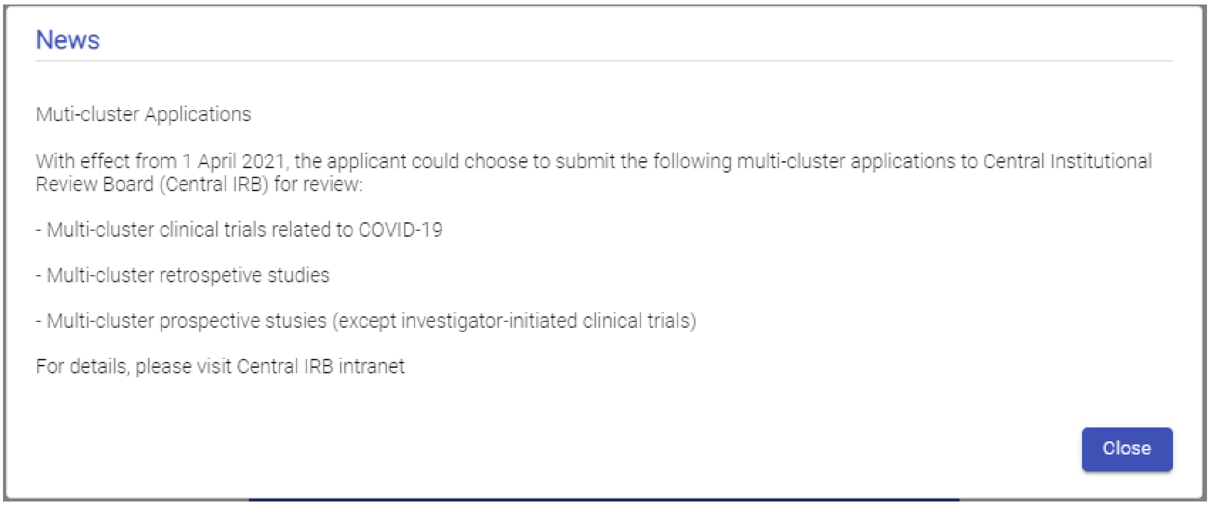


Figure 1.4 Pop up dialog for News

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 (https://hacrerportal.ha.org.hk) 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.

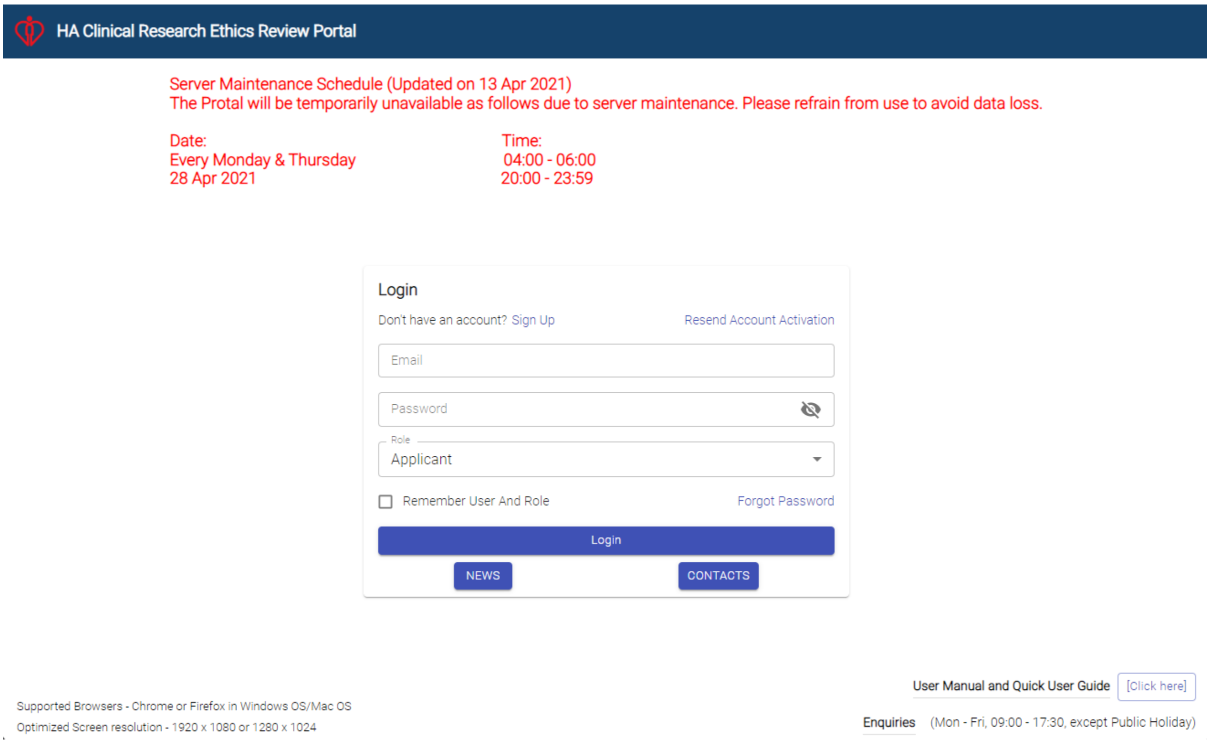


Figure 2.1 Login Page of the Portal

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;

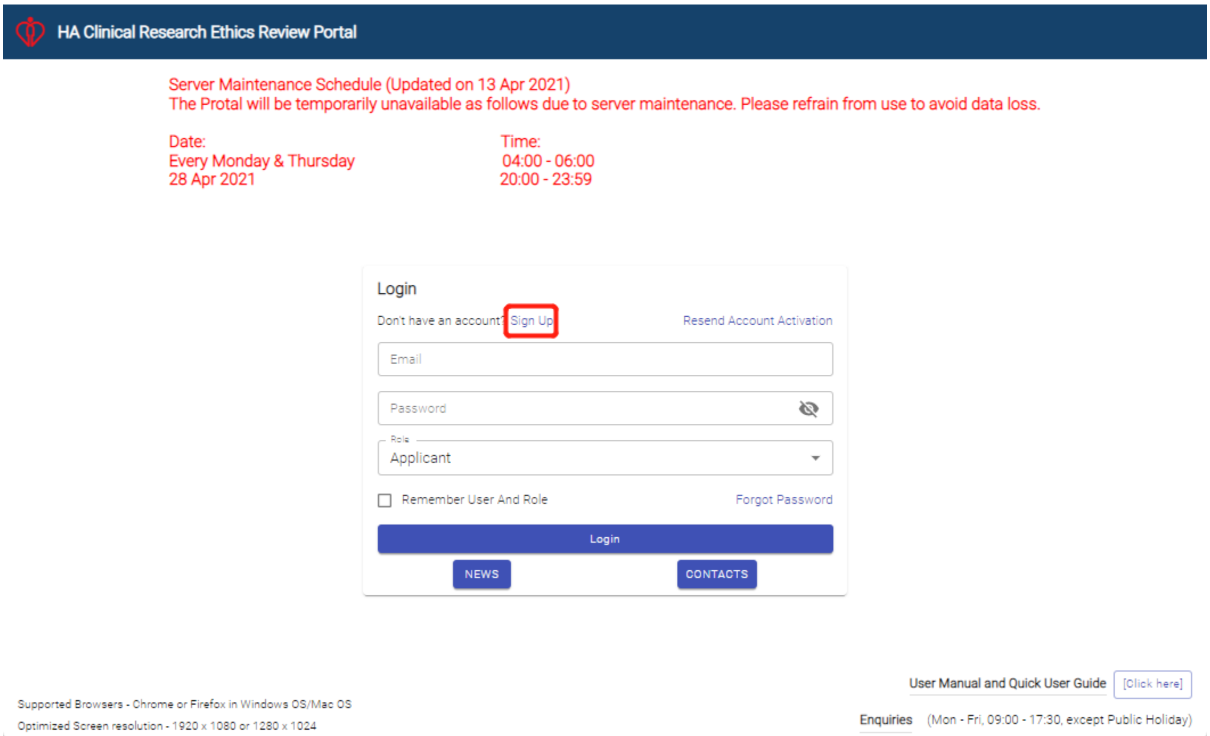


Figure 3.1.1.1 Login Page

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

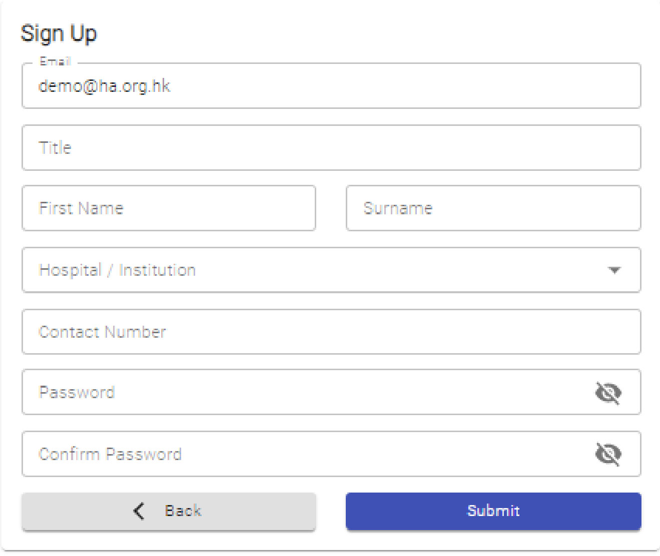


Figure 3.1.1.2 Sign-Up Form for an authorized email account

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 hacco@ha.org.hk. More contact information is available at https://hacrerportal.ha.org.hk.
>
> 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 do not have an authorized email account (refer to Section 3.1.1 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;

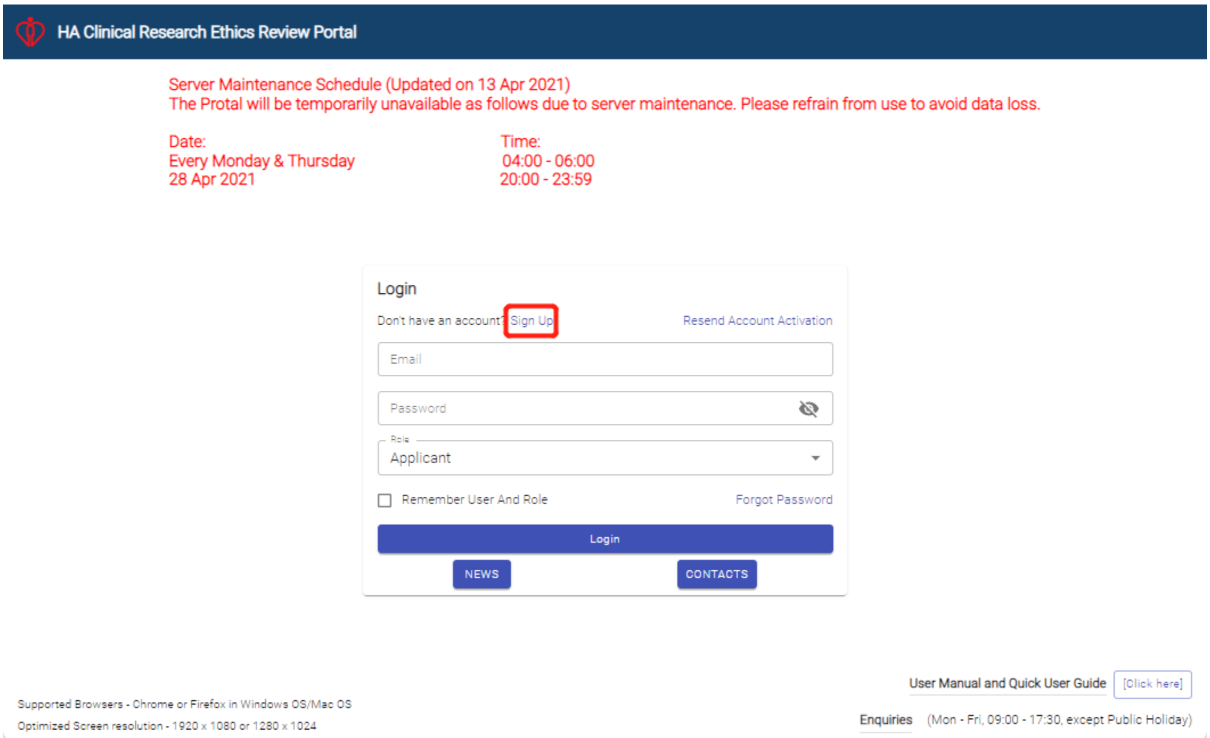


Figure 3.1.2.1 Login Page

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 Section 3.1.1;
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;

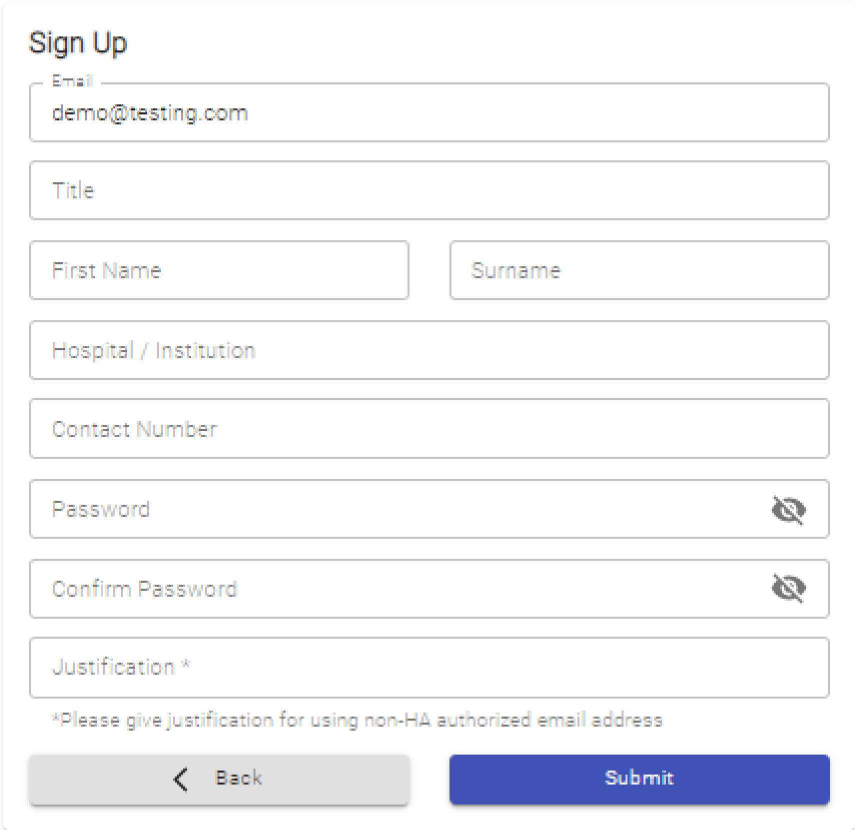


Figure 3.1.2.2 Sign-Up Form for unauthorized email account

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 Portal (HA CRER Portal).

Please click here to activate your account.

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

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

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.

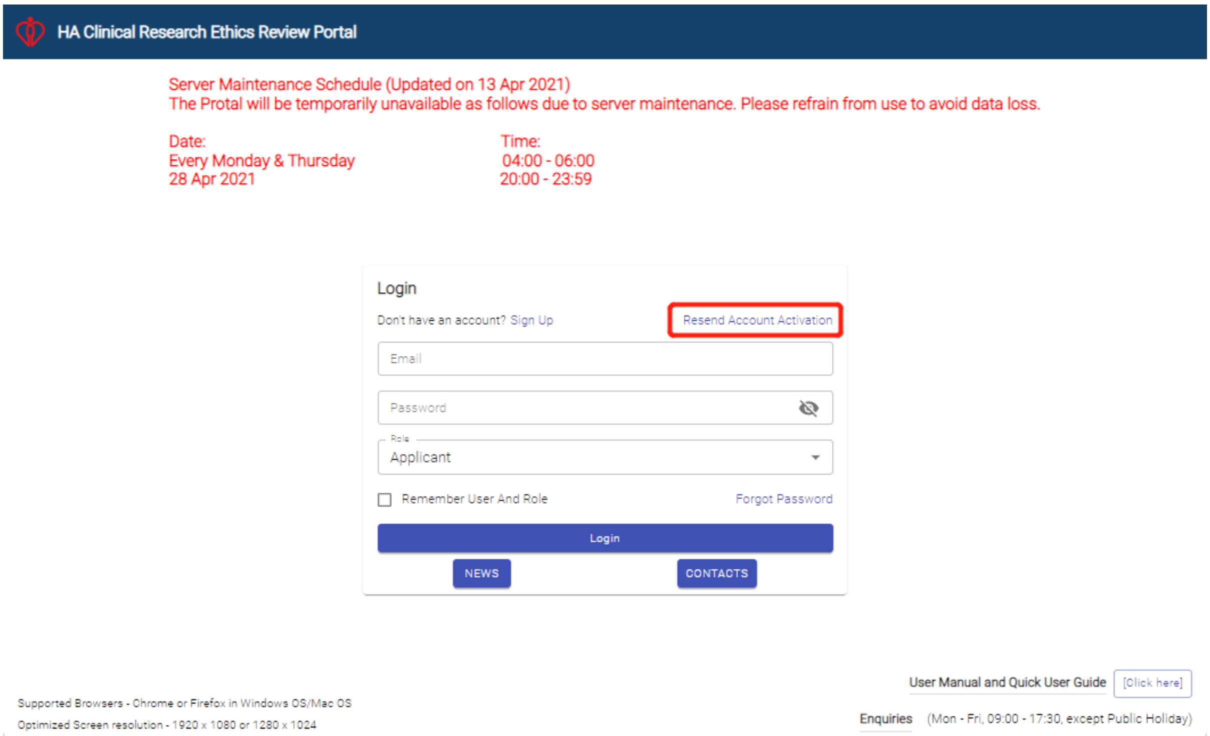


Figure 3.2.1 Action button for Account Reactivation

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

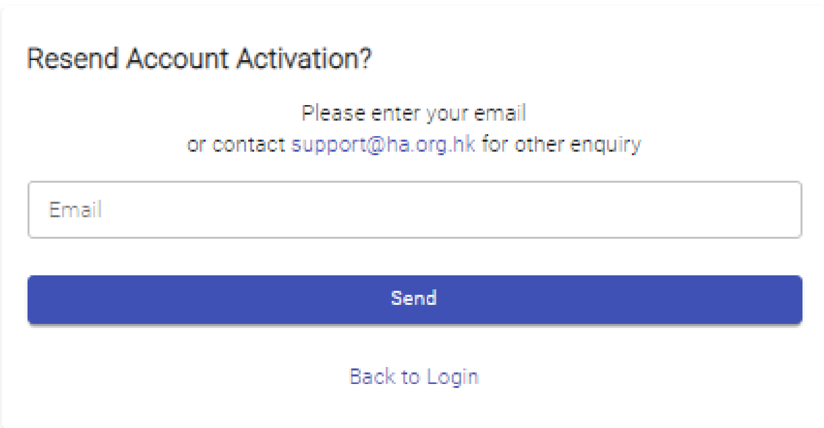


Figure 3.2.2 Popup dialog for Account Reactivation

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 here to reactivate your account.

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

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.

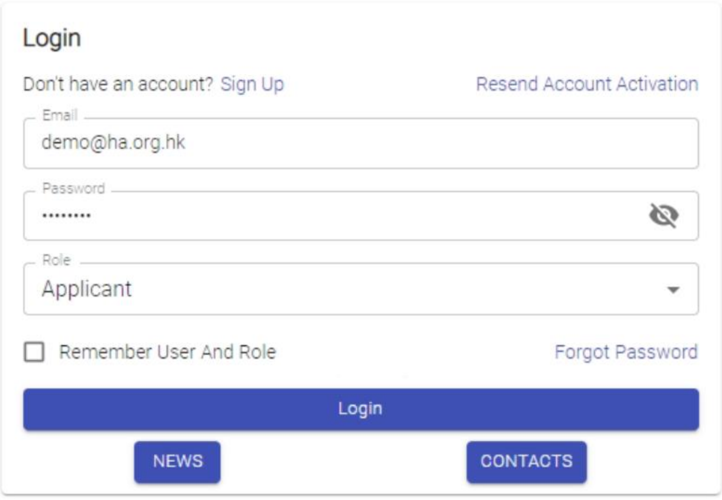


Figure 3.3.1 Login Page

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

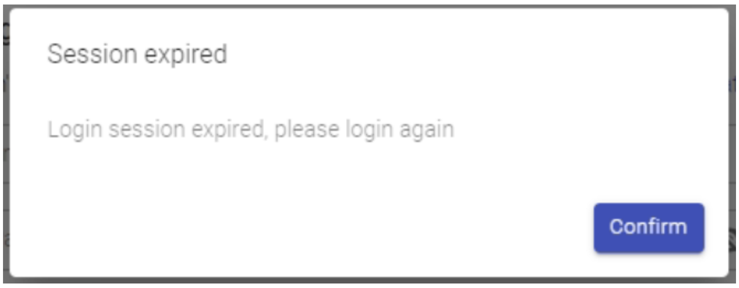


Figure 3.3.2 Popup message for session expired

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

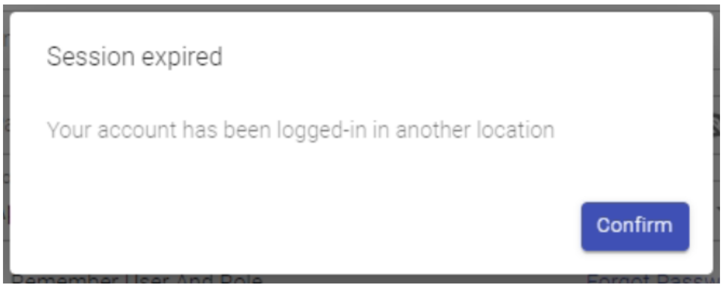


Figure 3.3.3 Popup message for multiple users' login

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 Forgot Password.

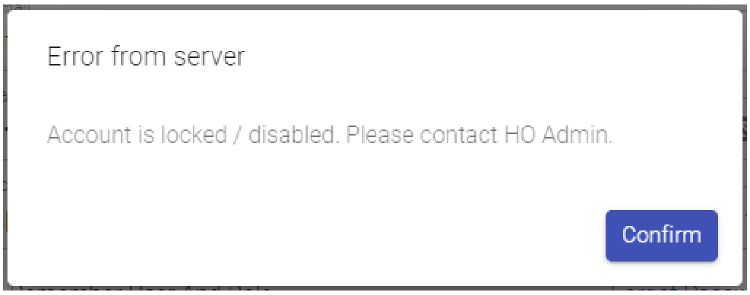


Figure 3.3.4 Popup message after 5 failed logins

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;

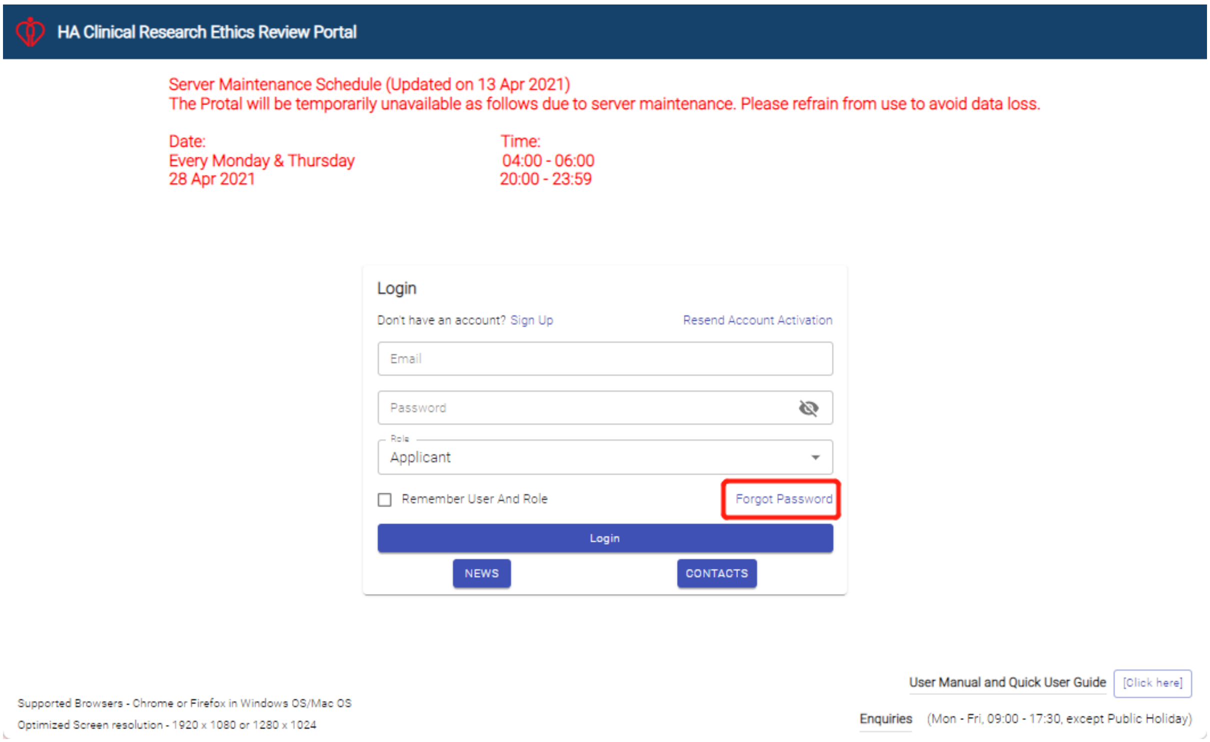


Figure 3.4.1 Action button for Password Reset

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

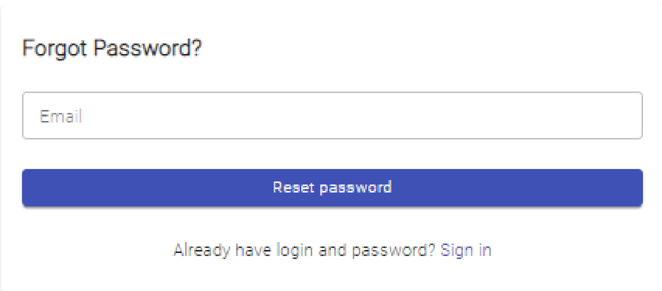


Figure 3.4.2 Popup dialog for Password Reset

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 here to reset your password.

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

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 Page

4.1 Landing Page Layout of Applicant

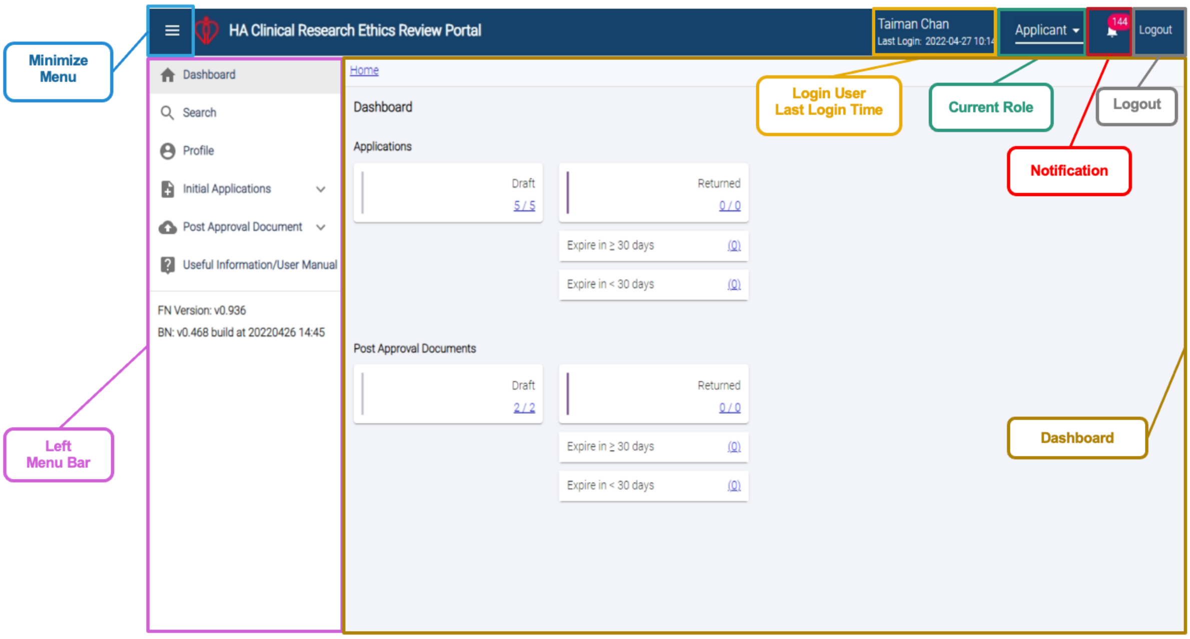


Figure 4.1.1 Landing Page of Applicant

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.

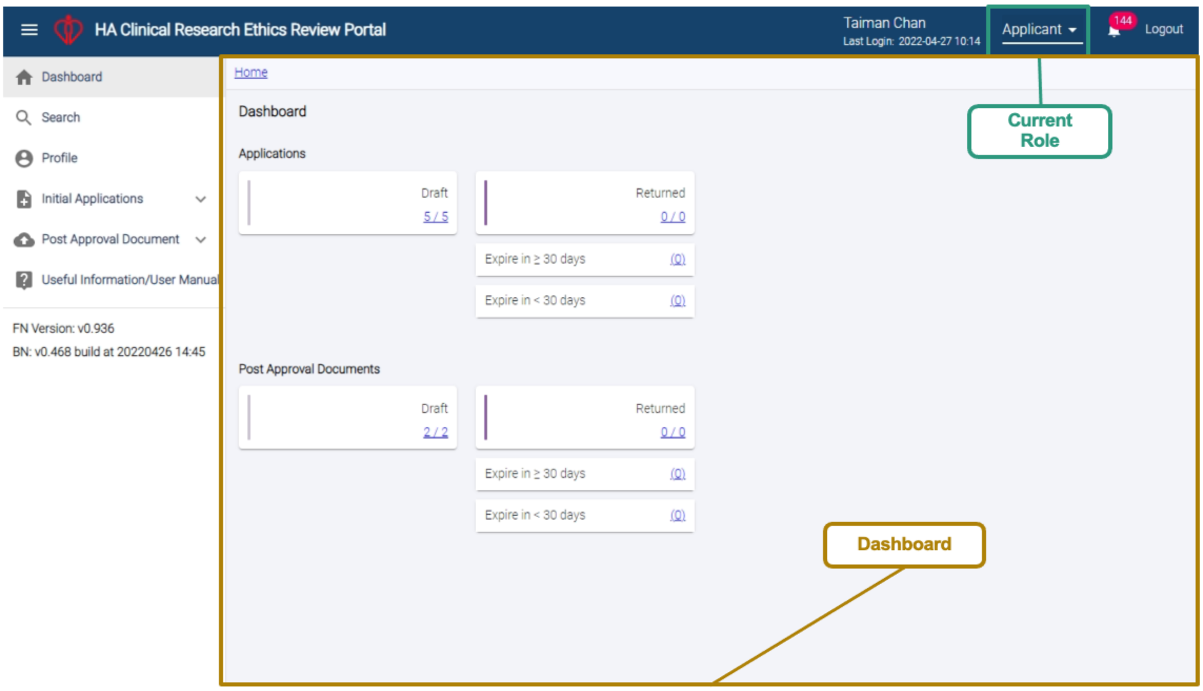


Figure 4.2.1 Dashboard Page of Applicant

Below is the summary of the status on Dashboard.

Status	**Description**
Draft (a/b)	Initial Applications/Post Approval Documents in draft status **a:** No. of draft Initial Application or Post Approval Document required further action by Applicant **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. **a:** No. of returned Initial Applications or Post Approval Documents required further action by Applicant **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.

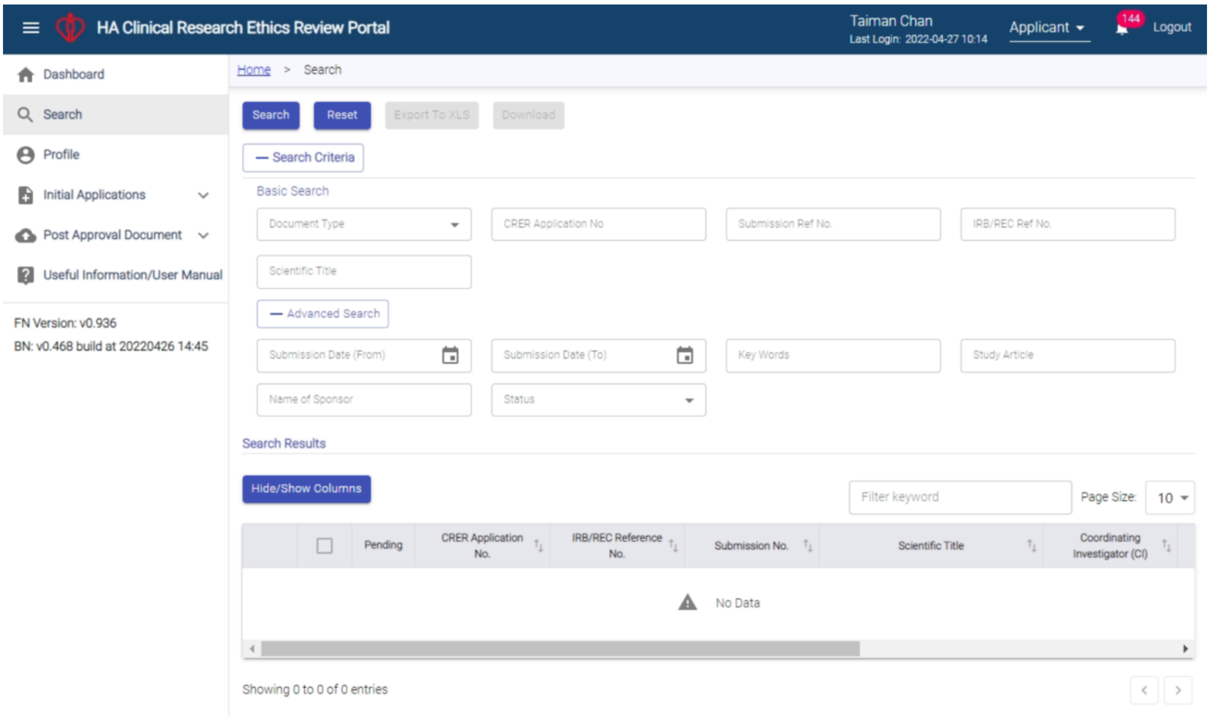


Figure 4.3.1 Application Search

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.

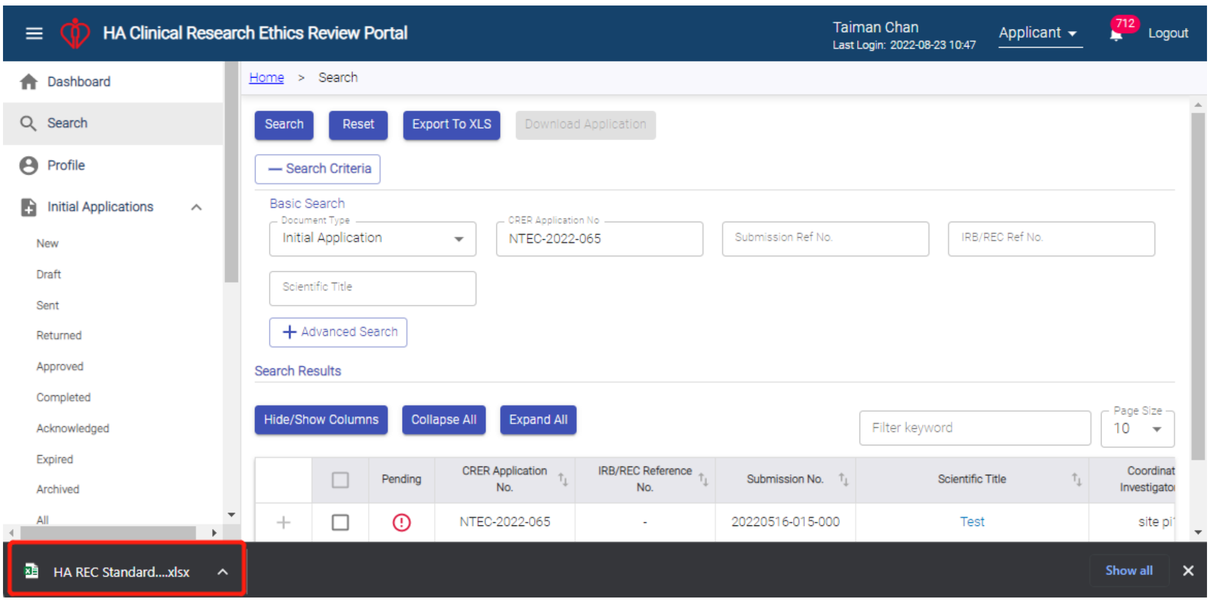


Figure 4.3.2 Result table after application search

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:

1. Select “Initial Application” in Document Type and input search criteria if any;
   (The disabled **Download** button will then change to disabled **Download Application** button.)
2. 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.

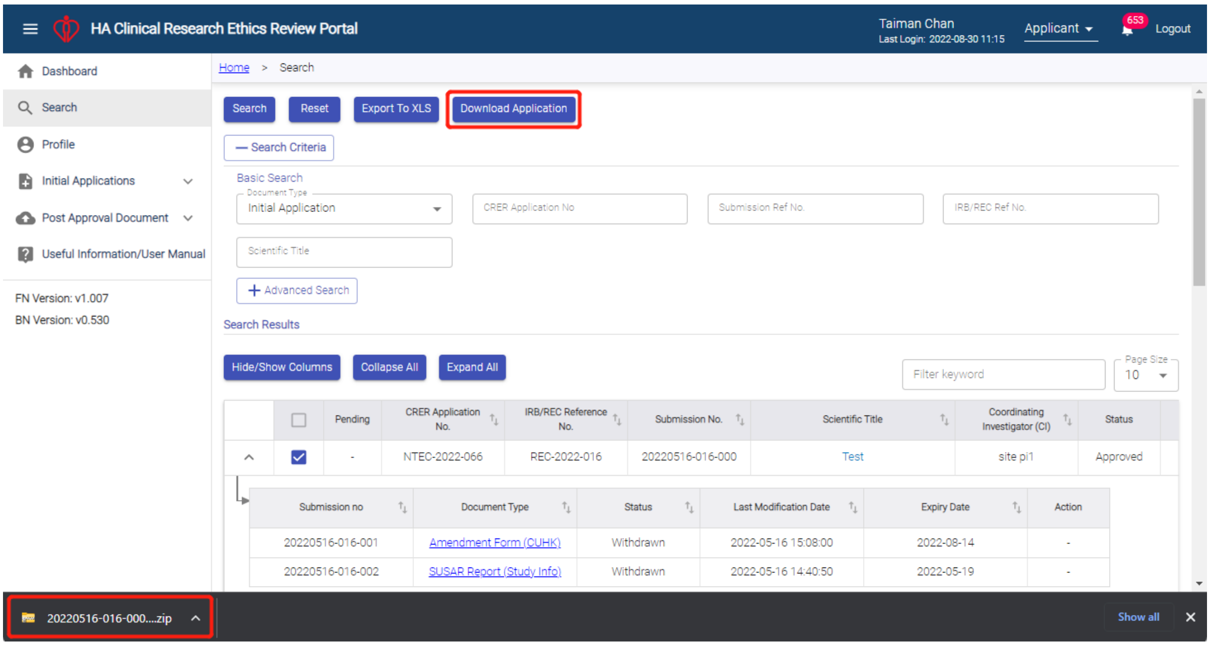


Figure 4.3.1.1 Download Initial Application

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.
    - Press “**X**” to minimize the right context menu bar.

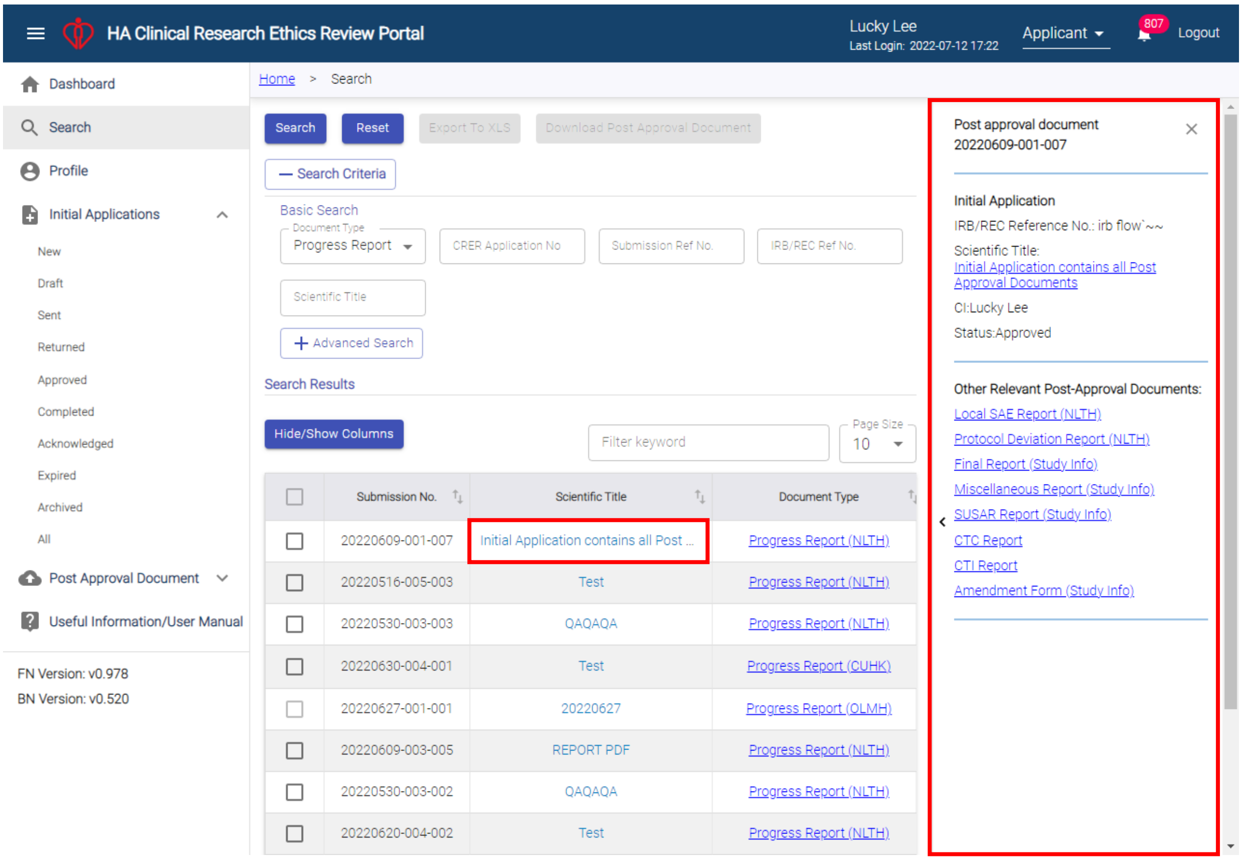


Figure 4.3.2.1 Right Context Menu of specific Post Approval Document

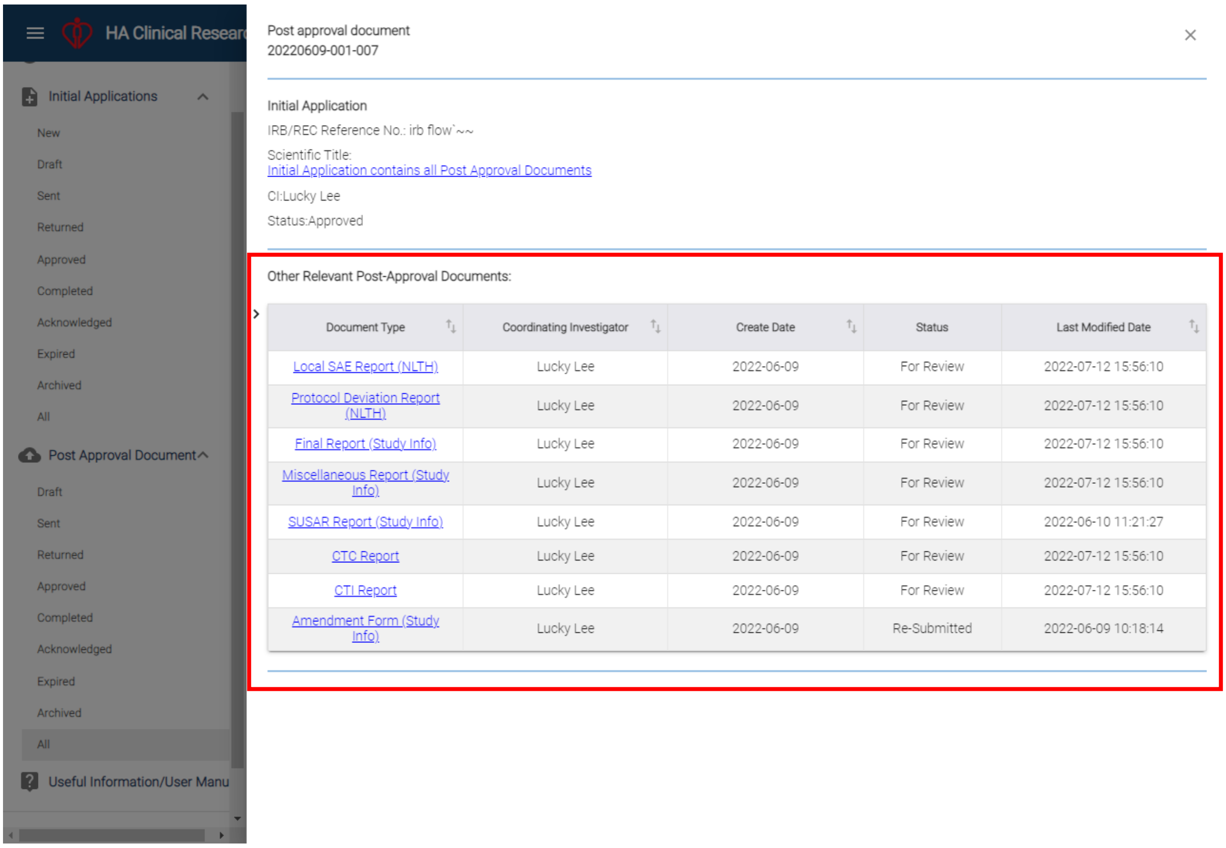


Figure 4.3.2.2 Details of Relevant Post Approval Documents

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:

1. 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.)
2. 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.

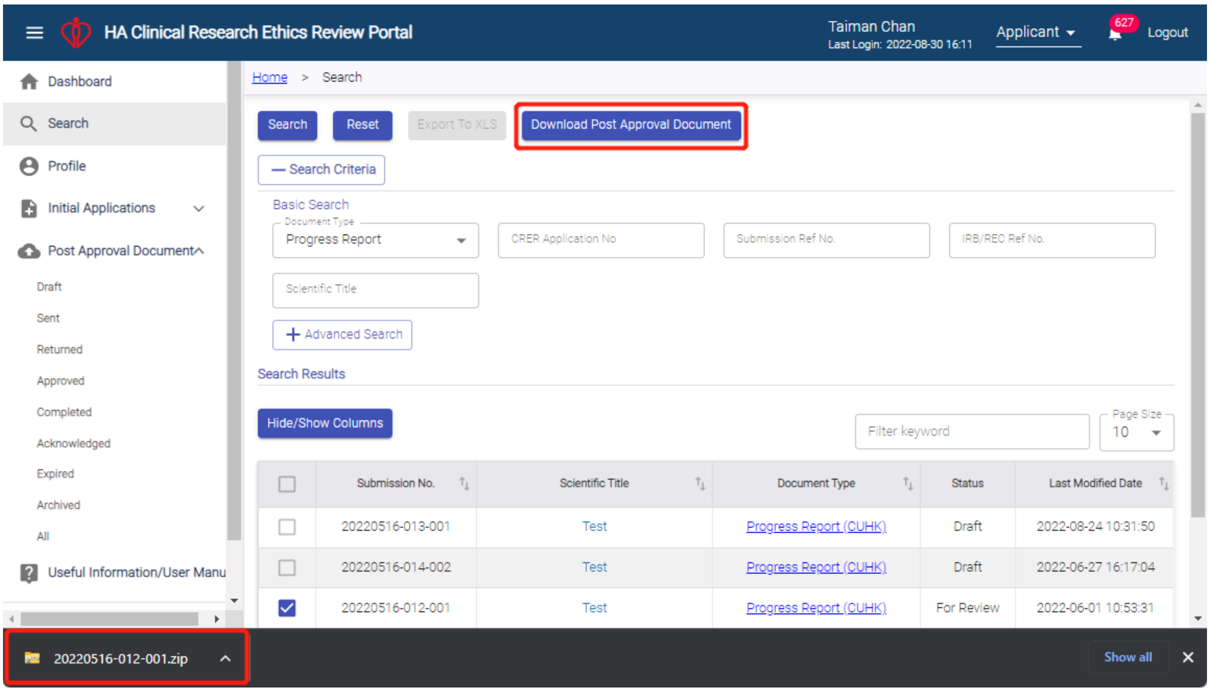


Figure 4.3.2.3 Download Post Approval Document

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.

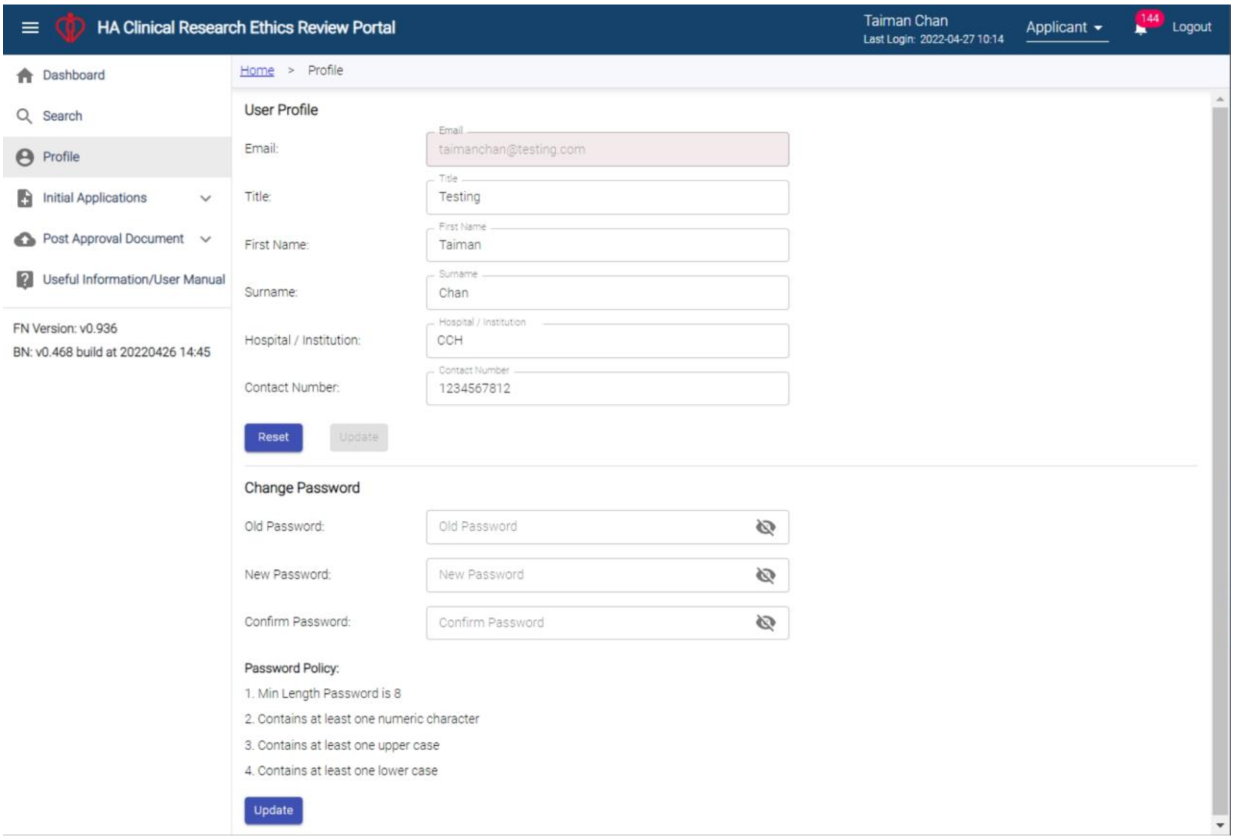


Figure 4.4.1 User Profile Page

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 Search Page. You can click **Refresh** button to get the latest Application/Post Approval List.

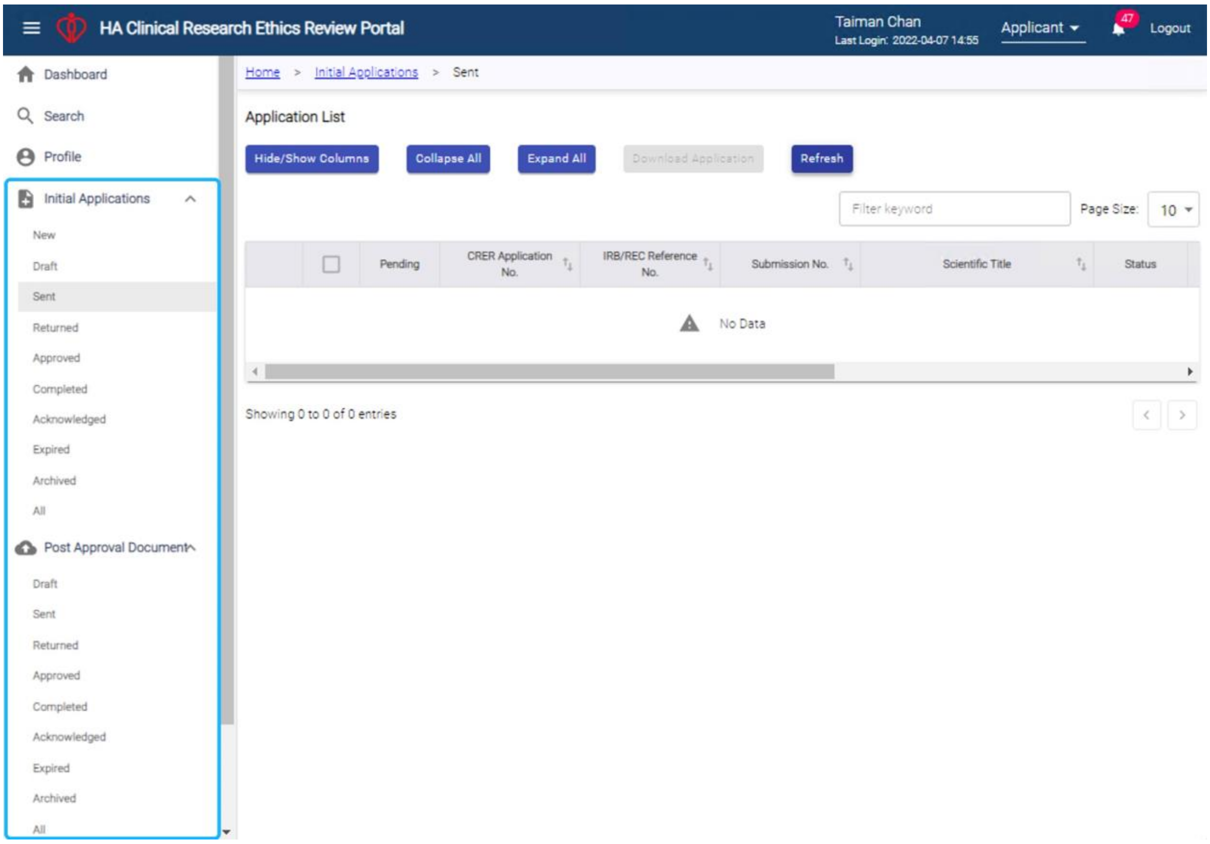


Figure 4.5.1 Status Folder of Initial Application or Post Approval Document

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

Folder	**Description**
New	To create a new Initial Application 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
Sent	Submitted Initial Application/Post Approval Documents with following statuses: - Submitted - Re-submitted - Requested for Return - 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.

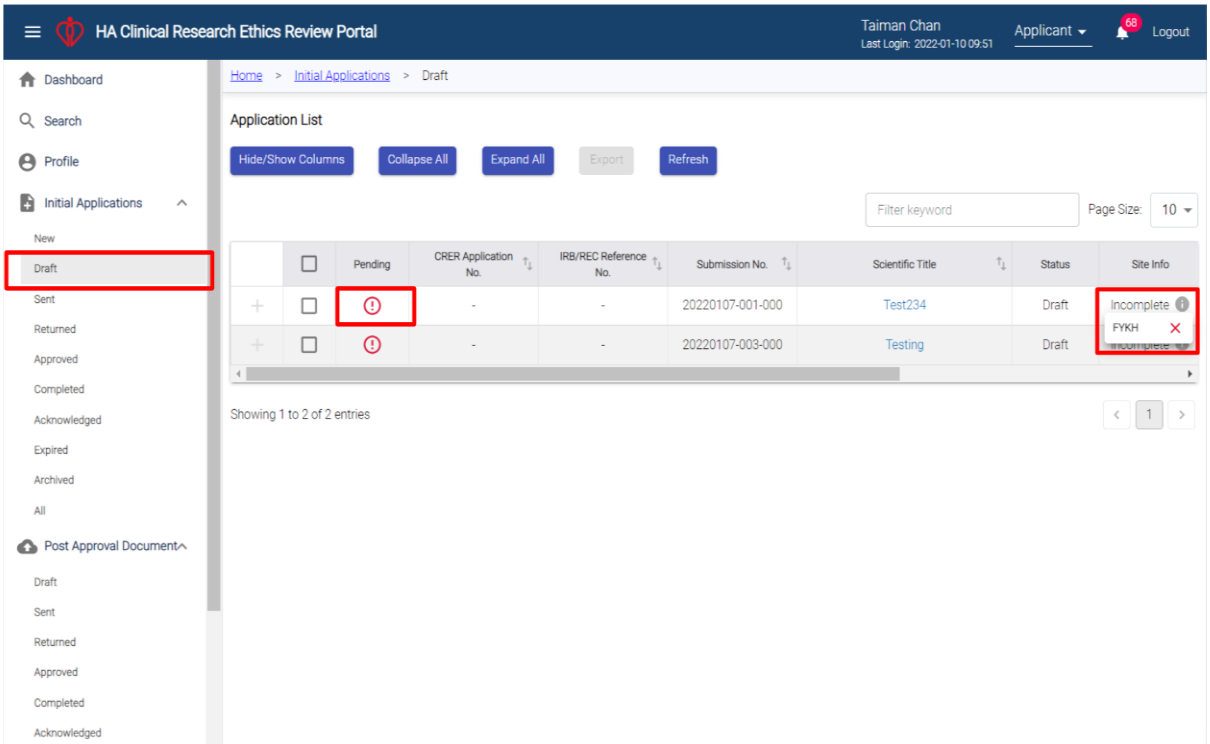


Figure 4.5.2 Application List in Draft Status

Remarks:

Warning Sign of Pending Column		Completion Status of Site Info Column	
Status	**Description**	**Status**	**Description**
!	• CI/Delegates: Initial Application not yet submitted to CCO/Secretary, need to handle by CI/Delegate(s) • Site PI/Delegates: Initial Application not yet submitted to CI, need to follow up by Site PI/Delegate(s)	**√**	Site info sent to CI
-	• CI/Delegates: Initial Application submitted to CCO/Secretary • Site PI/Delegates: Initial Application submitted to CI	**X**	Site info not yet sent to CI
		Info icon	Initial Application is submitted

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.

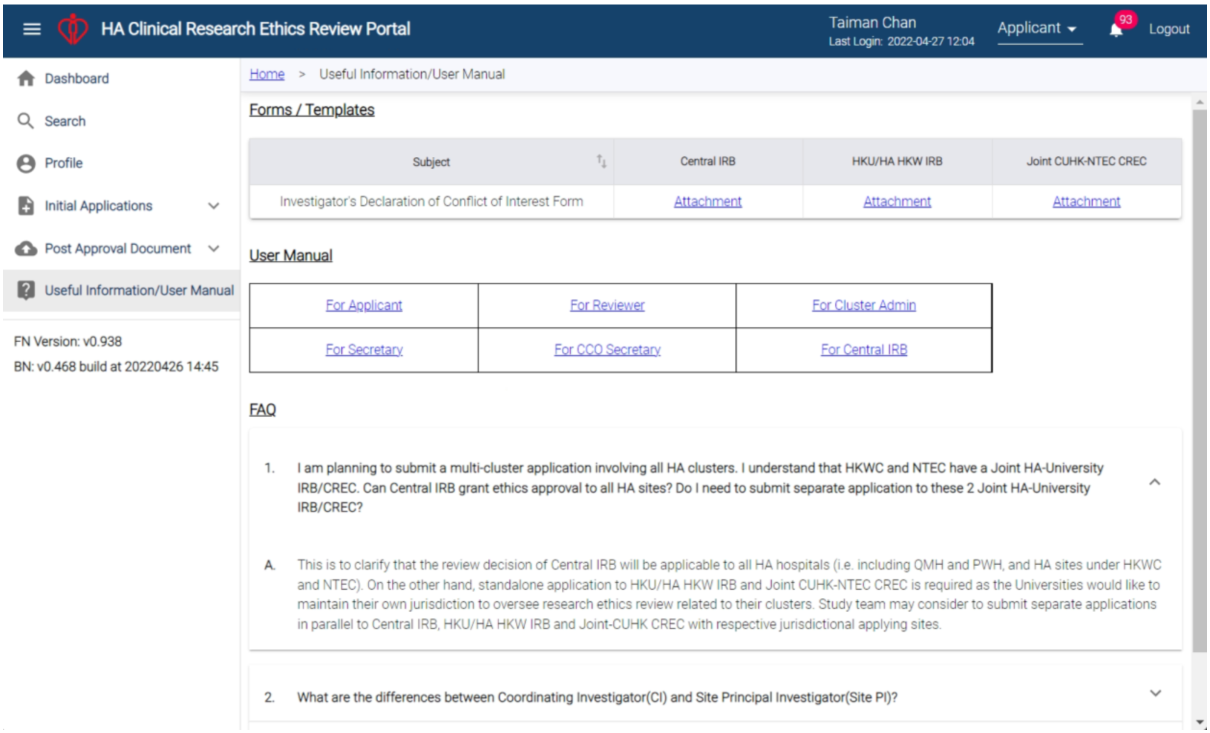


Figure 4.6.1 Screen of Useful Information/User Manual Page

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.

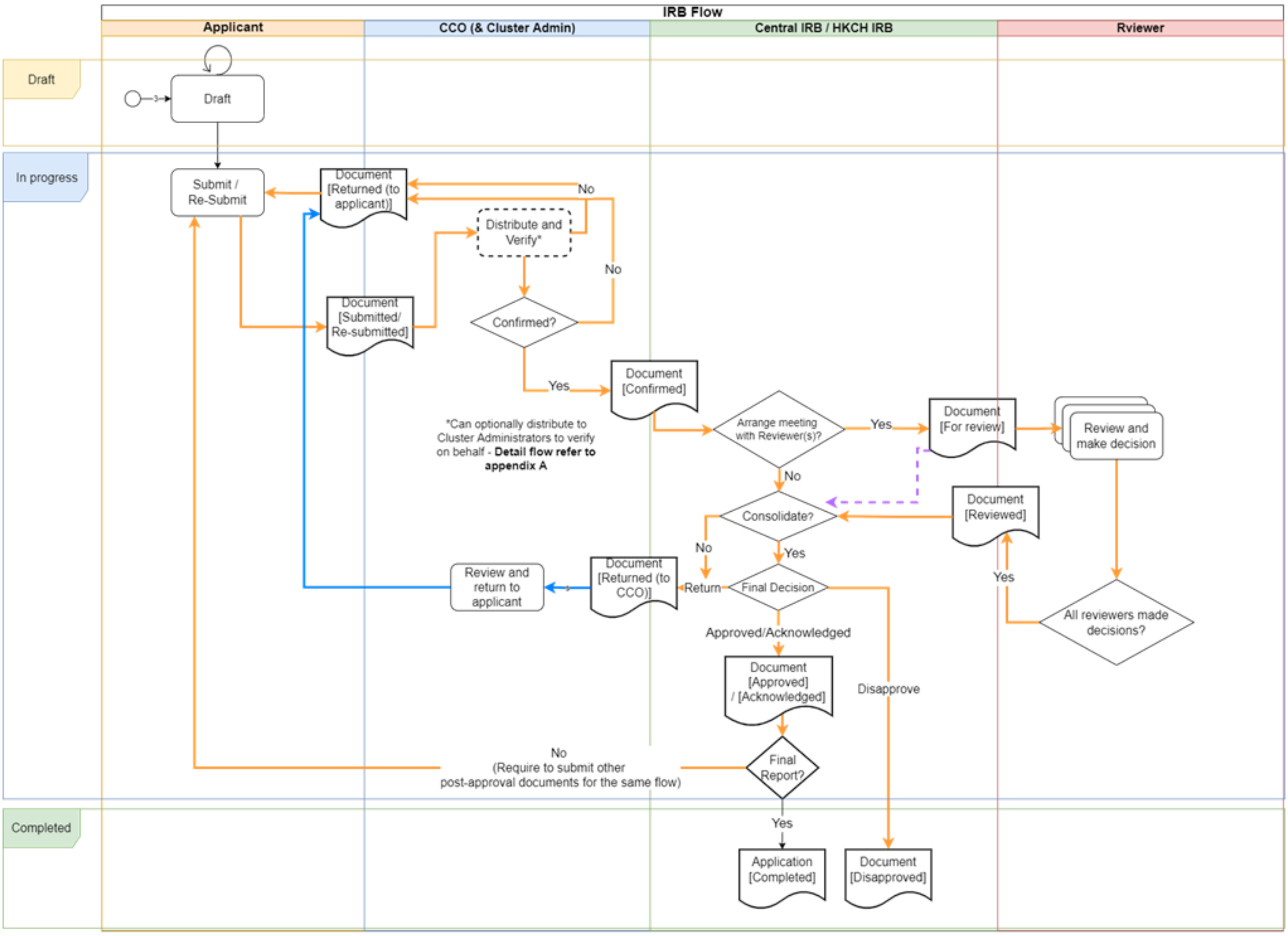


Figure 5.1 IRB flow of Initial Application submission

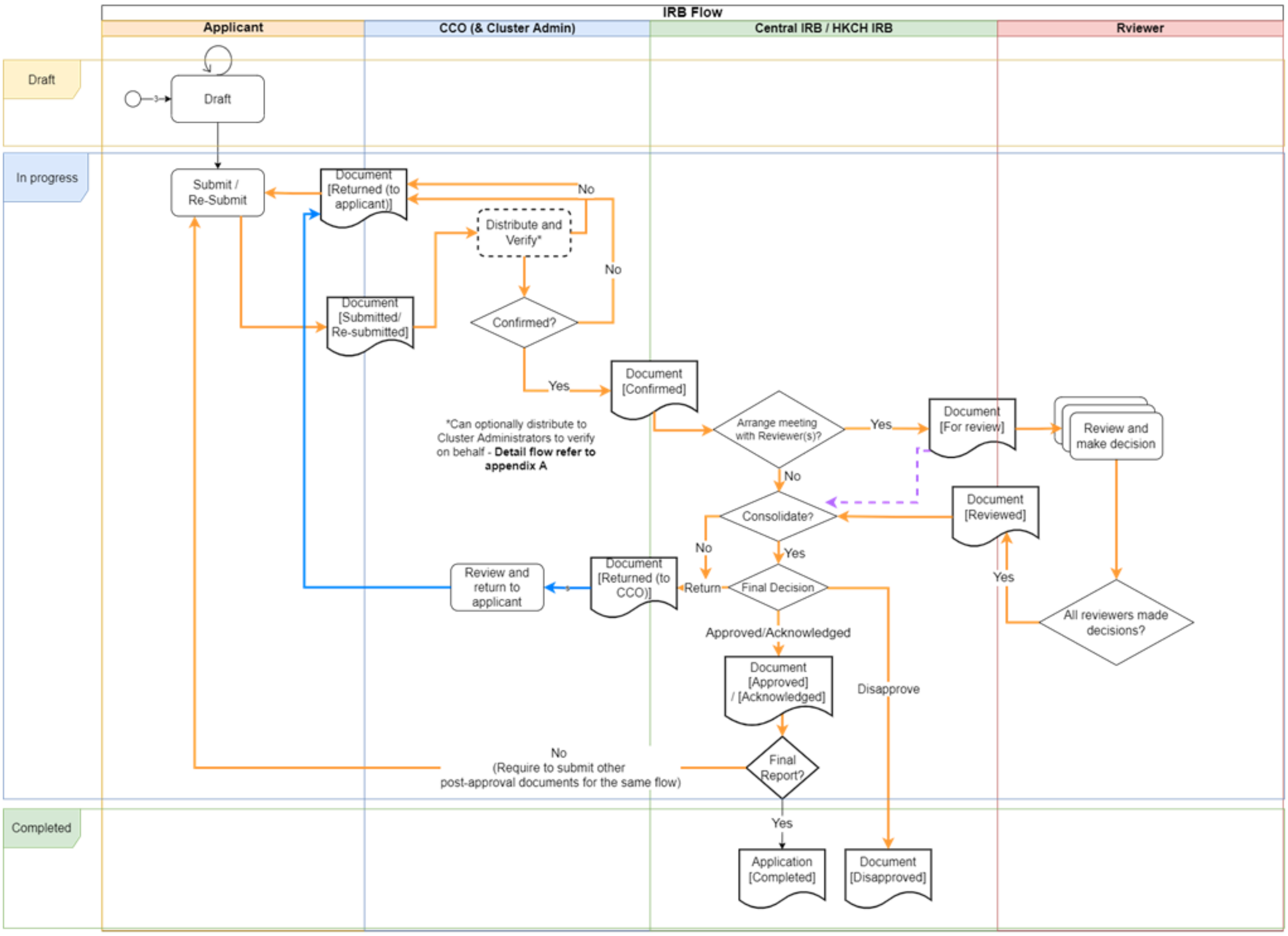


Figure 5.2 HKWC/NTEC flow of Initial Application submission

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).

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

Function	Applicant Roles	
	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 CI
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)

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.

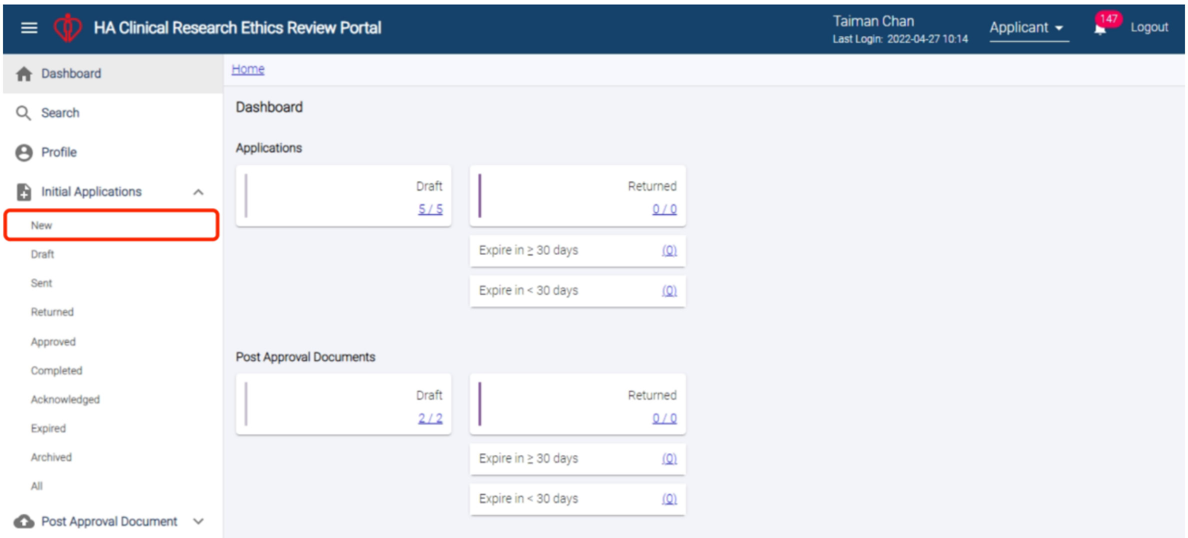


Figure 5.2.1 Initial Application Creation

5.2.1 Acknowledgement

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

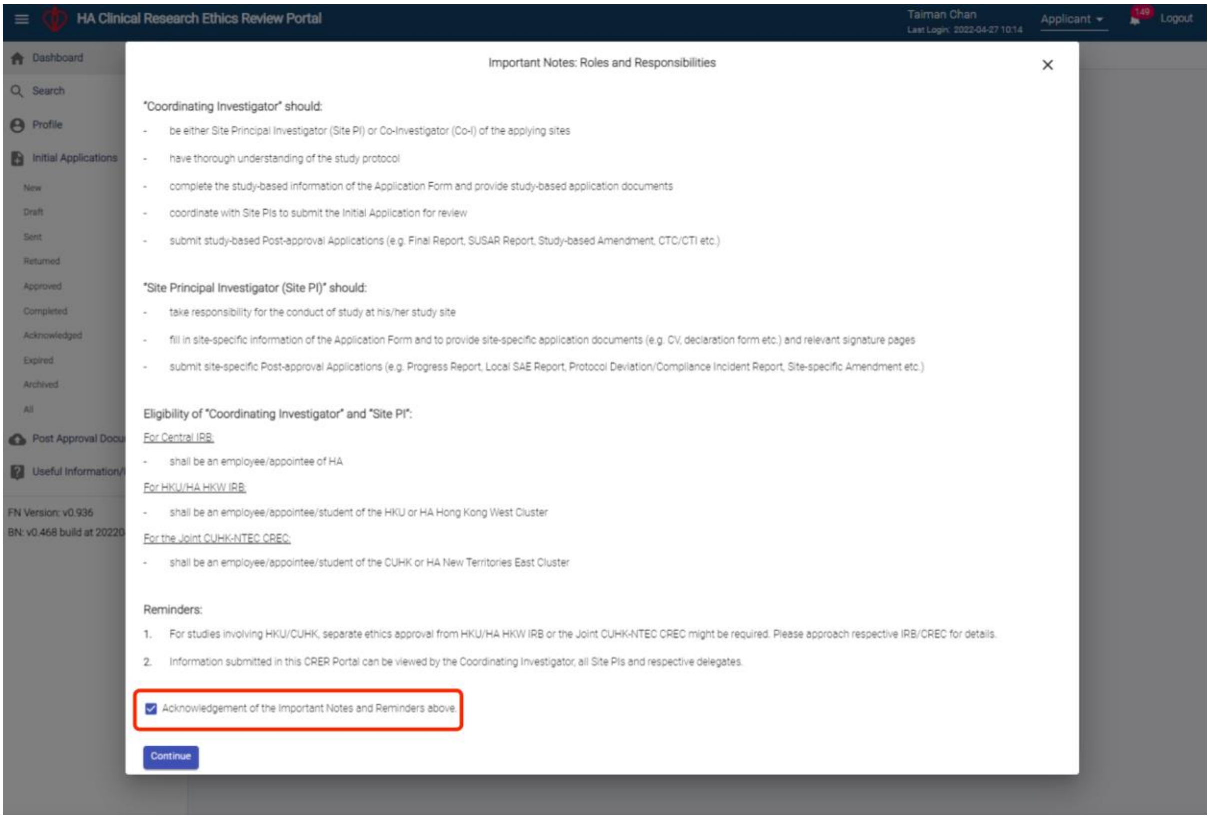


Figure 5.2.1.1 Acknowledgement on Important Notes

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(?)* as Figure 5.2.2.1:
    - Central IRB: IRB Flow
    - HKU/HKW IRB: HKU/HA HKW IRB Flow
    - Joint CUHK-NTEC CREC: NTEC Flow

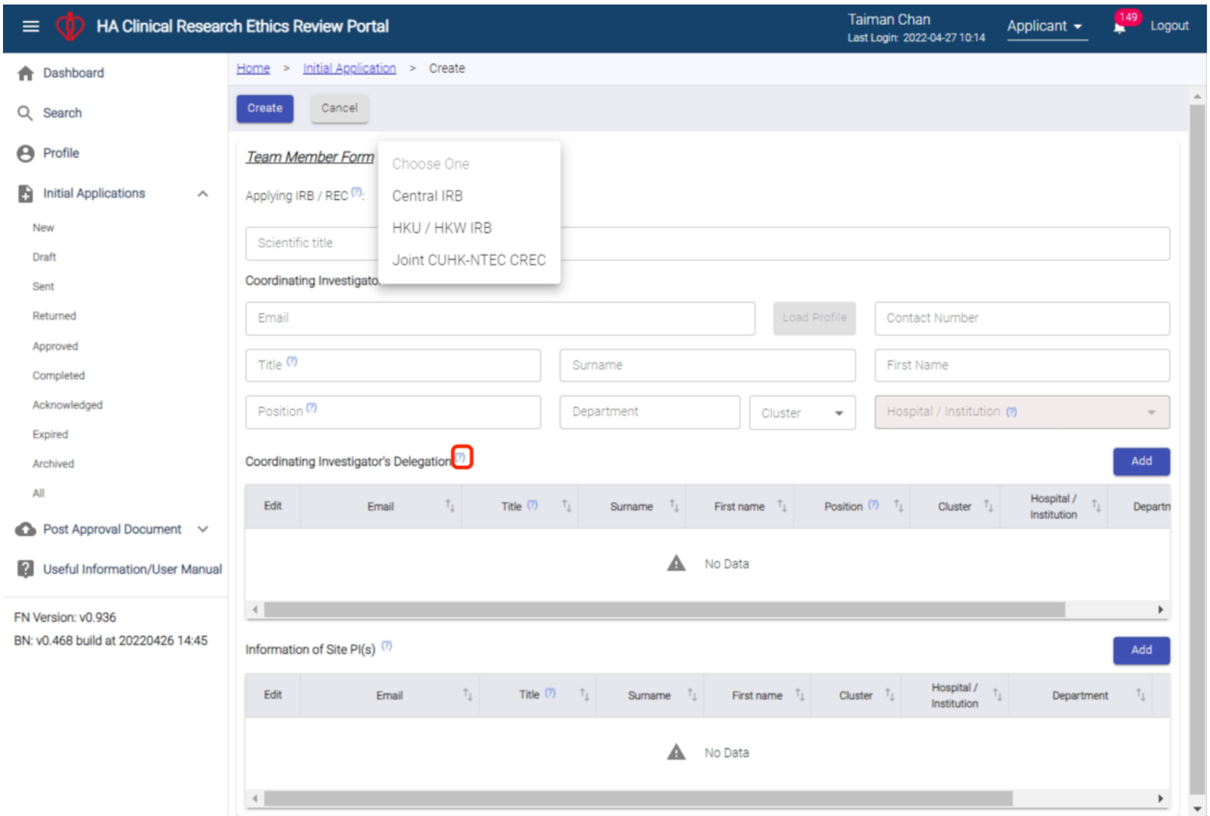


Figure 5.2.2.1 Team Member Form

2. Fill in the Scientific Title;
3. Provide information for Coordinating Investigator*;
4. Under CI's Delegation, press **Add** button to add info for CI's delegate(s) (Maximum: 3) in the pop-up form, if any;
5. 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)

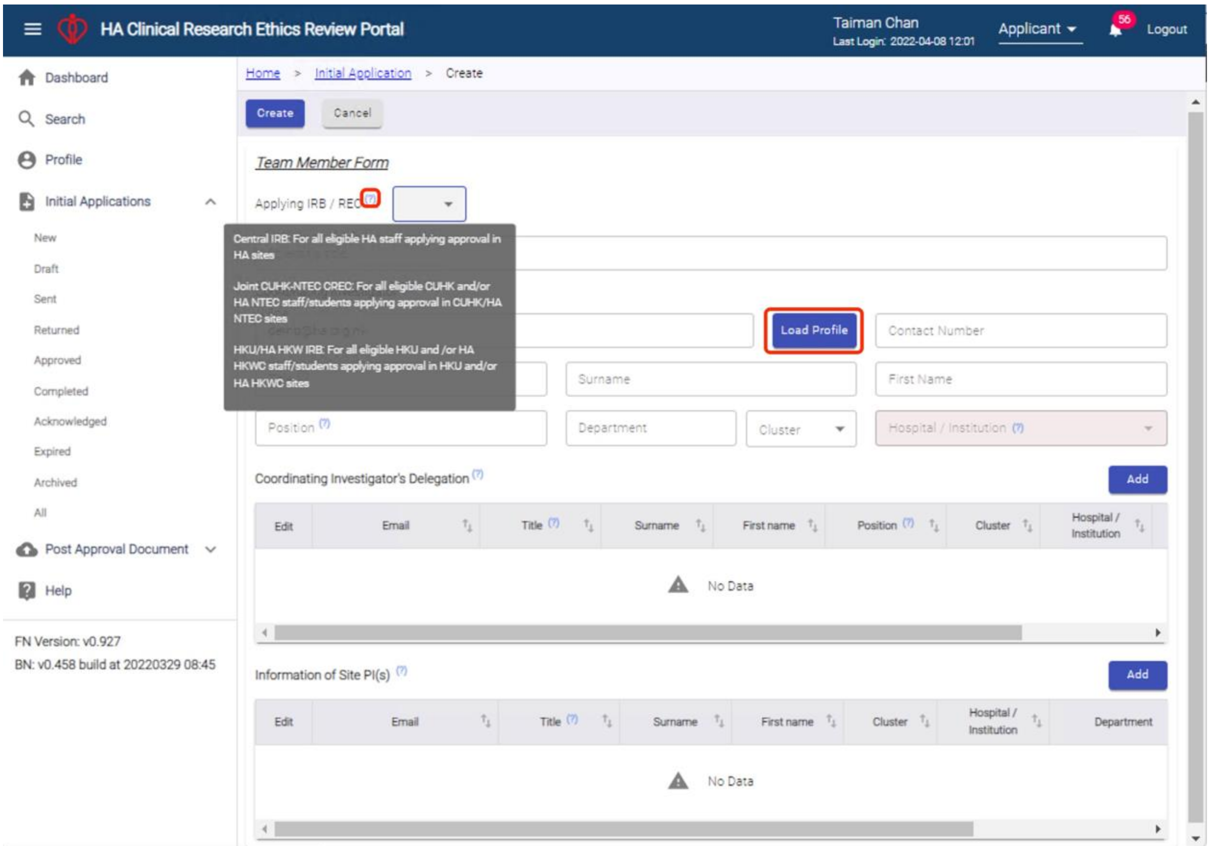


Figure 5.2.2.2 Tooltips and Load Profile button

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.

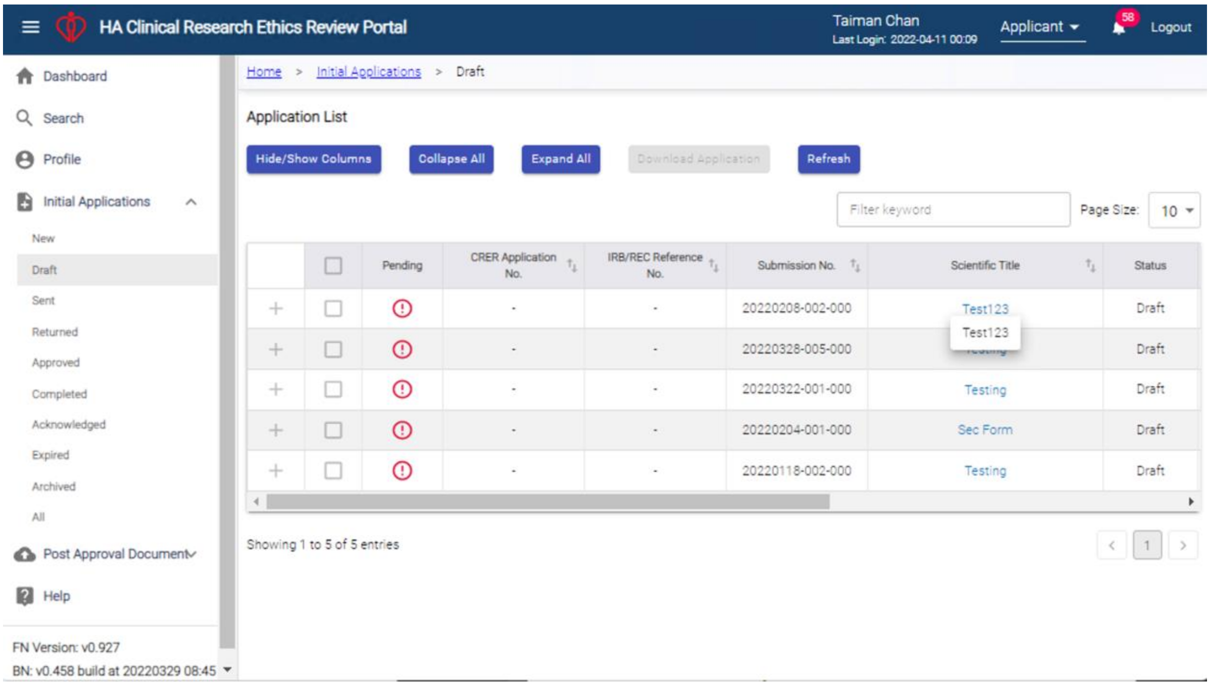


Figure 5.2.3.1 Application List in Draft Status

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

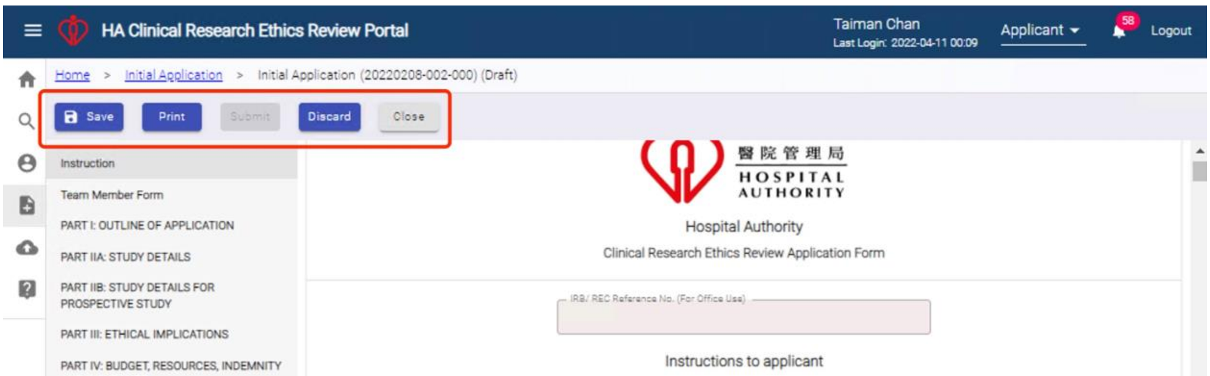


Figure 5.2.3.2 Action buttons for CI in Initial Application

Below is the description of each action button:

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	To discard/withdraw the application
	• **Discard** button is only available in the draft Initial Application
	    ○ "Application is discarded." message will pop up for confirmation
	• **Withdraw** button is available after the Initial Application is submitted
	    ○ "Application is Withdrawn." message will be pop up for confirmation
	• Initial Application can be found as "Withdrawn" status in "Archived" Application List

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.

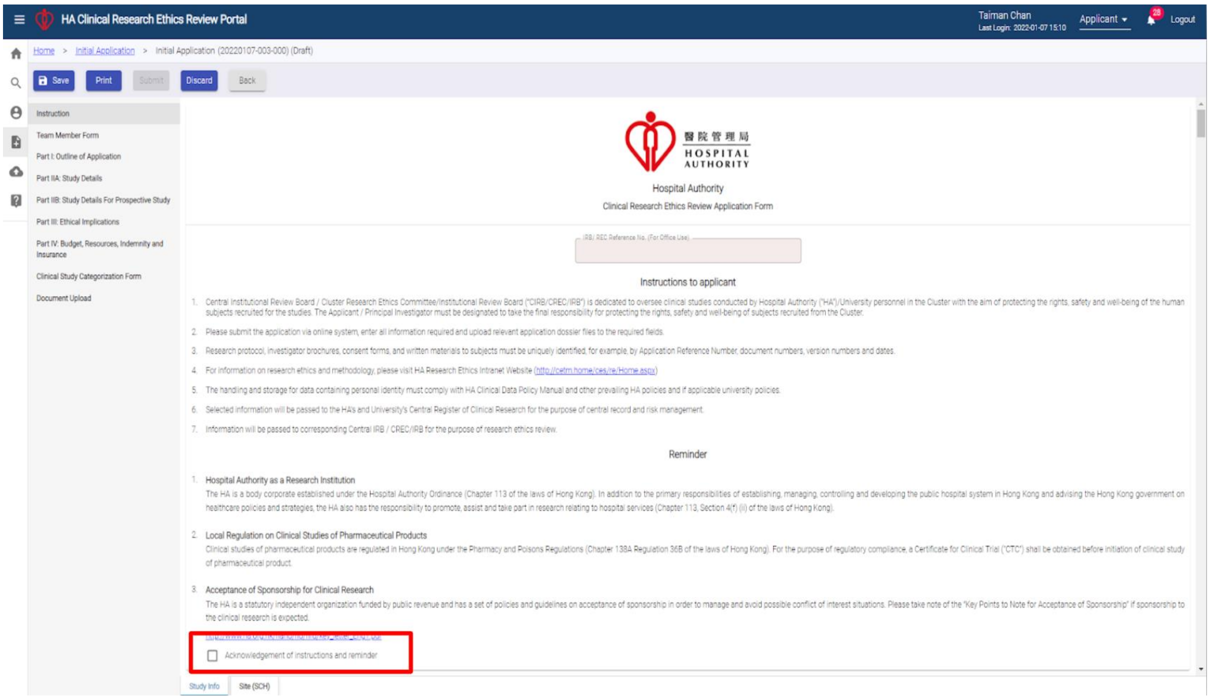


Figure 5.2.3.1.1 Instructions of Initial Application

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.

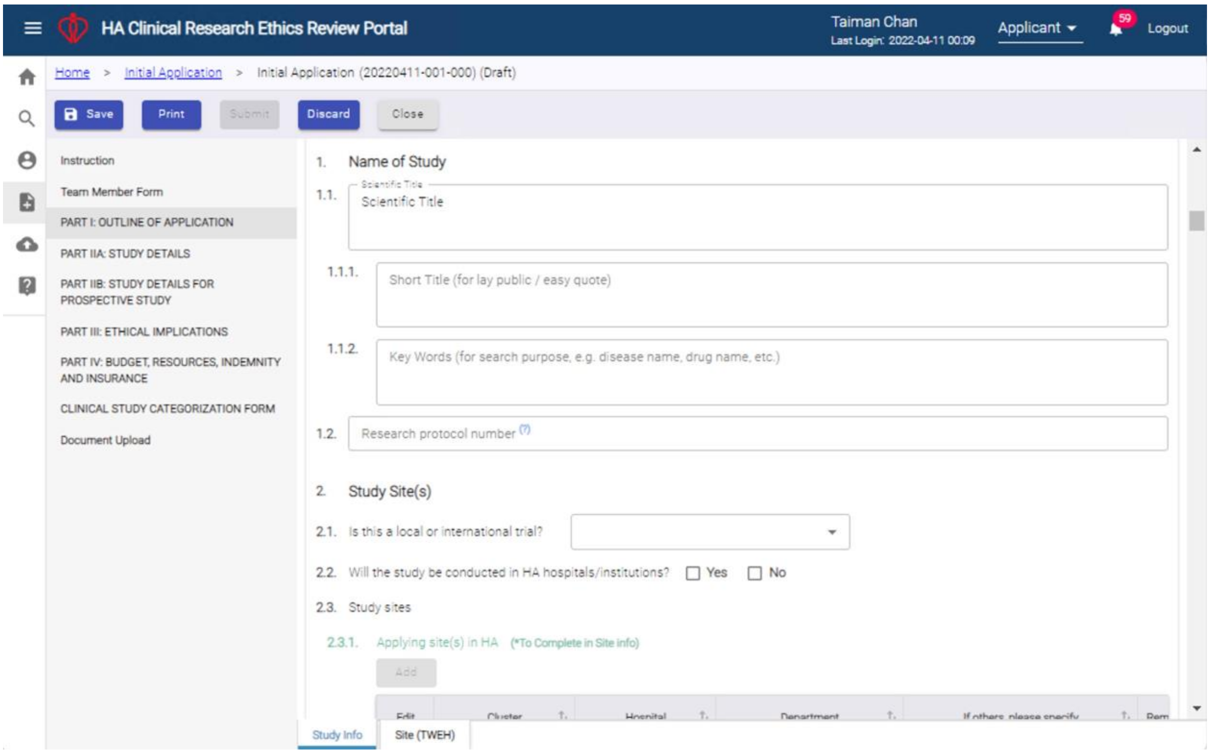


Figure 5.2.3.2.1 Part I: Outline of Application

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.

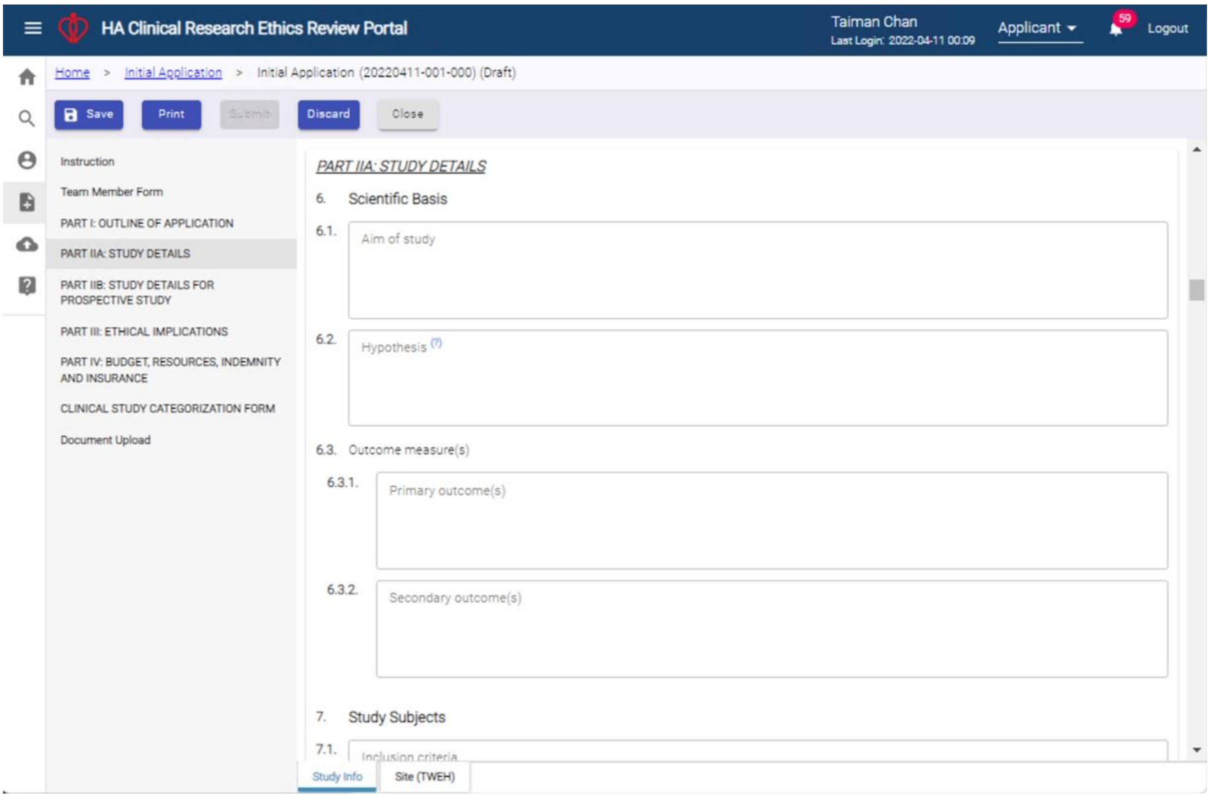


Figure 5.2.3.3.1 Part IIA: Study Details

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,
     - Press **Add** button and fill in the pop-up form for Q11.2.2 Study Article Details
     - 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.

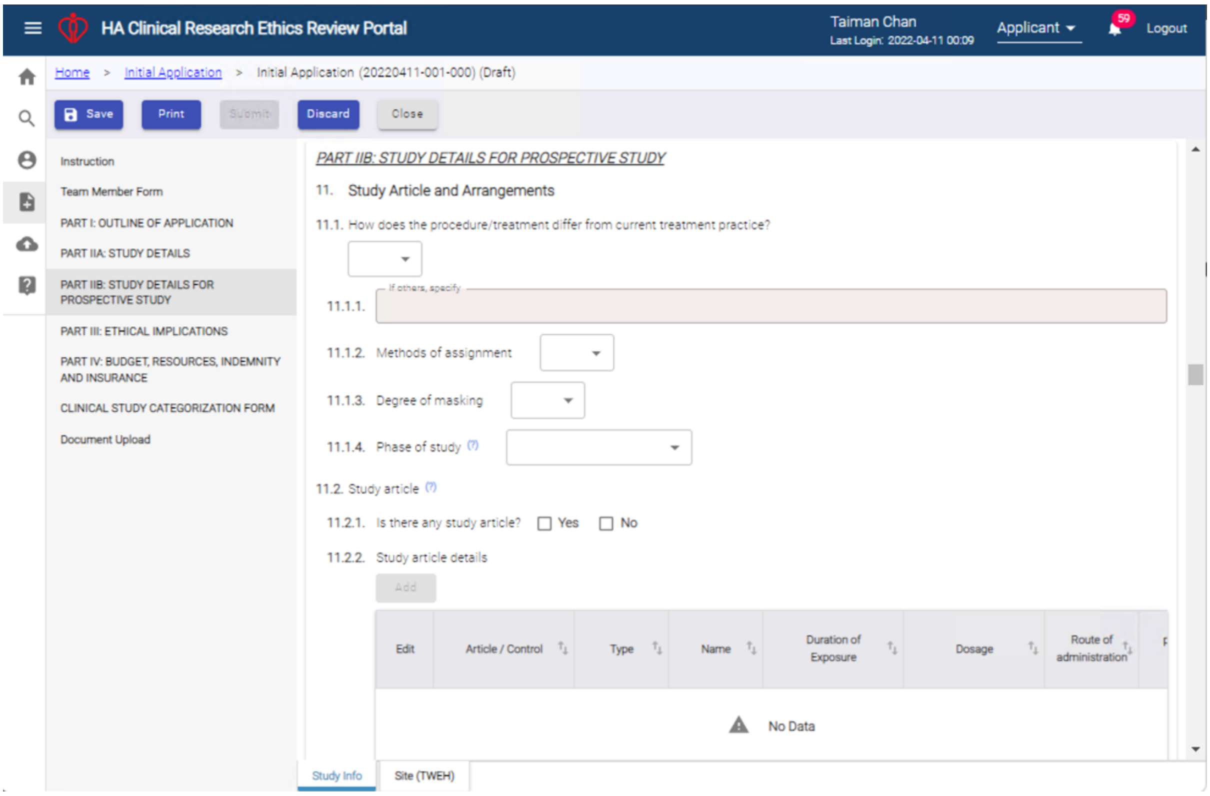


Figure 5.2.3.4.1 Part IIB: Study Details for Prospective Study

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.

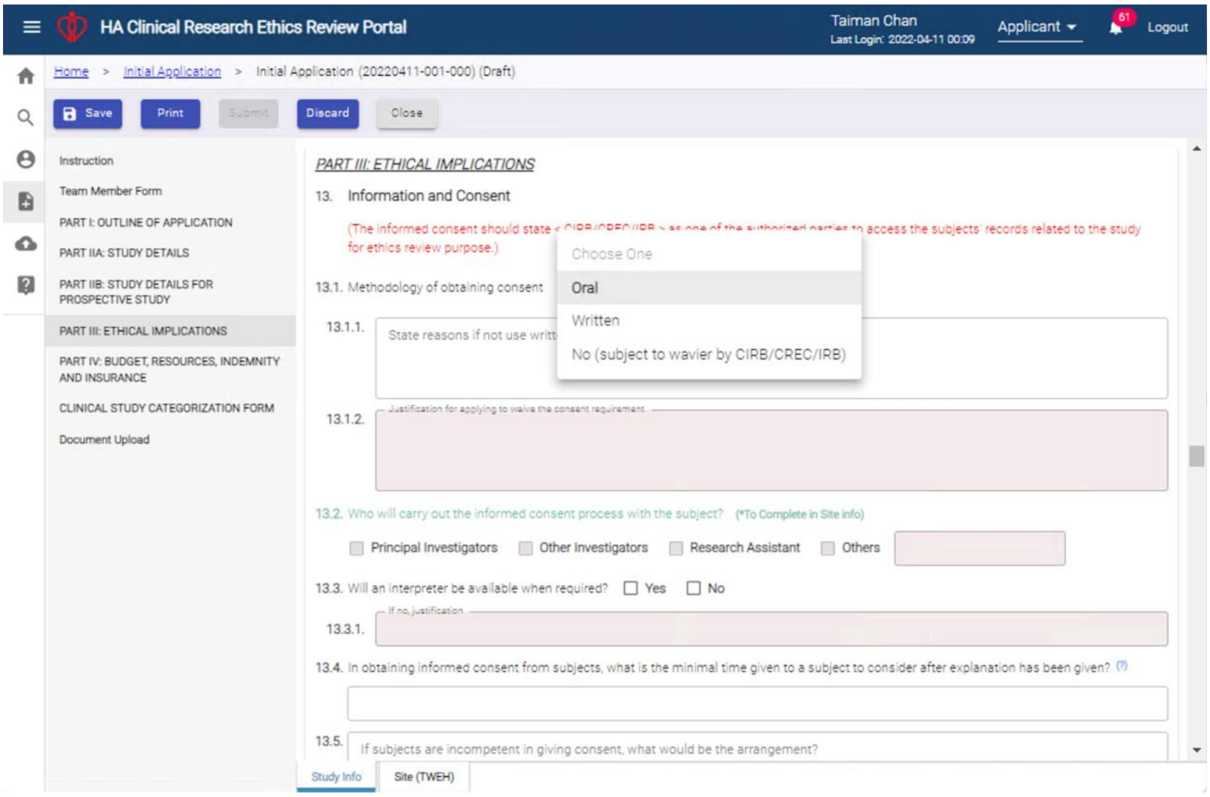


Figure 5.2.3.5.1 Ethical Implications

5.2.3.6 Part IV

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

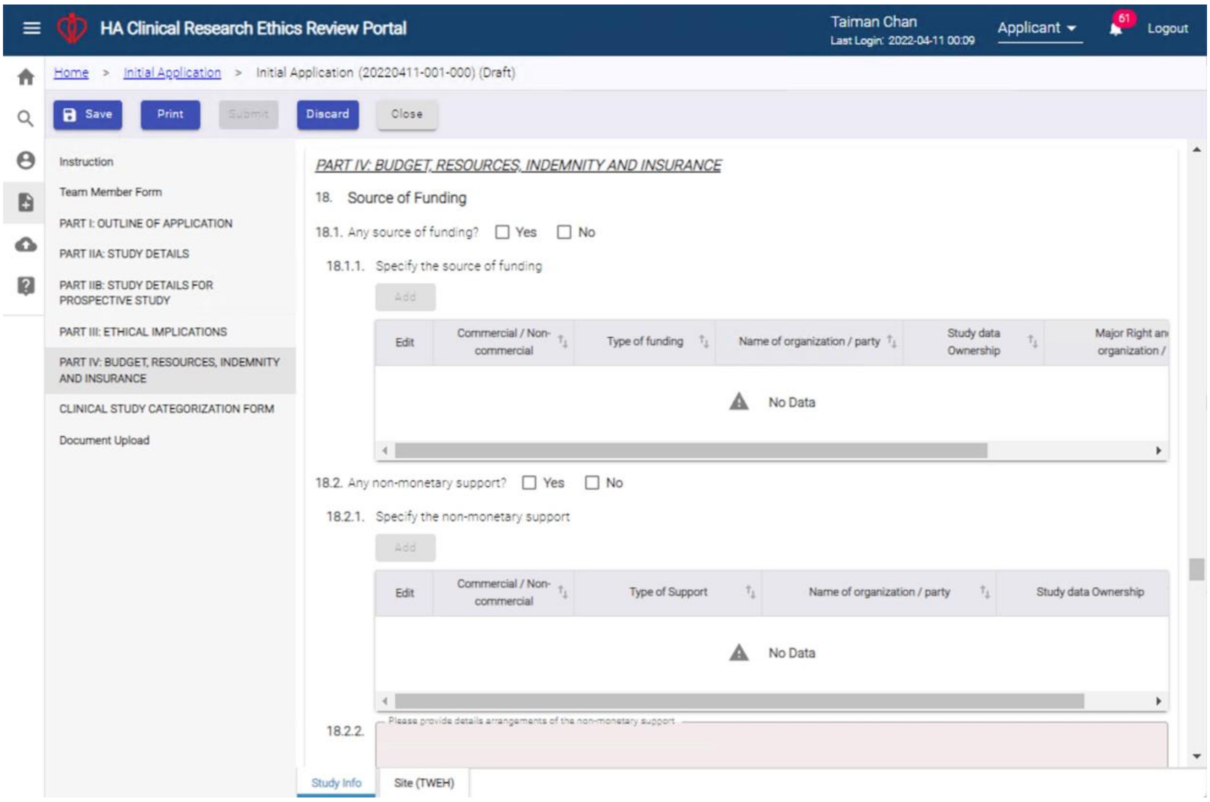


Figure 5.2.3.6.1 Part IV Budget, Resources, Indemnity and Insurance

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
        - 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 "**here**" to go through the Notes for Completion before filling in the Clinical Study Categorization Form.

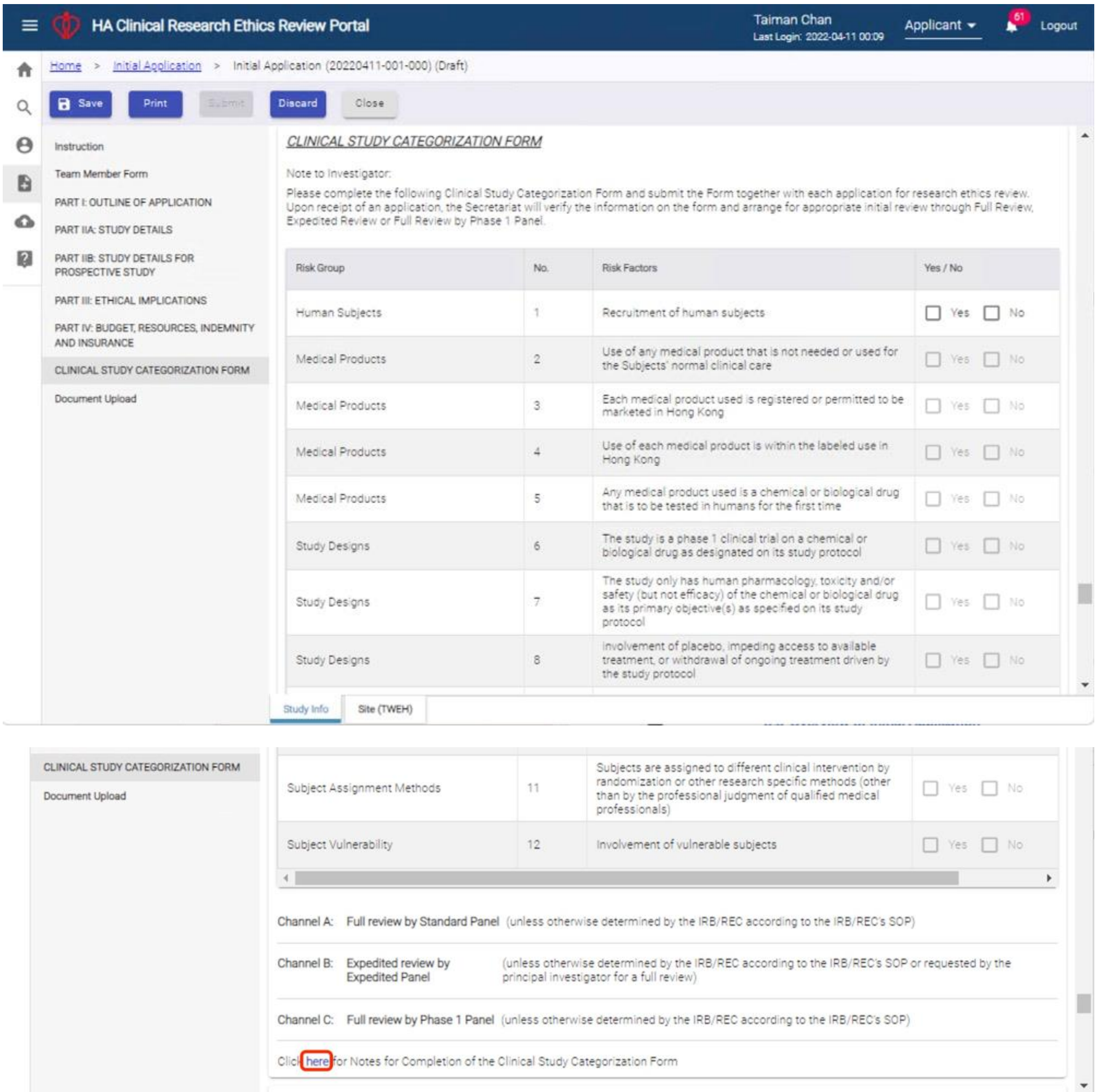


Figure 5.2.3.7.1 Clinical Study Categorization Form

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

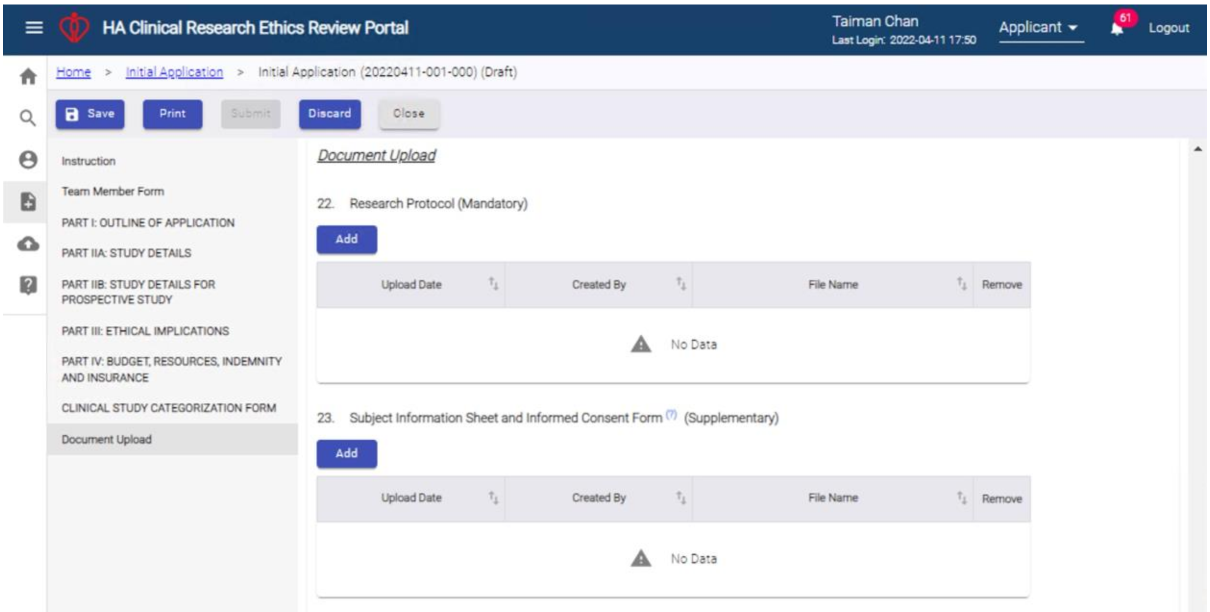


Figure 5.2.3.8.1 Document Upload

1. 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;

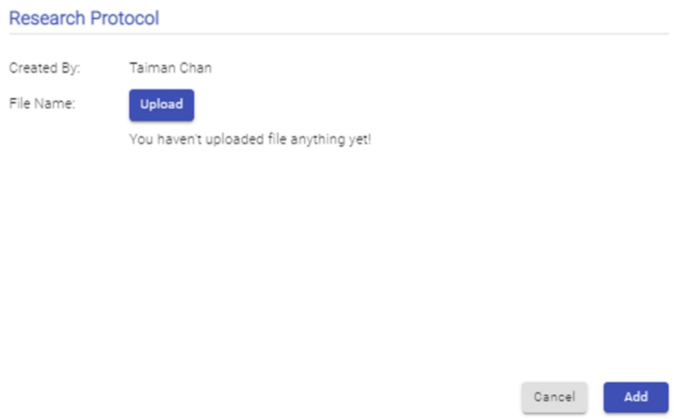


Figure 5.2.3.8.2 Pop-up Dialogs for document upload

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.

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.

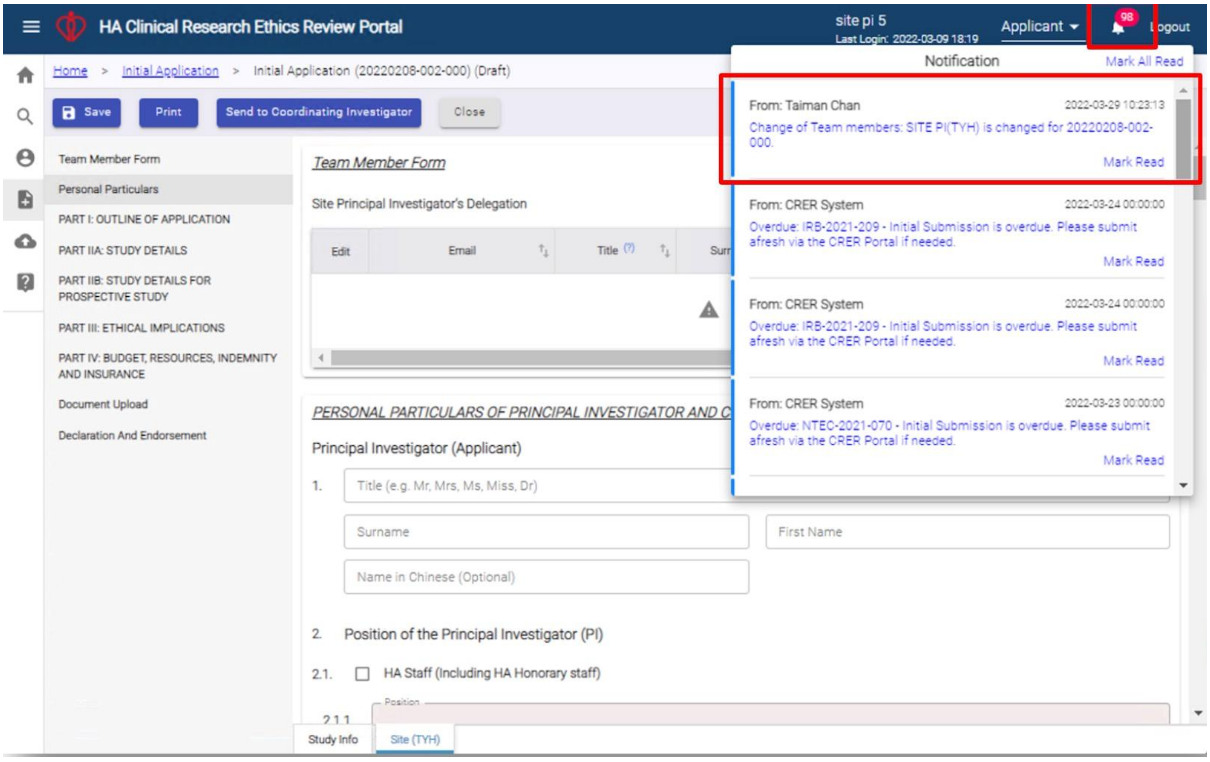


Figure 5.2.4.1 Notification of Site Info Creation

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;

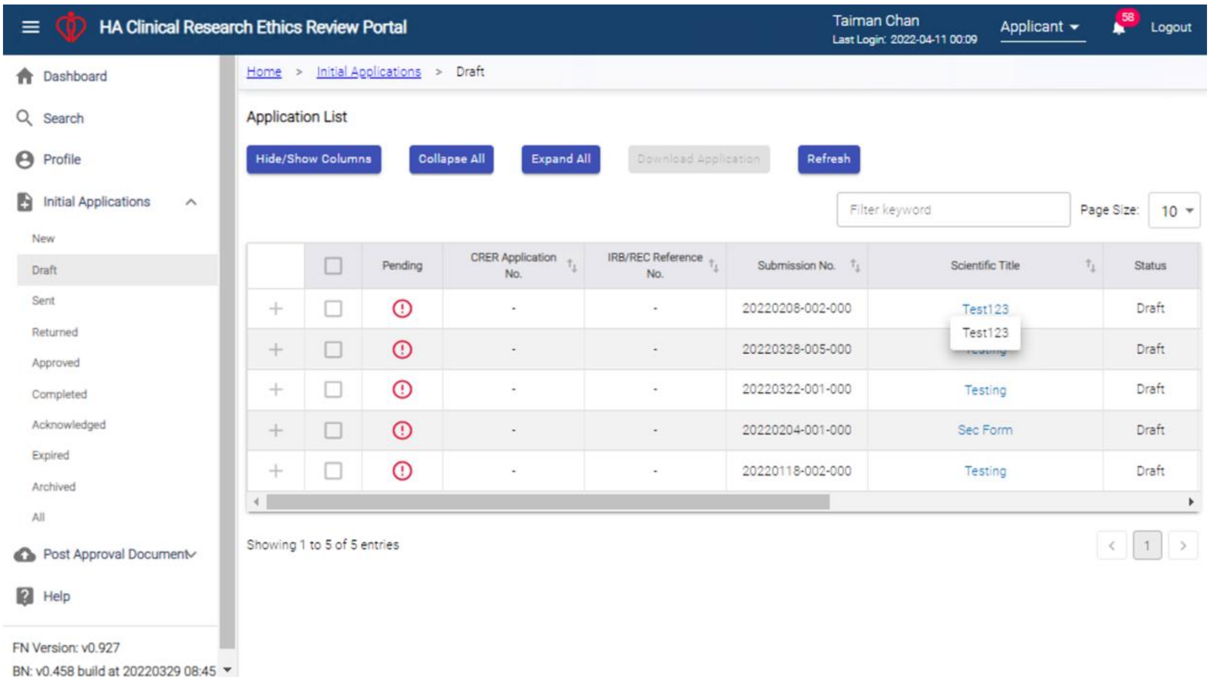


Figure 5.2.4.2 Application List in Draft Status

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.

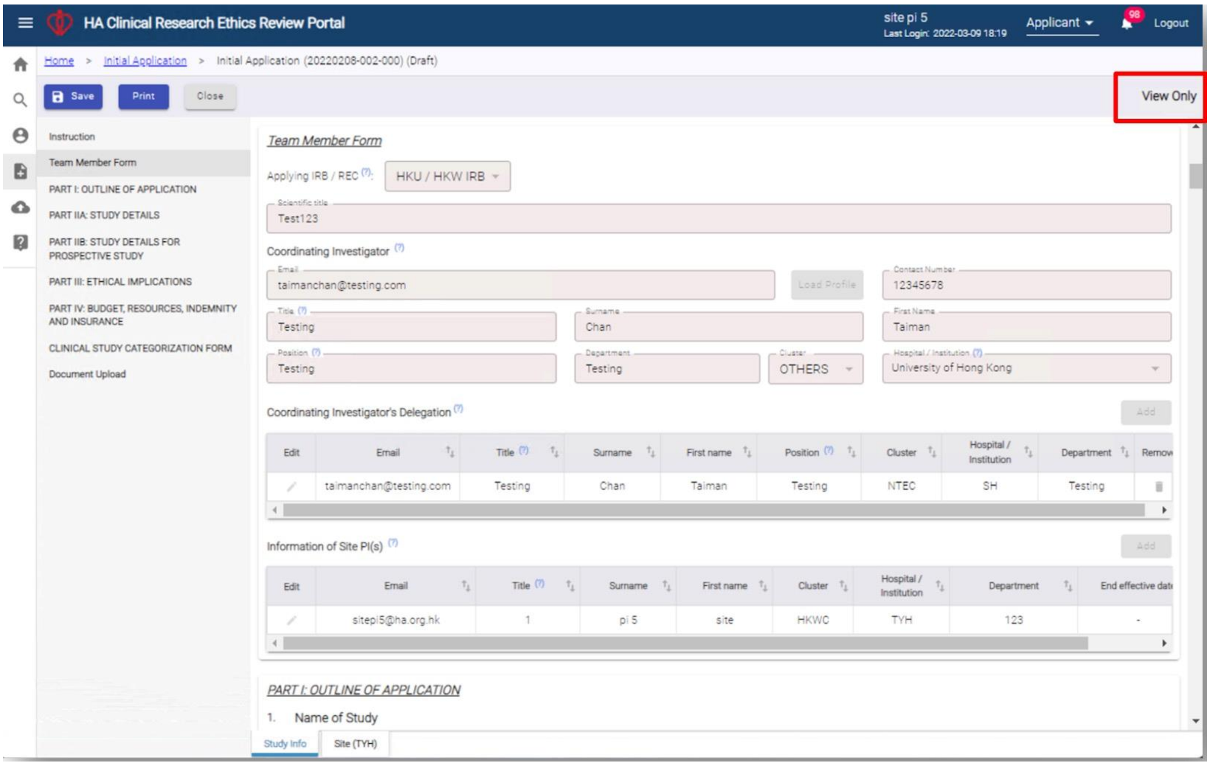


Figure 5.2.4.3 "View only" Study Info for Site PI(s)/Delegate(s)

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**.

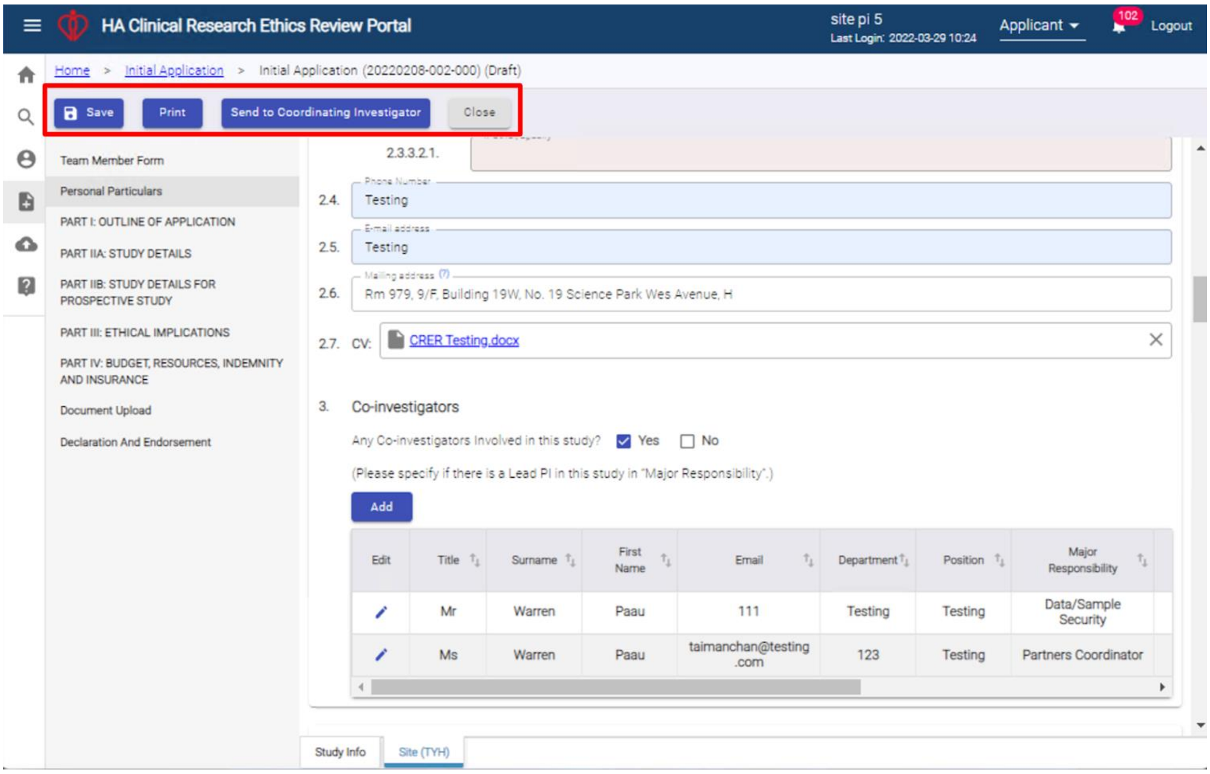


Figure 5.2.4.4 Action buttons for Site PI(s)/Delegate(S) in Initial Application

Below is the description of each button:

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

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.

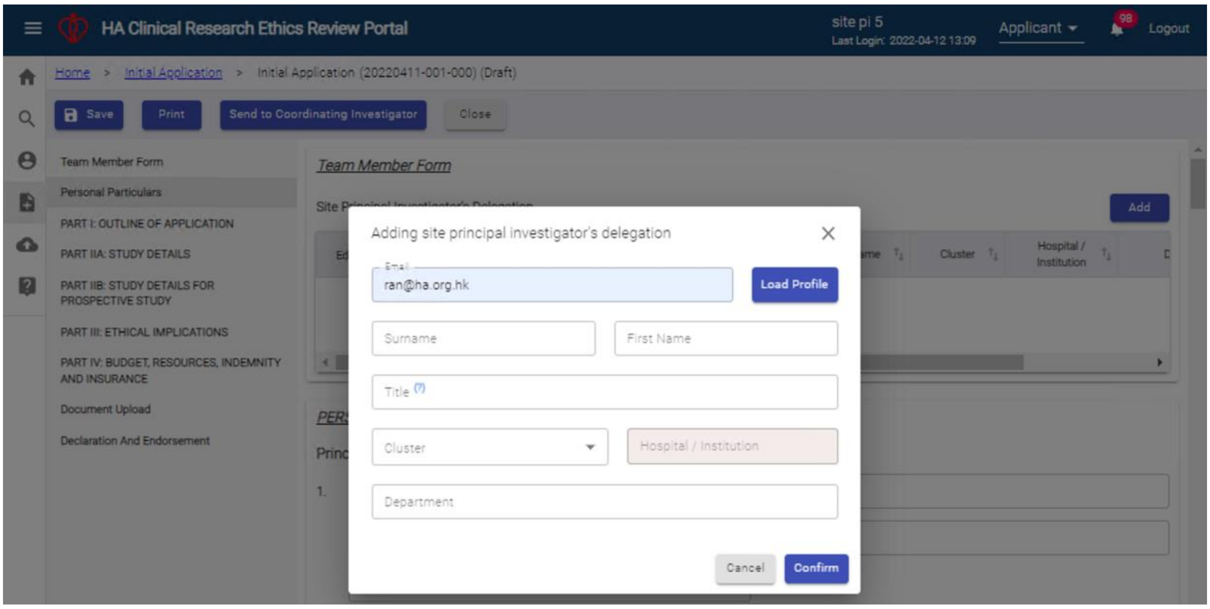


Figure 5.2.4.1.1 Pop-Up dialogs for Adding Site PI's Delegate(s)

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 Co-investigator 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

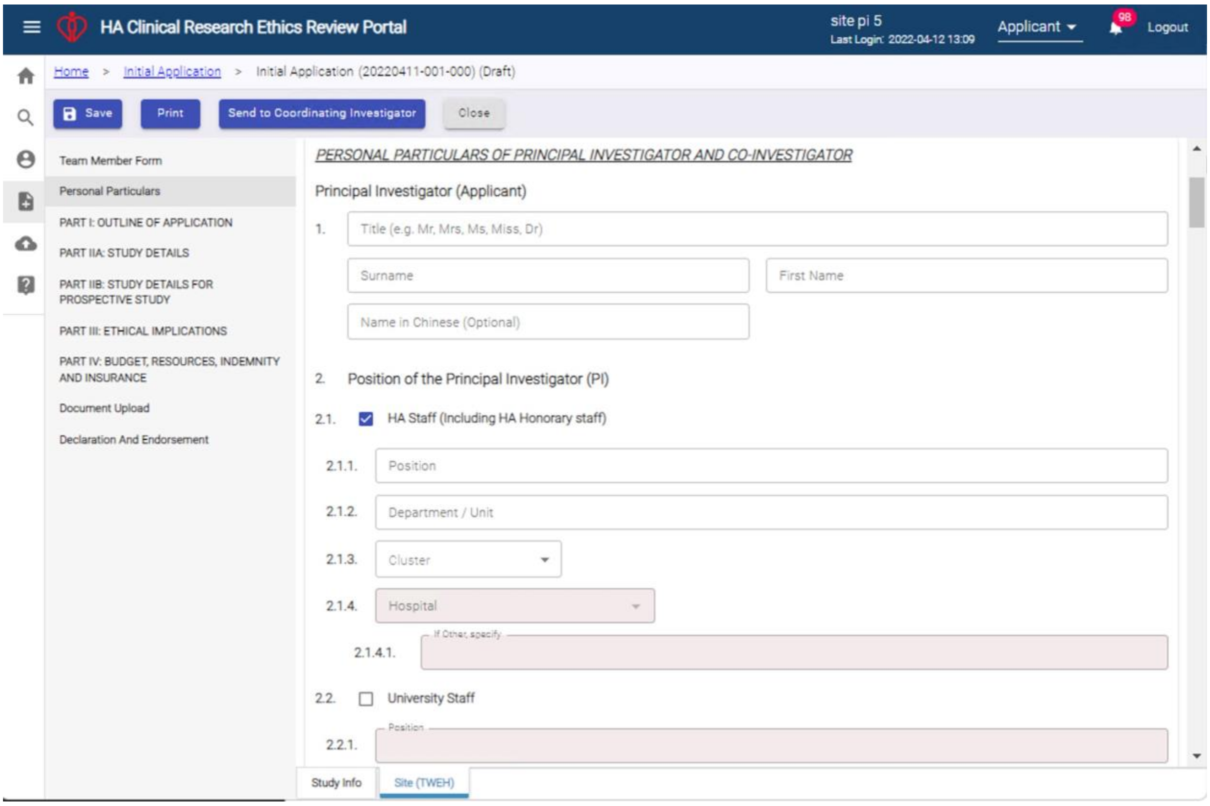


Figure 5.2.4.2.1 Personal Particulars

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

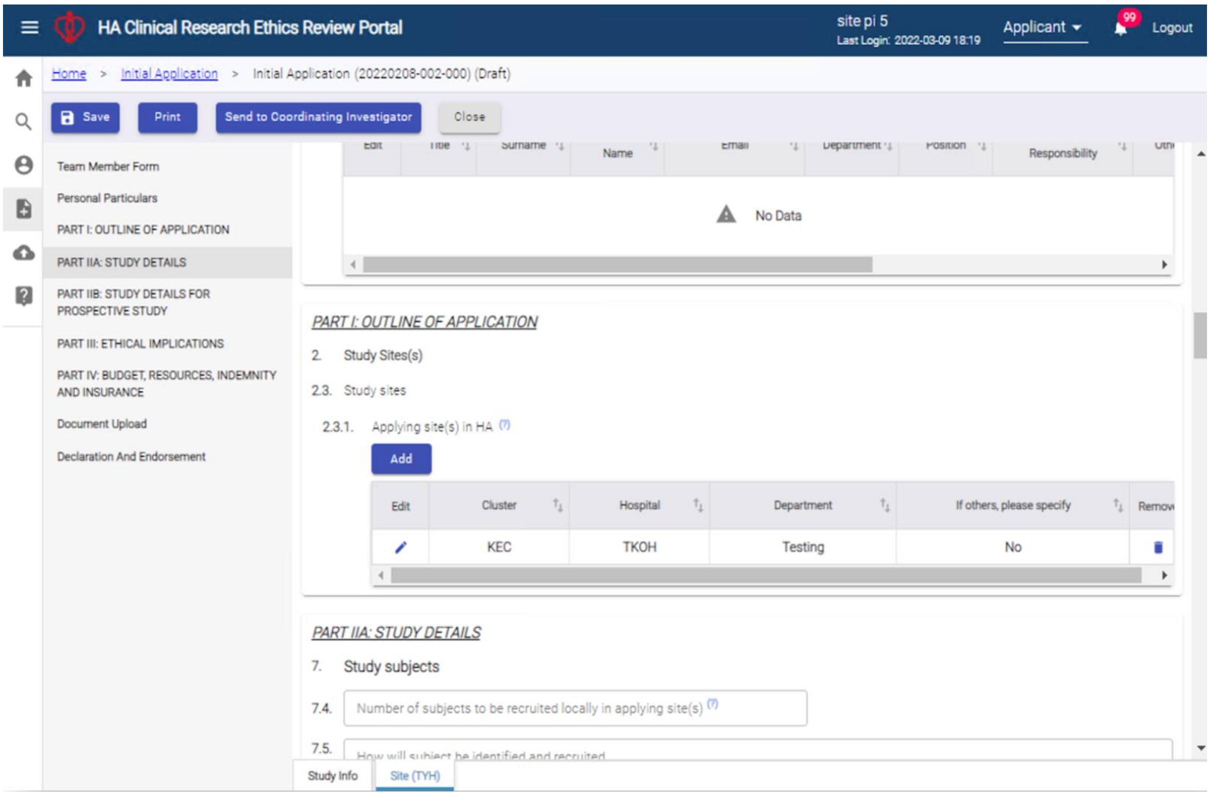


Figure 5.2.4.3.1 Part I: Outline of Application in Site Info

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

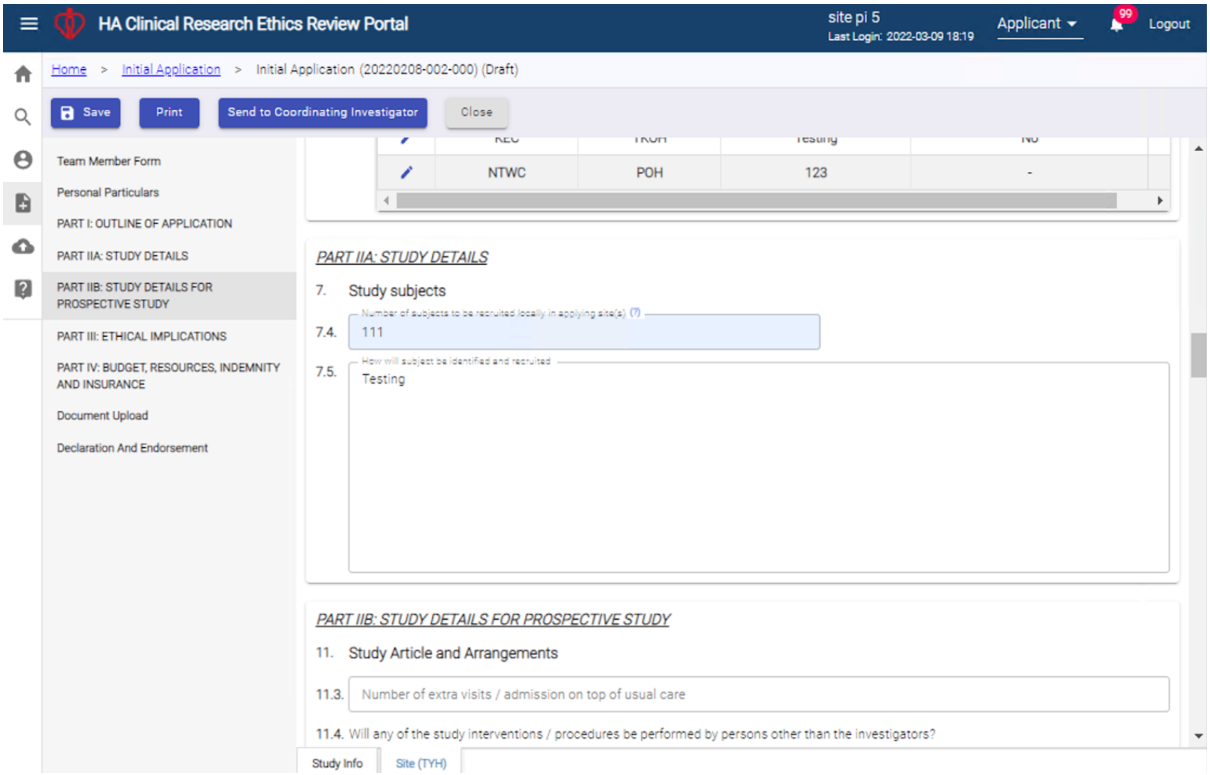


Figure 5.2.4.4.1 Part IIA: Study Details in Site Info

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

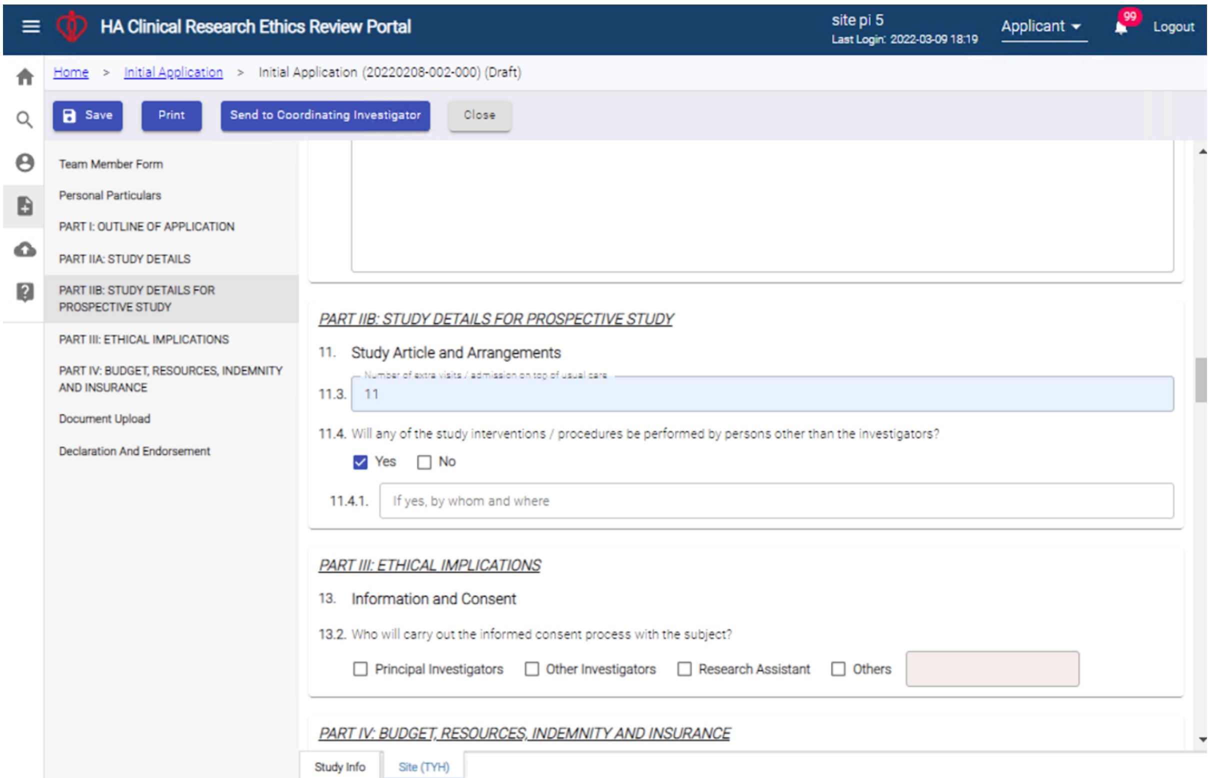


Figure 5.2.4.5.1 Part IIB: Study Details for Prospective Study in Site Info

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.

1. 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.

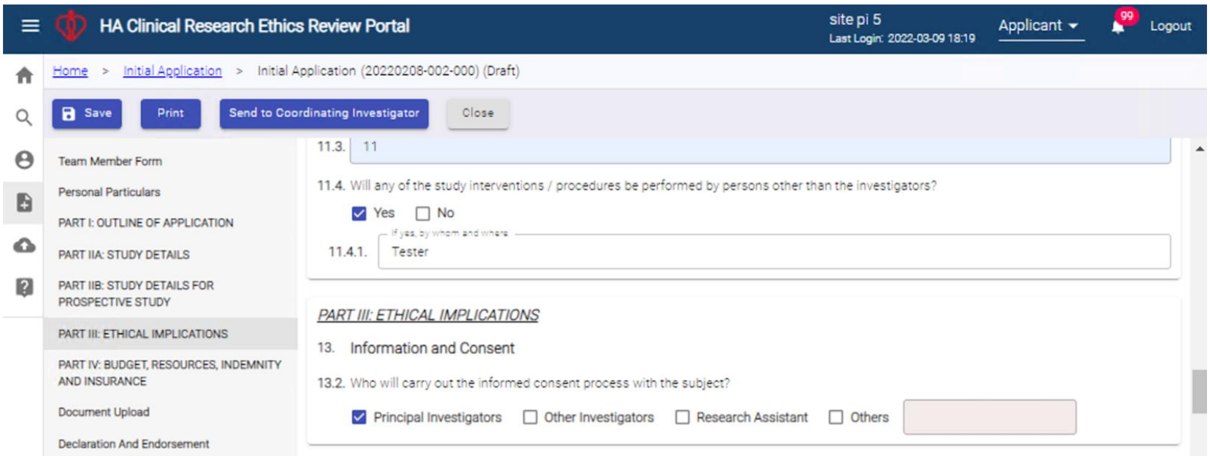


Figure 5.2.4.6.1 Part III: Ethical Implications in Site Info

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

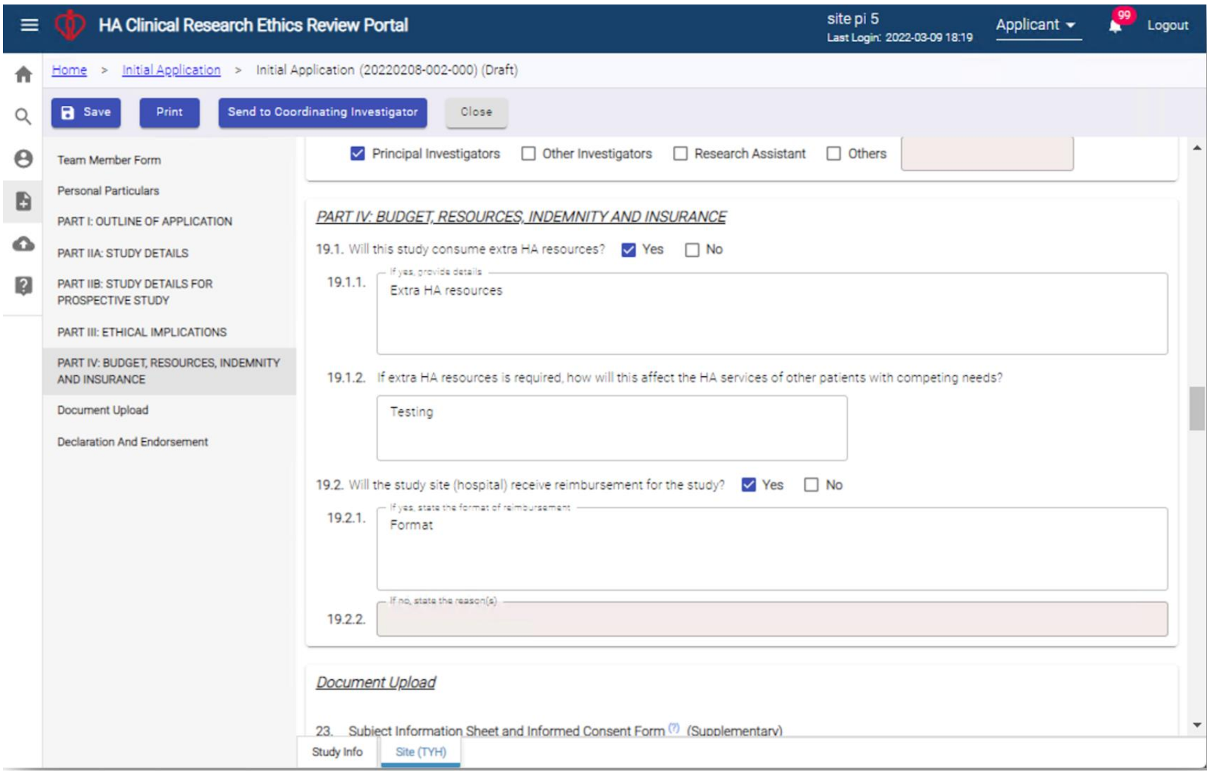


Figure 5.2.4.7.1 Part IV: Budget, Resource, Indemnity and Insurance in Site Info

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.

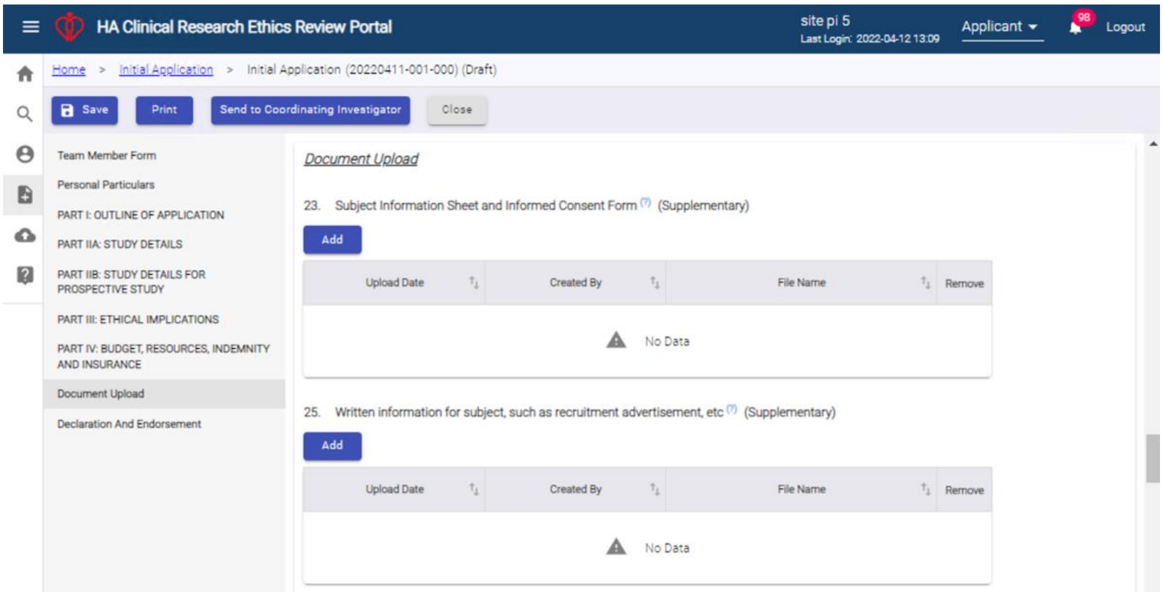


Figure 5.2.4.8.1 Document Upload in Site Info

1. 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.

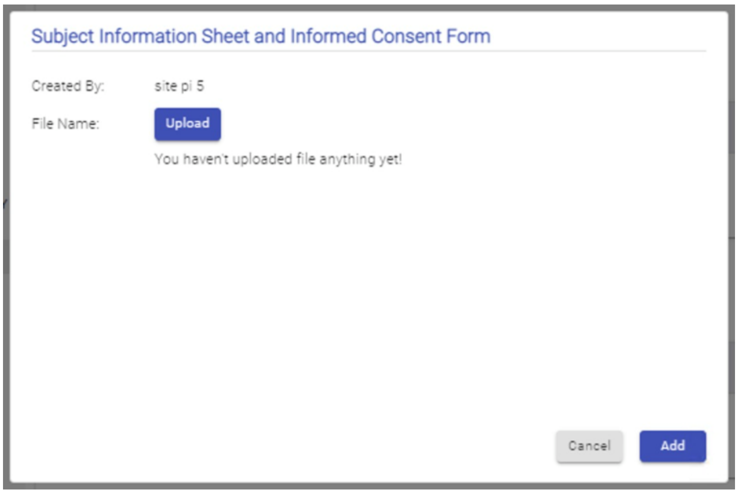


Figure 5.2.4.8.2 Pop-up Dialogs for Document Upload

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[3] of HA
- Section C. Endorsement by Head of Department[4] of the Universities
- Section D. Endorsement by COS(s) or Head(s) of the Collaborating Department(s) in HA or in Universities.

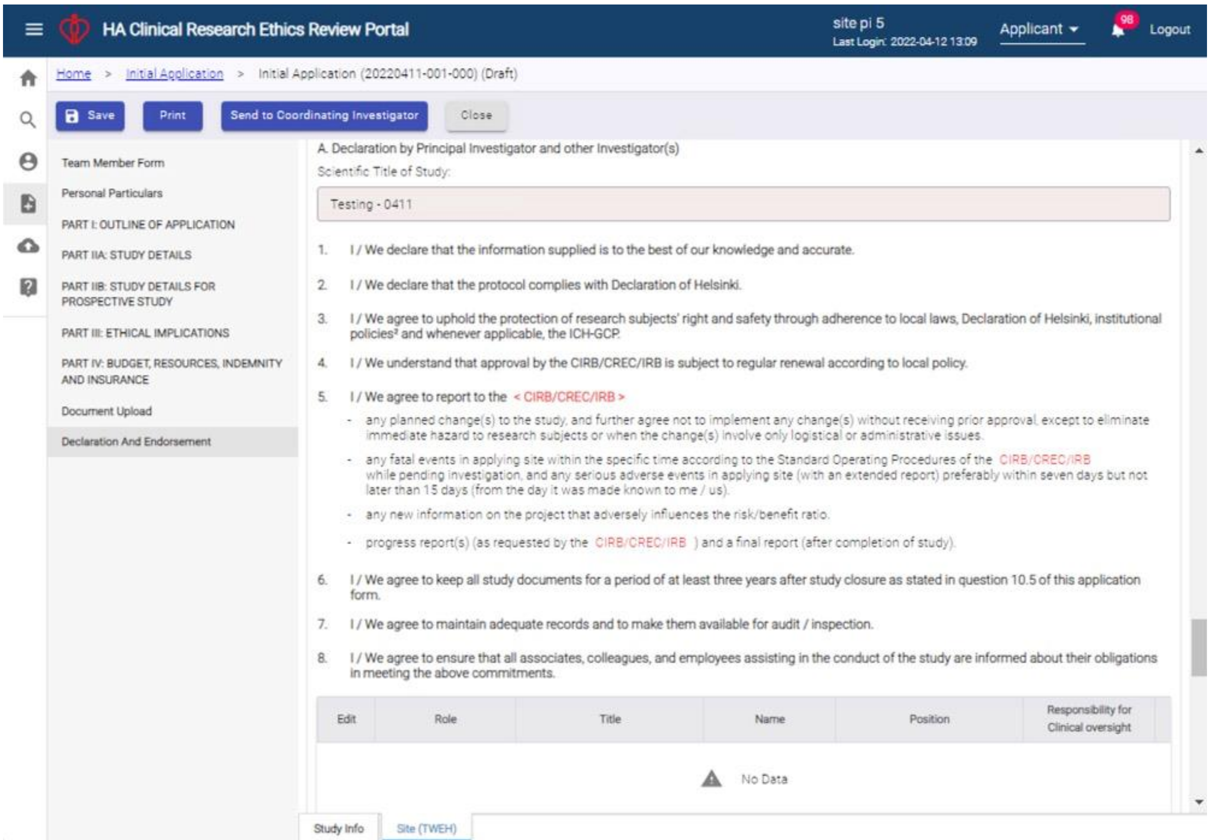


Figure 5.2.4.9.1 Declaration and Endorsement in Site Info

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;

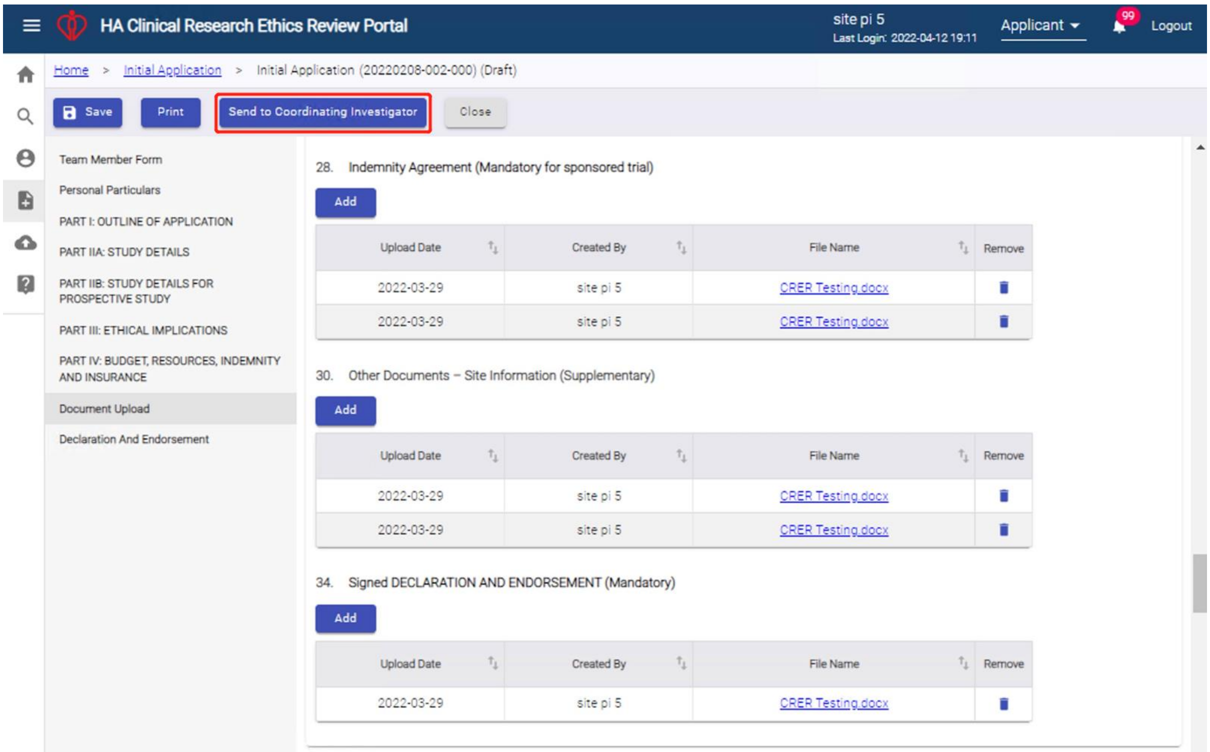


Figure 5.2.5.1 Screen of "Send to Coordinating Investigator" button in Site Info

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

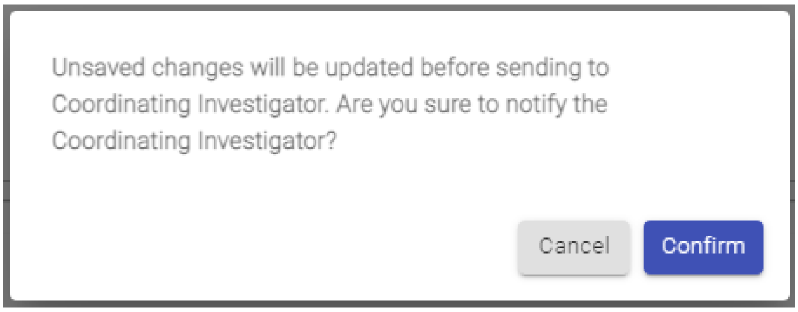


Figure 5.2.5.2 Pop-up dialogs of Reminder for Unsaved Changes in Site Info before submission

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;

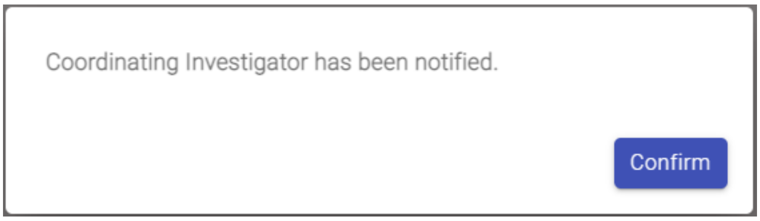


Figure 5.2.5.3 Pop-up dialogs for Confirmation for Site Info Submission

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;

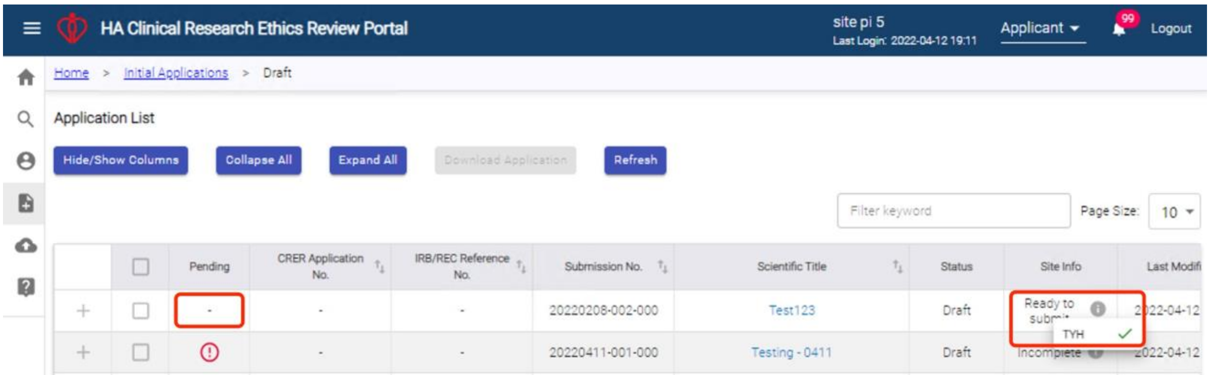


Figure 5.2.5.4 Changes on Application List after Site Info is submitted

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.

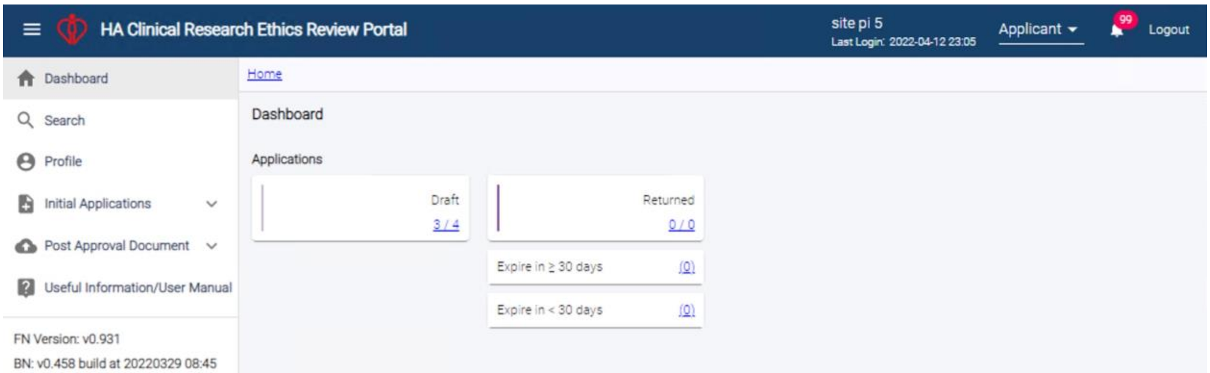


Figure 5.2.5.5 Changes on Dashboard for Application after Site Info is submitted

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.>".

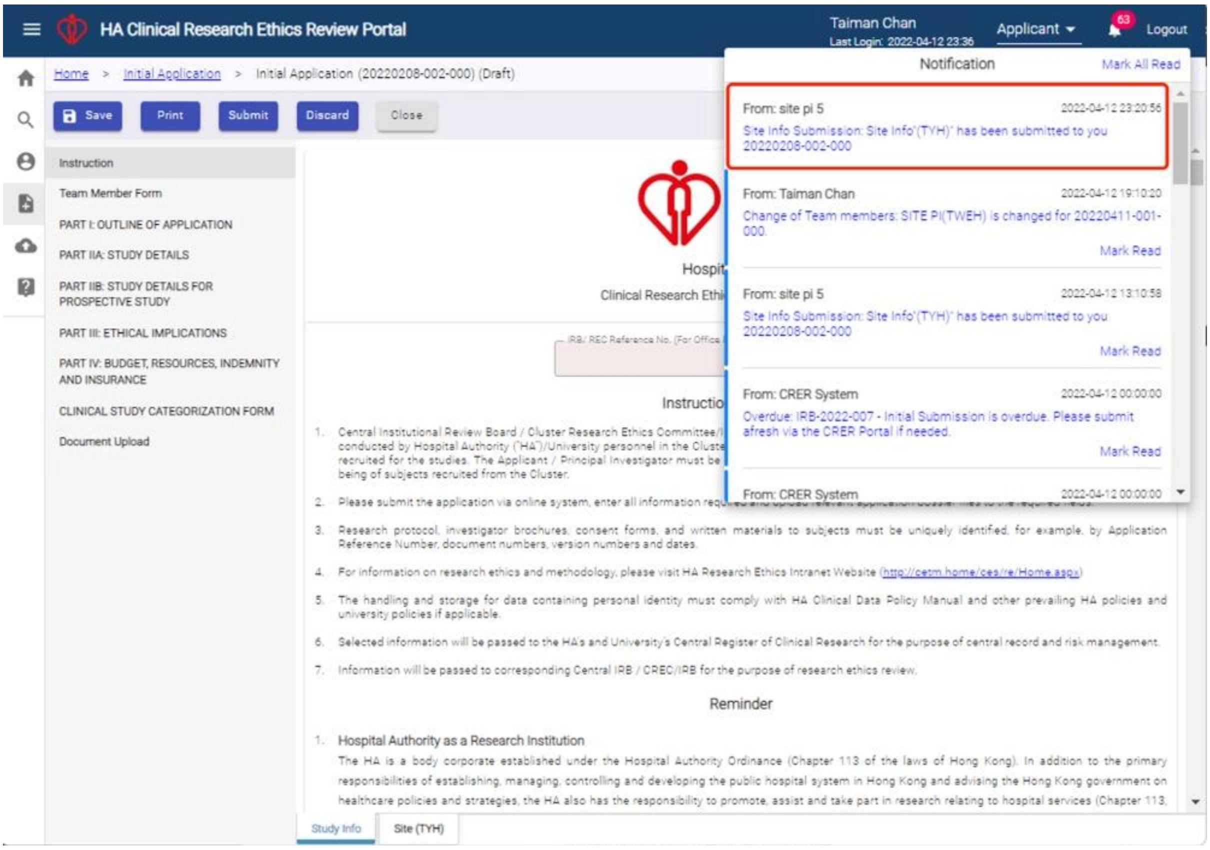


Figure 5.2.6.1 Screen of Initial Application after clicking notification of Site Info Submission

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 [Re-submit the Site Info by Site PI/Delegate(s)](#).

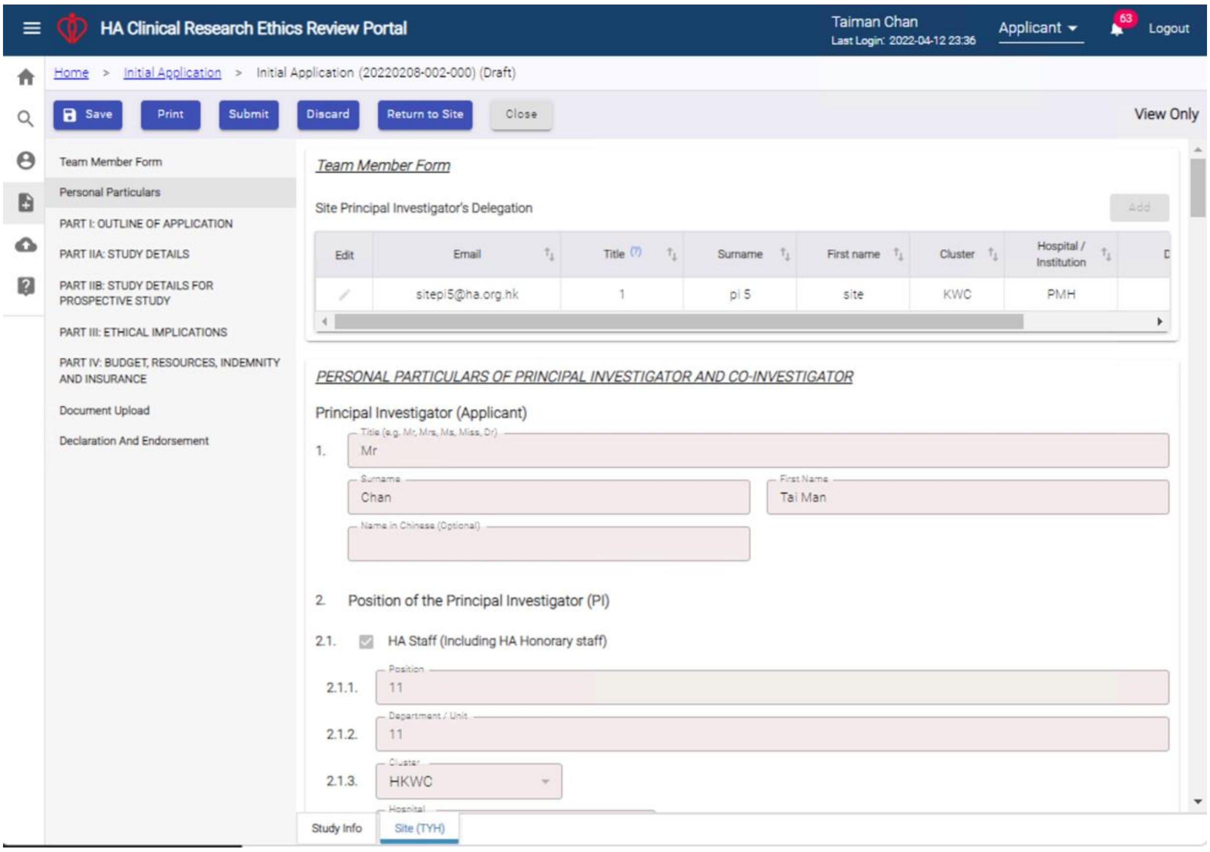


Figure 5.2.6.2 Screen of "View-only" Site Info of Initial Application

Figure 5.2.6.3 Popup dialog before returning Site Info to Study Site

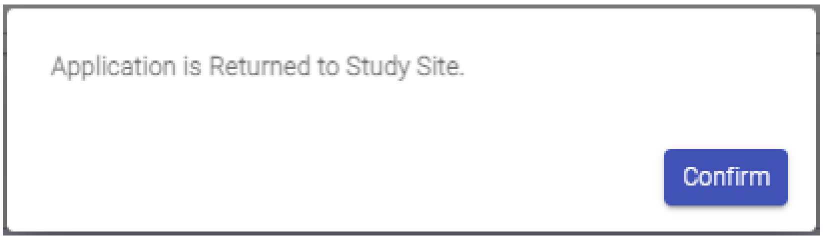


Figure 5.2.6.4 Popup dialog after returning Site Info to Study Site

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.

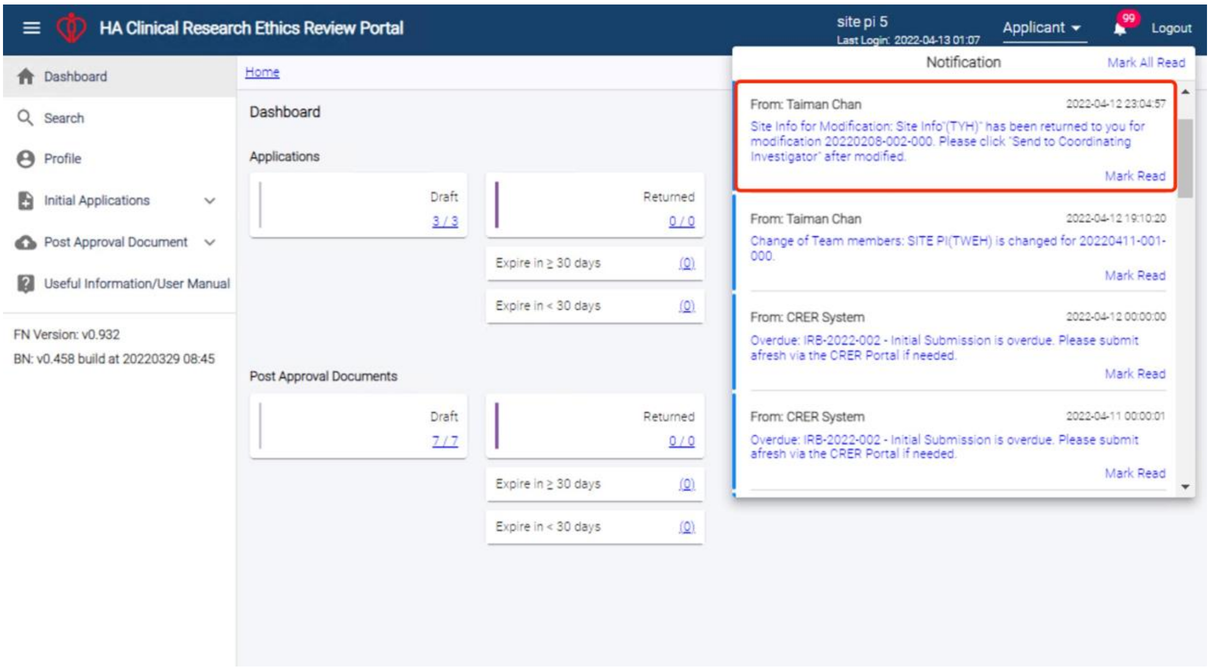


Figure 5.2.7.1 Notification of Site Info returned for modification

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

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

As a CI/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.

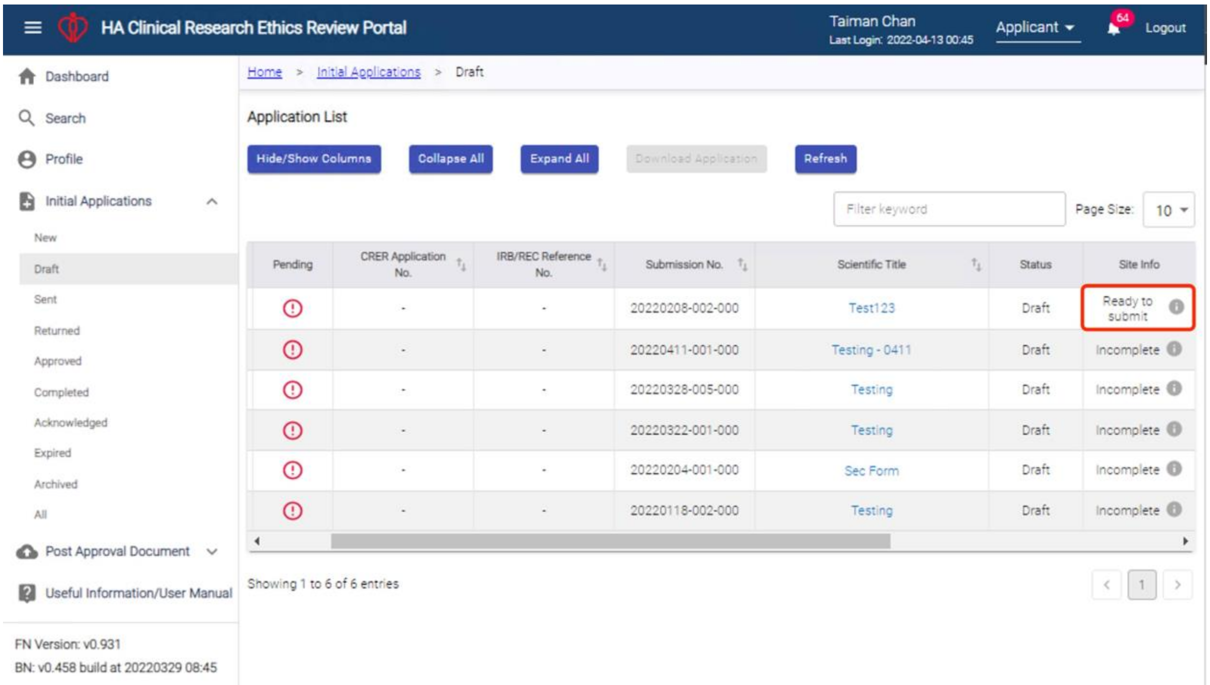


Figure 5.2.8.1 Screen of “Ready to Submit” Site Info status in Application List

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

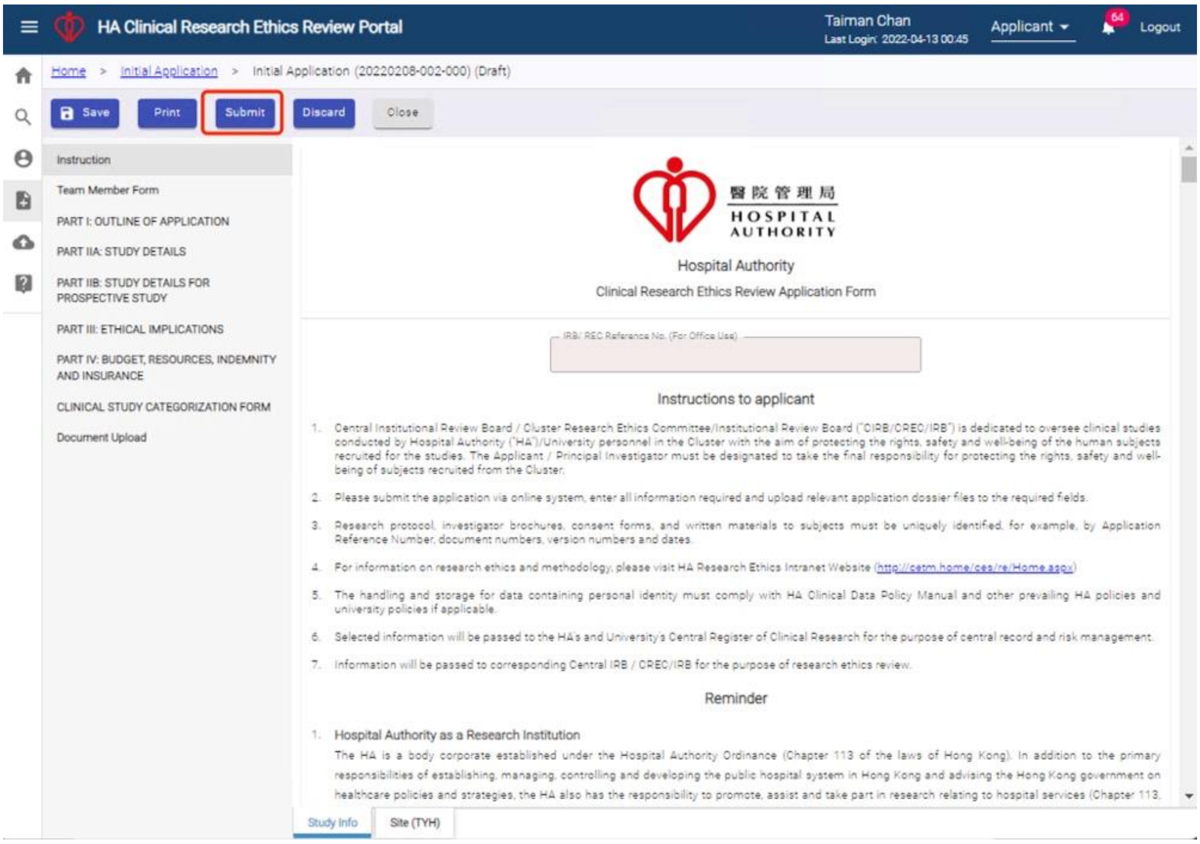


Figure 5.2.8.2 Screen of Submit button in Study Info of Initial Application

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

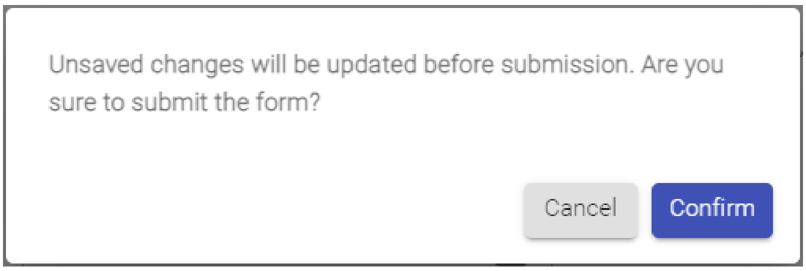


Figure 5.2.8.3 Pop-up dialog of Reminder for Unsaved Changes in Study Info before submission

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

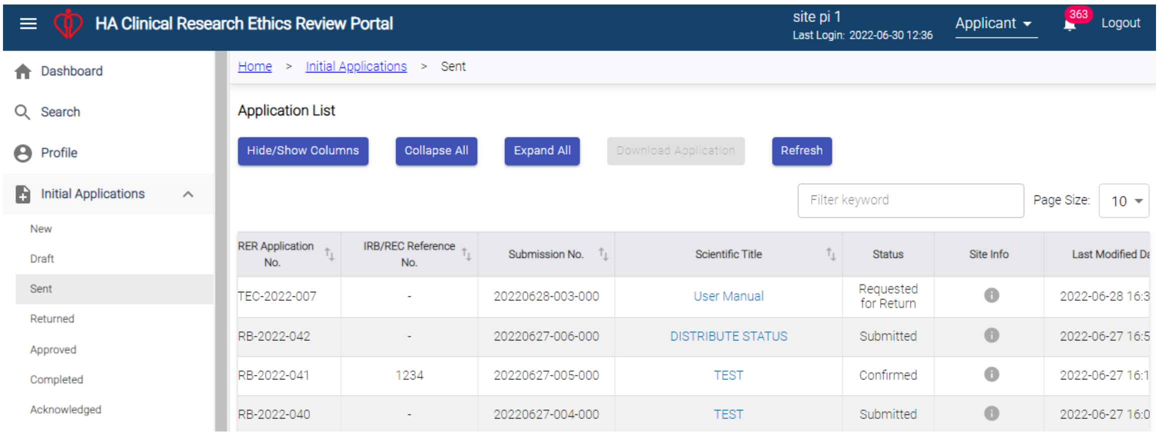


Figure 5.2.8.5 Changes on Application List after Initial Application is submitted

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.

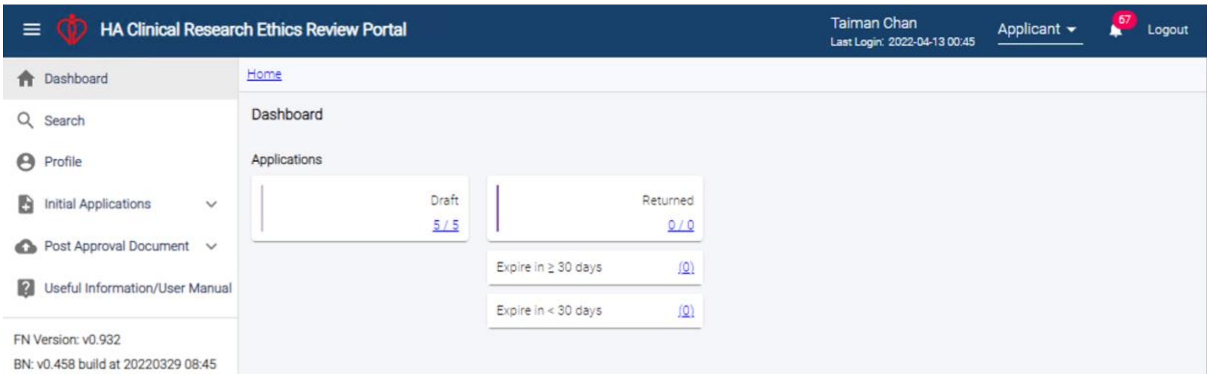


Figure 5.2.8.6 Changes on Dashboard for Application after Initial Application is submitted

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.

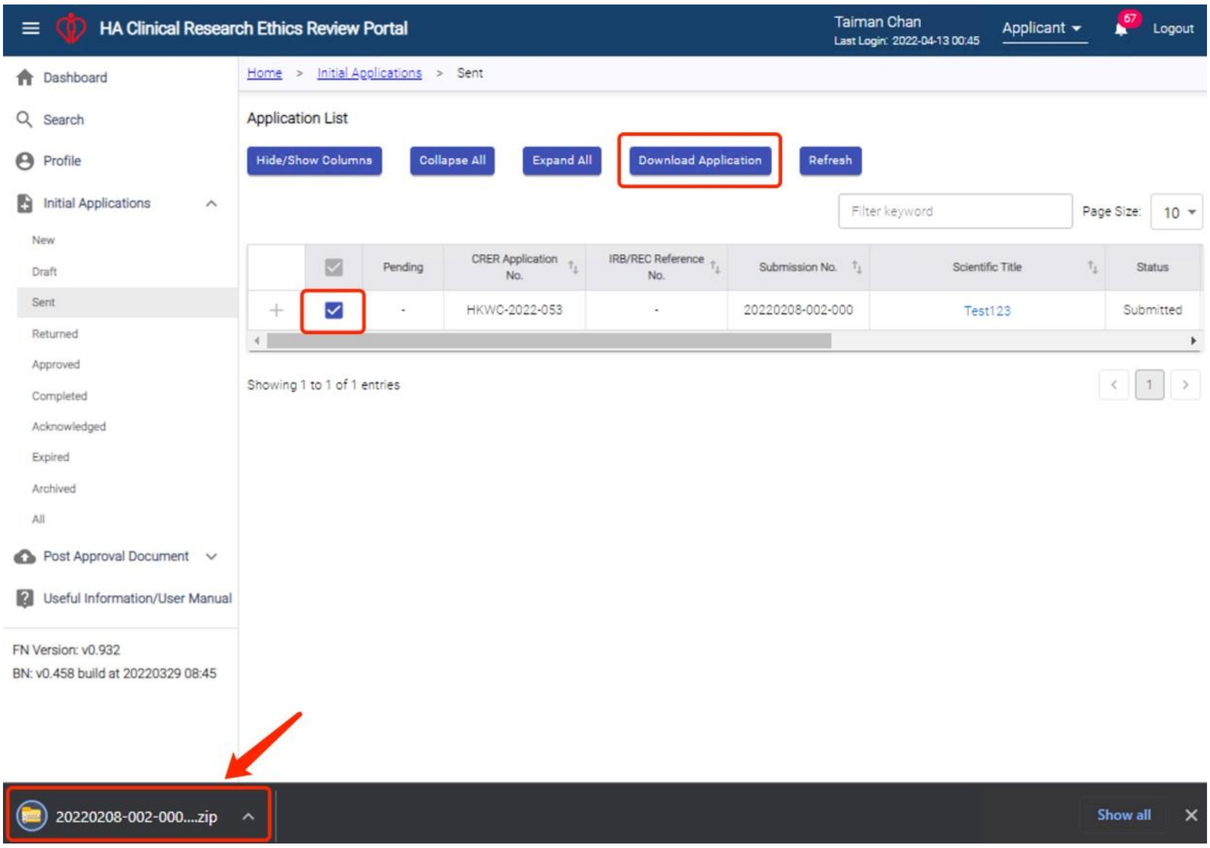


Figure 5.2.8.1.1 Download Initial Application

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.

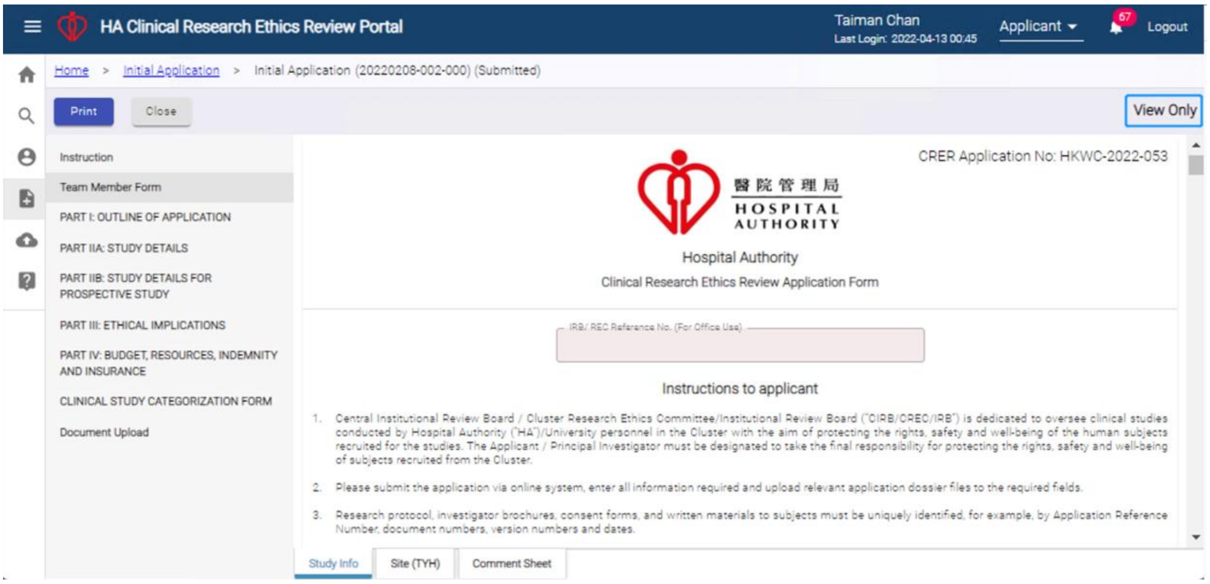
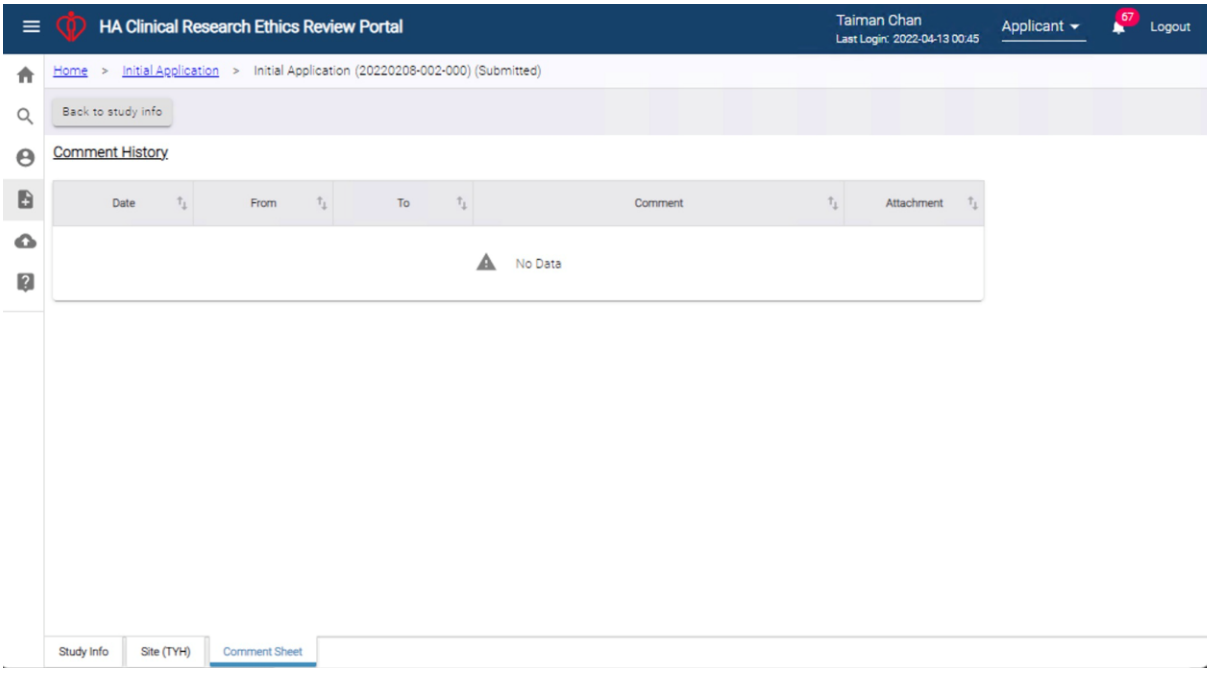


Figure 5.2.8.1.2 View-only mode for submitted Initial Application

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.



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.

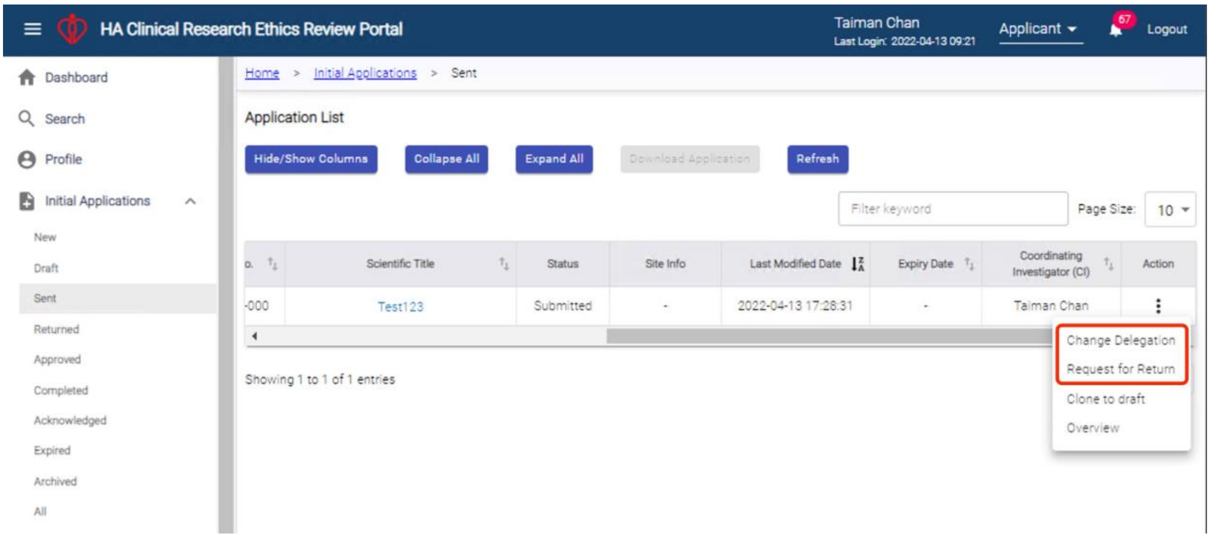


Figure 5.2.8.1.4 Screen of "Change Delegation" & "Request for Return" button in Application List

Refer to Request for Return of Initial Application and Change Delegation 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.

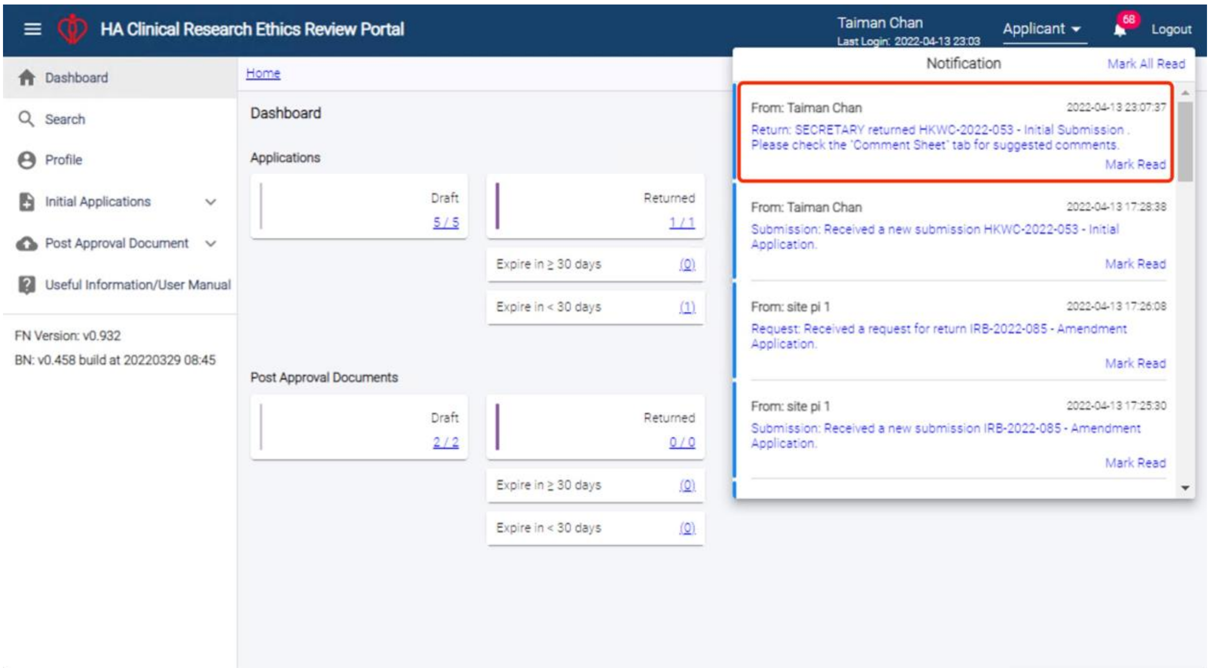


Figure 5.2.9.1 Notification for Returned Initial Application

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.

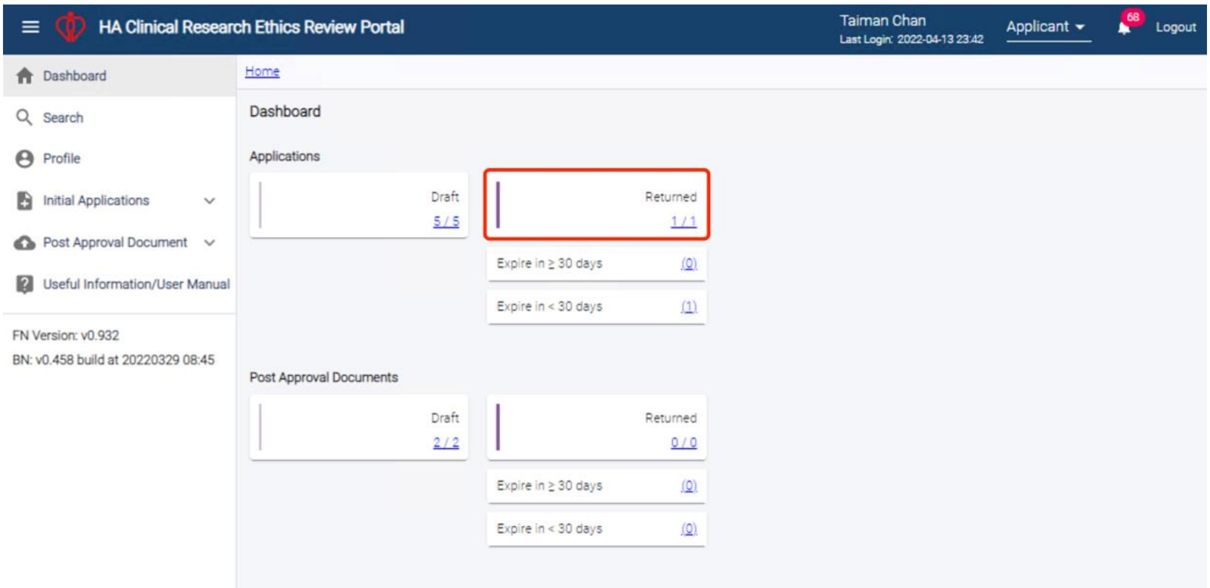


Figure 5.2.9.2 Changes on Dashboard for Returned Initial Application

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

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)

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.

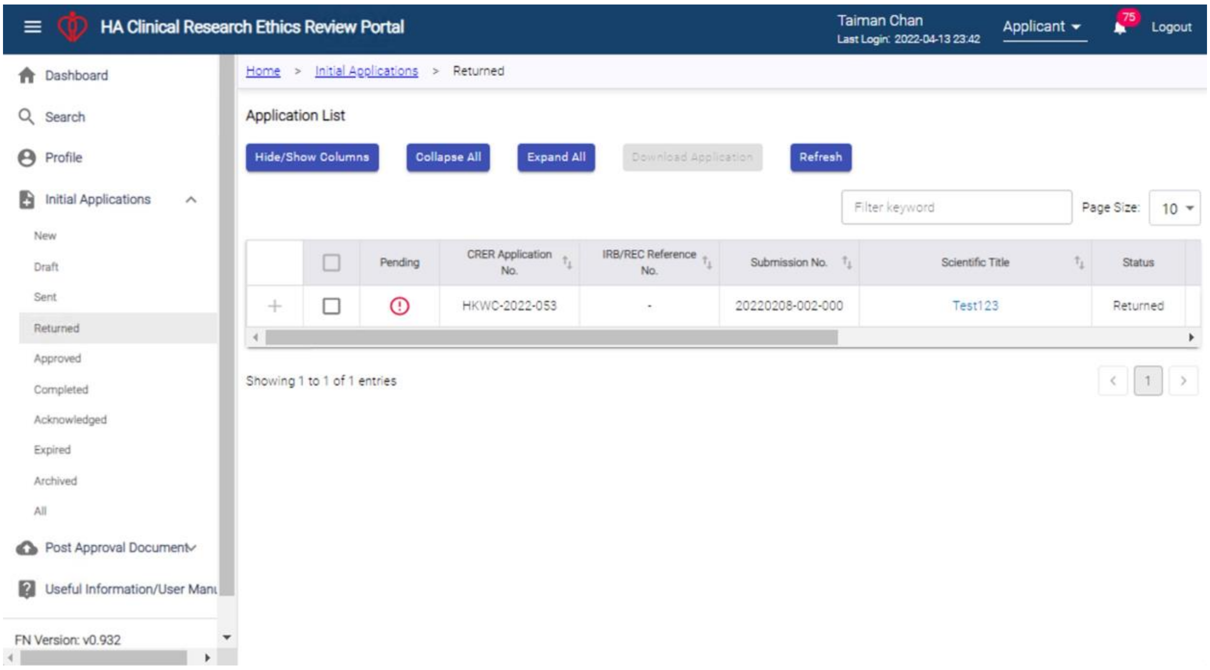


Figure 5.2.9.3 Returned Initial Application in “Returned” Application List

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.

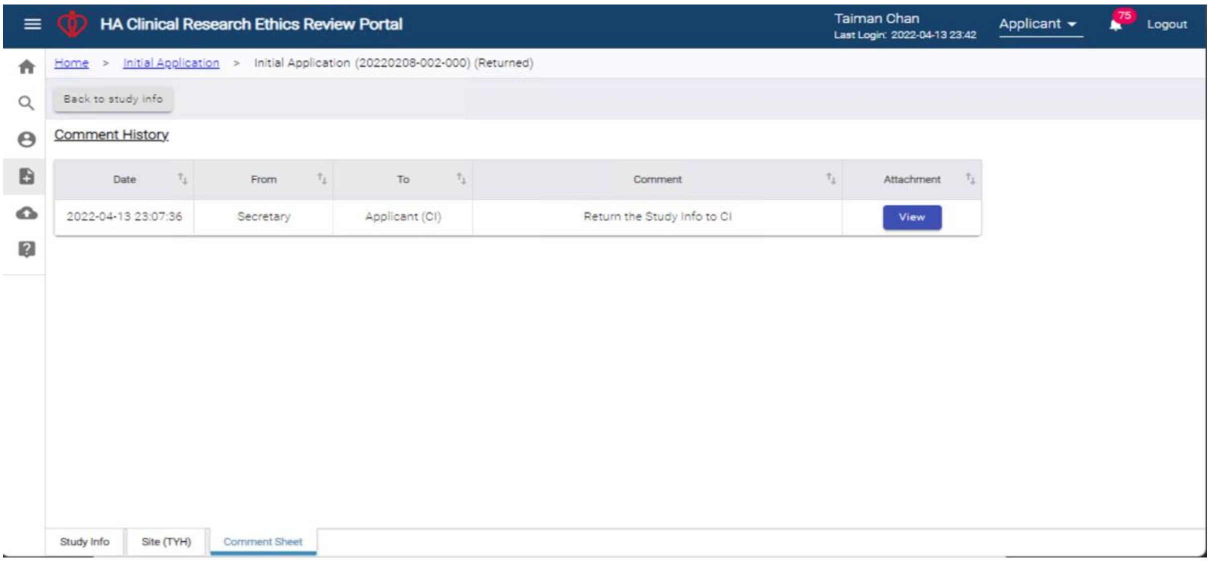


Figure 5.2.9.4 Comment tab of the Initial Application

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 Site PI/Delegate(s) to Submit the Site Info to CI/Delegate(s)
- 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;

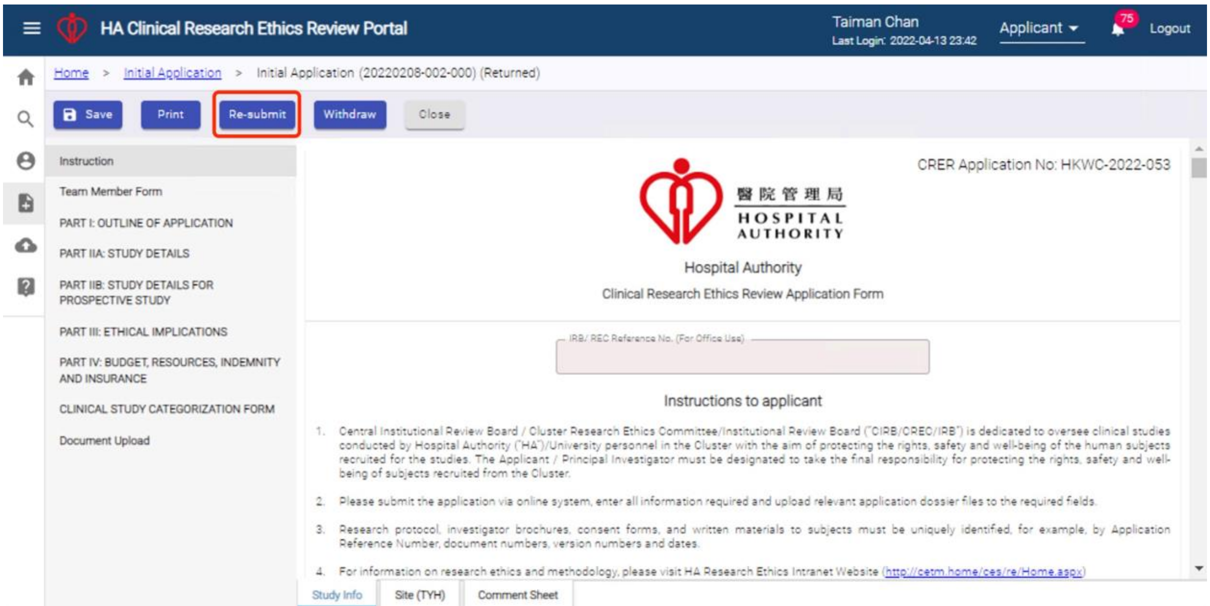


Figure 5.2.9.5 Screen of Re-Submit button in Returned Initial Application

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

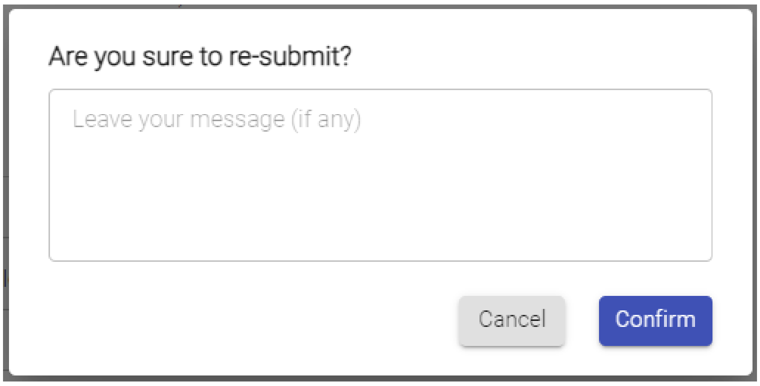


Figure 5.2.9.6 Pop-up dialog when resubmission

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

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 Re-submitted Initial Application.

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 ⩾ 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.

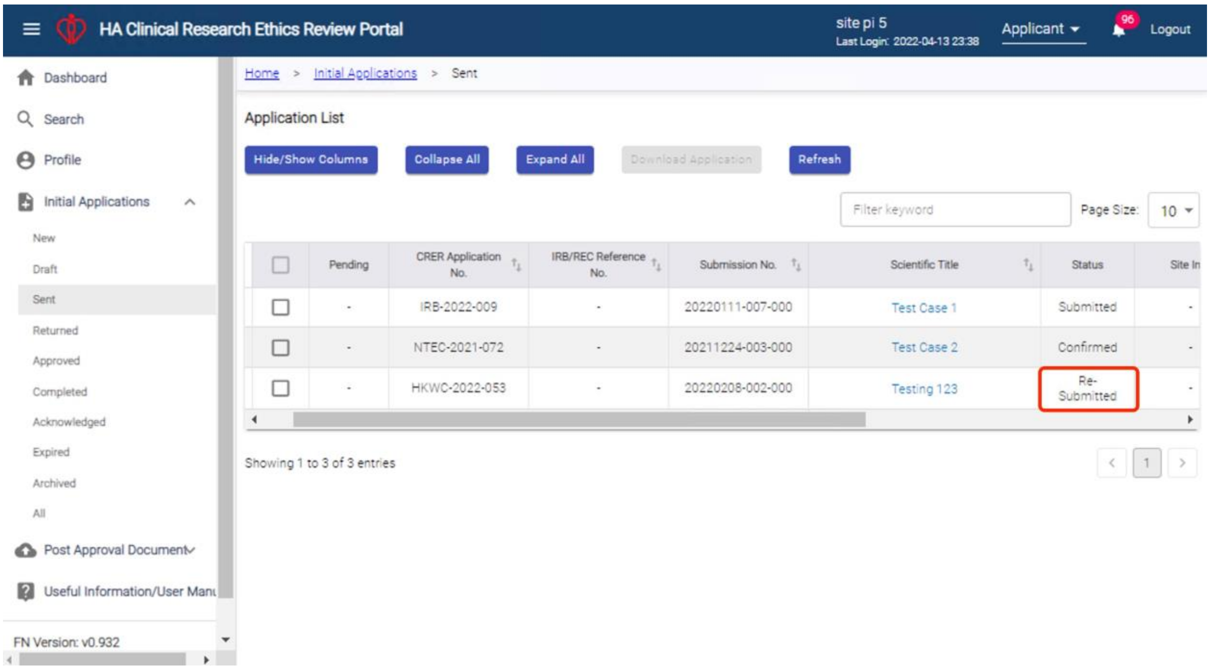


Figure 5.2.9.1.1 "Re-submitted" Initial Application in "Sent" Application List

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”.

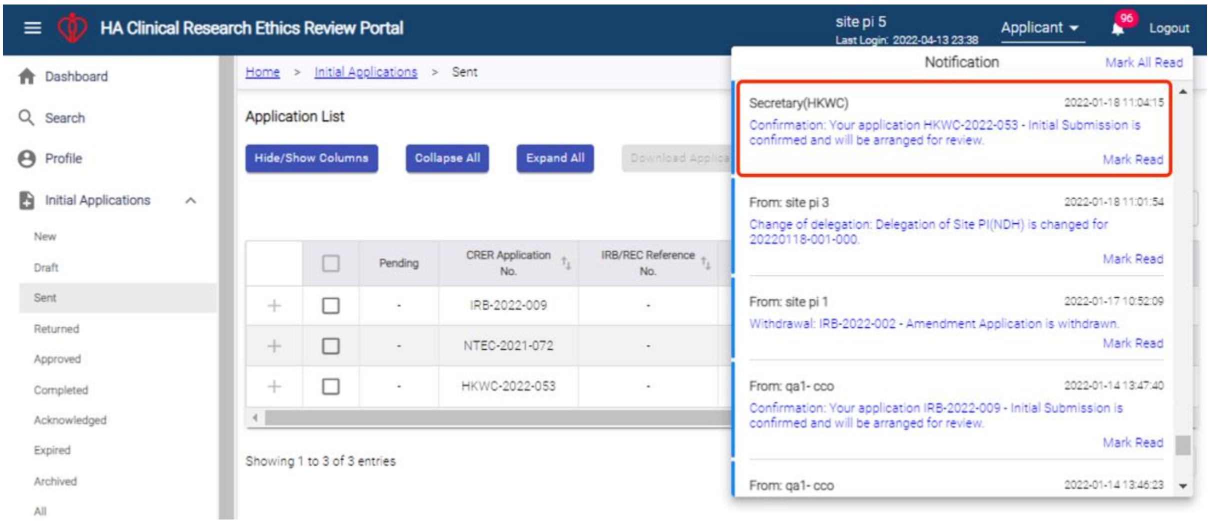


Figure 5.2.10.1 Notification of Confirmed Initial Application

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.

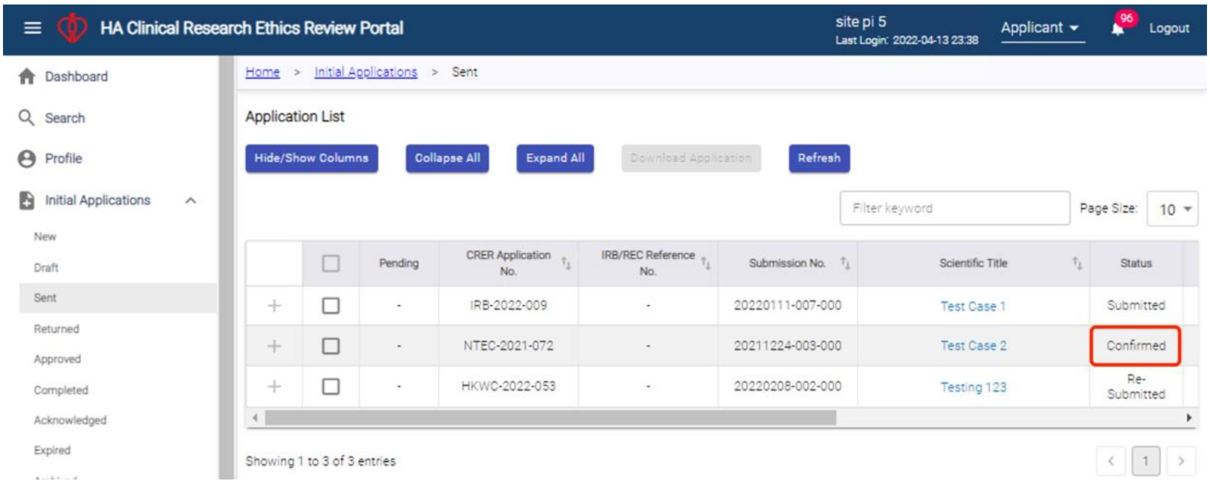


Figure 5.2.10.2 Confirmed Initial Application in “Sent” Application List

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

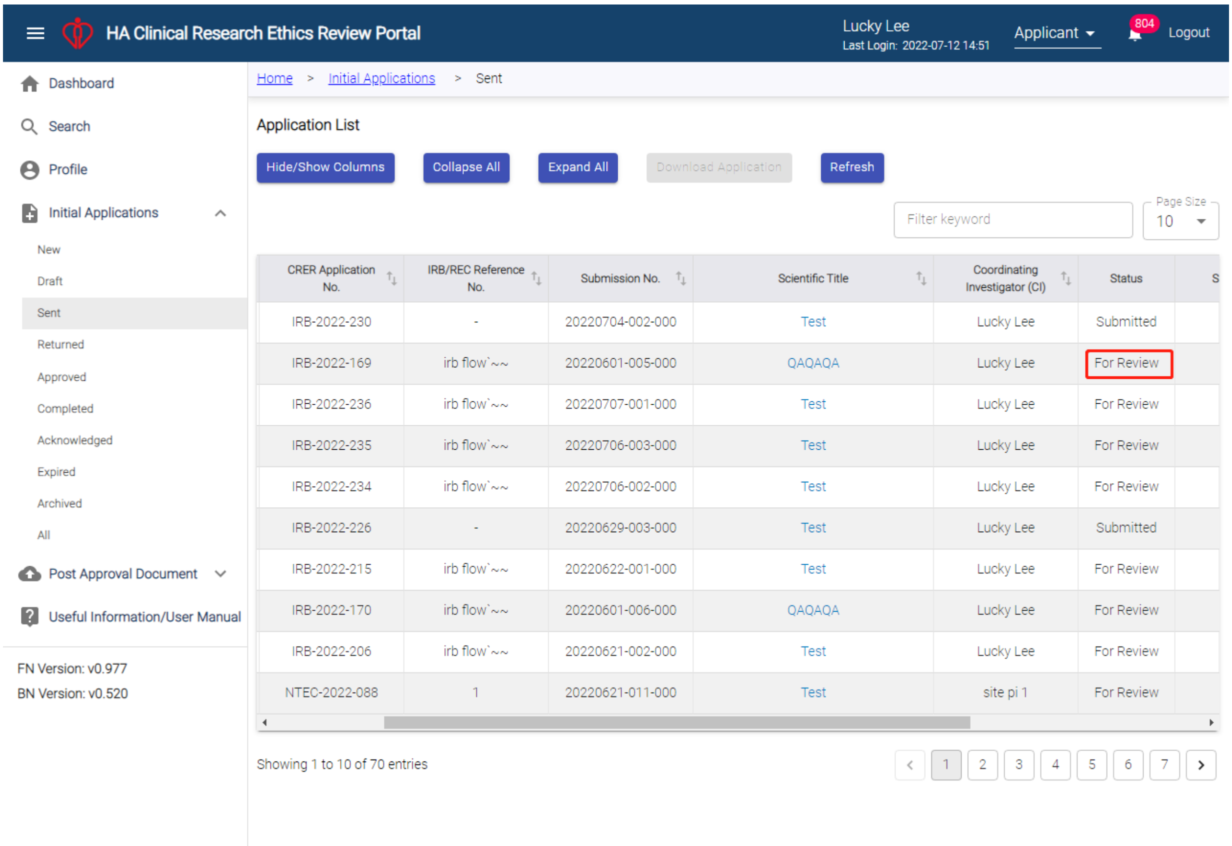


Figure 5.2.11.1 For Review Initial Applications in "Sent" Application List

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.

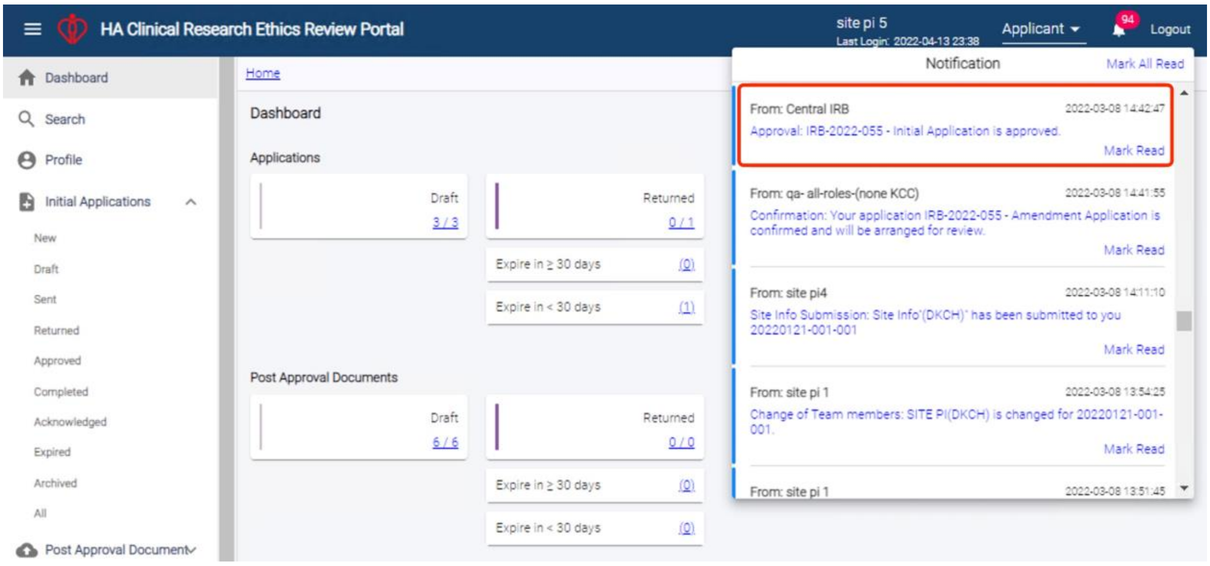


Figure 5.2.12.1 Notification of Approved Initial Application

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.

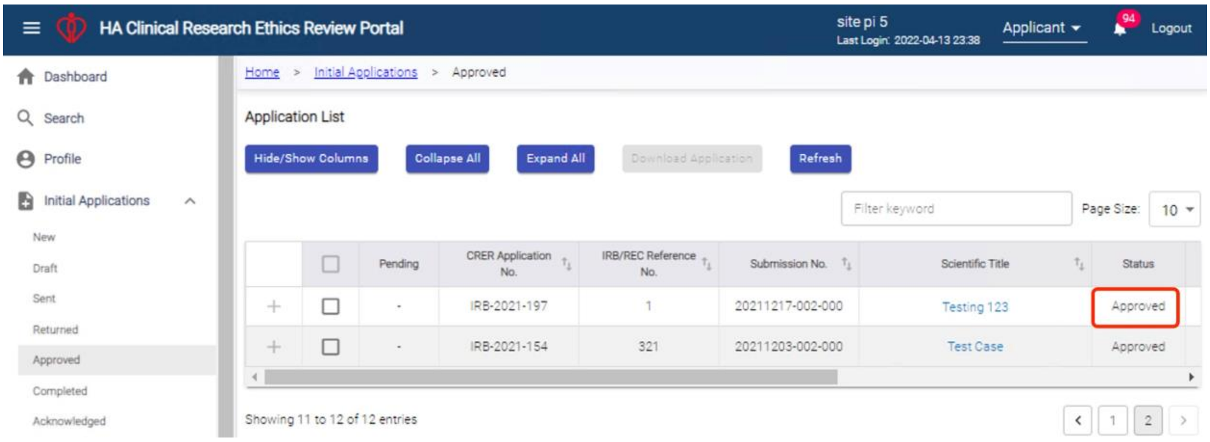


Figure 5.2.12.2 Approved Initial Application in “Approved” Application List

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.

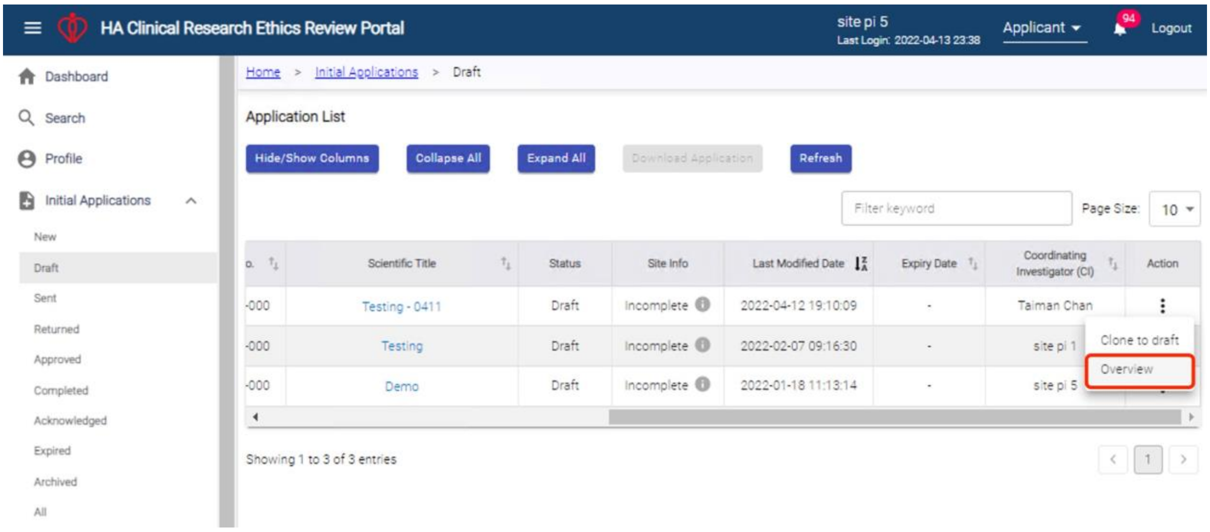


Figure 5.3.1 Screen of “Overview” button in Application List

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.

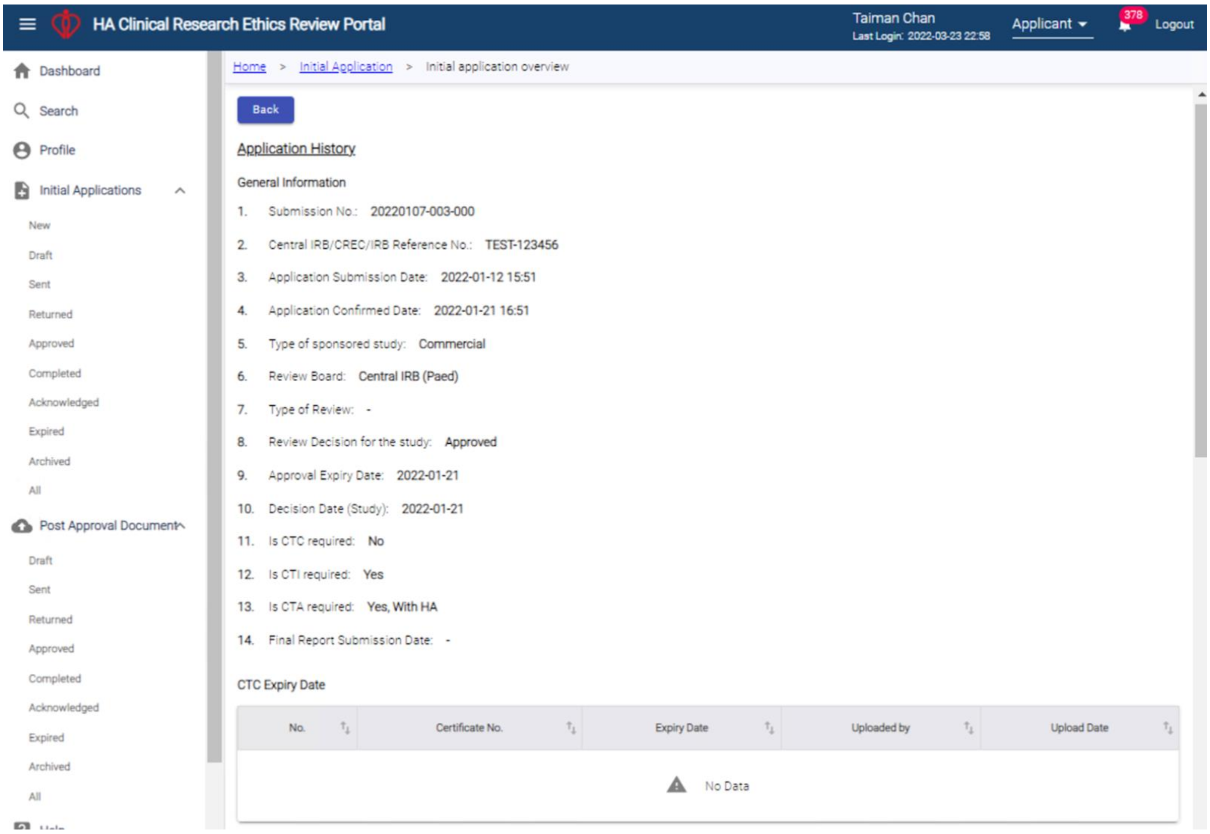


Figure 5.3.2 Screen of “Overview” Page of Initial Application

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:

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

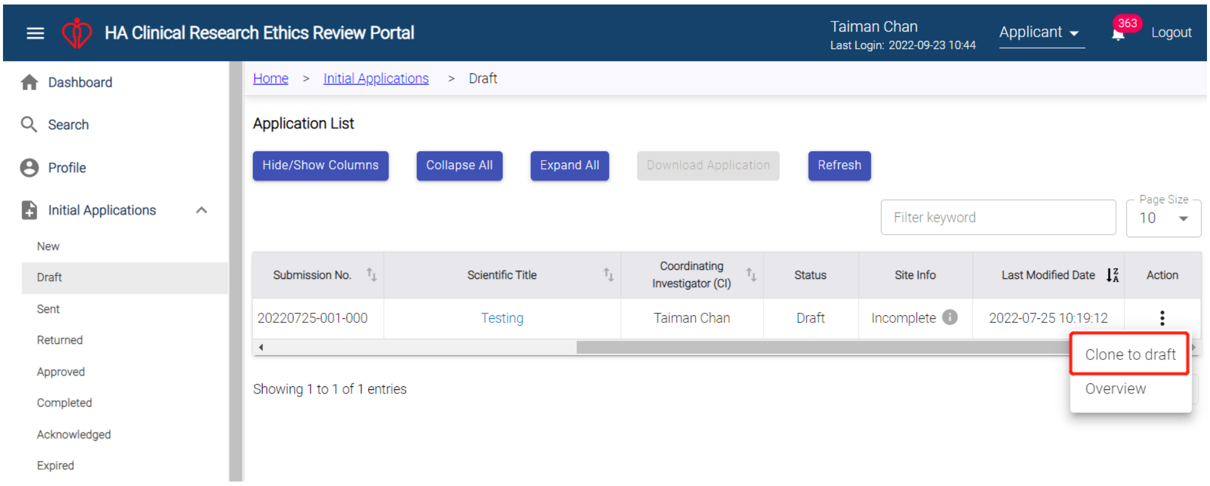


Figure 5.4.1 Screen of Clone to draft button in Application List

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;

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.>".

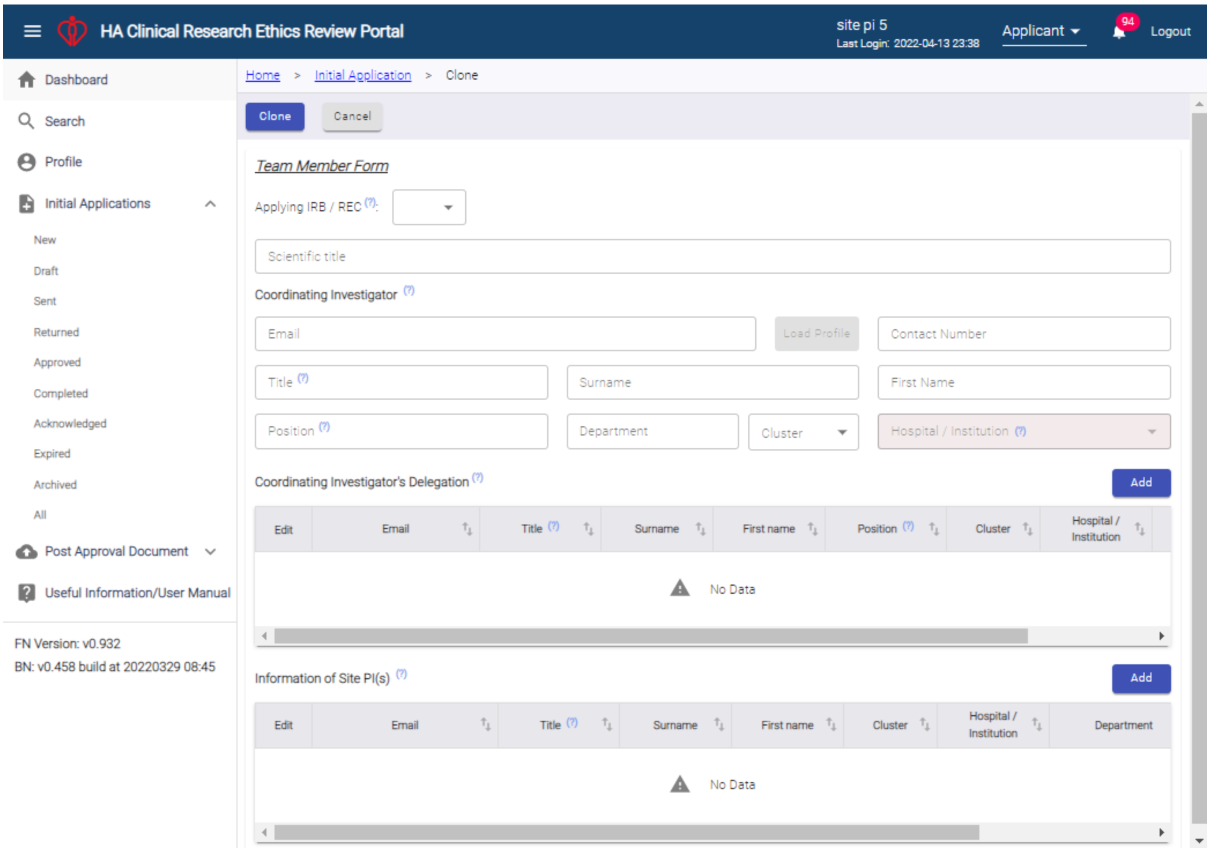


Figure 5.4.2 Team Member Form when "Cloning" Application

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:

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

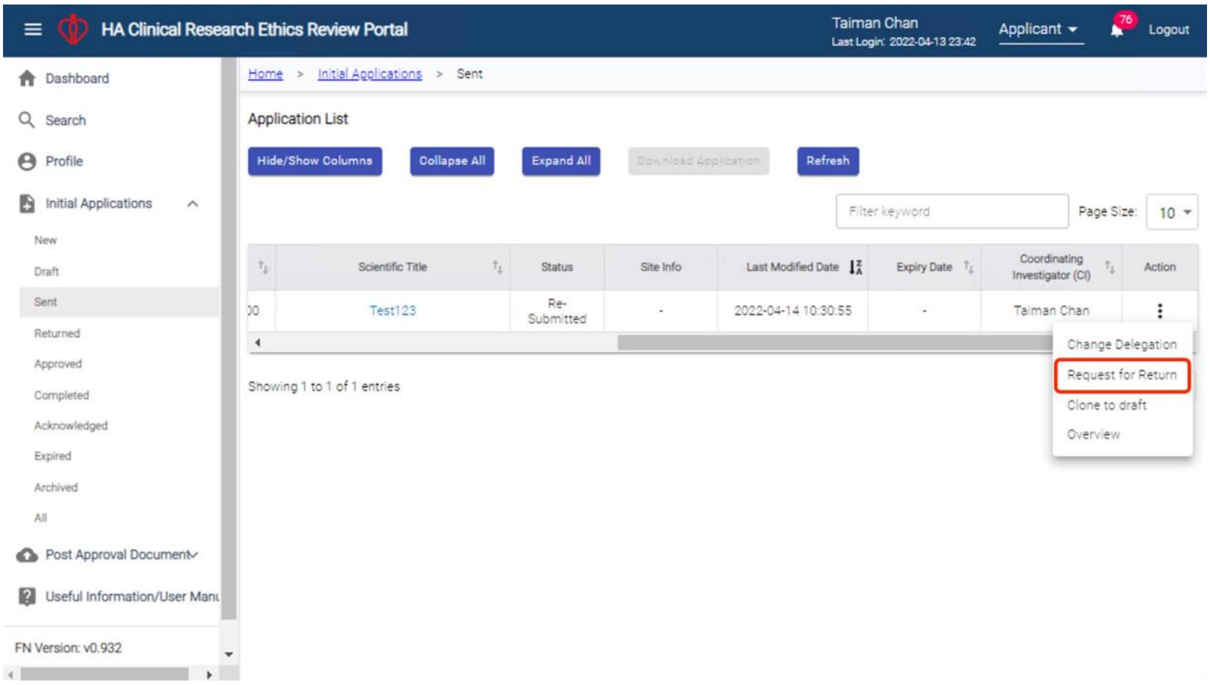


Figure 5.5.1.1 Screen of "Request for Return" button in "Sent" Application List

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;

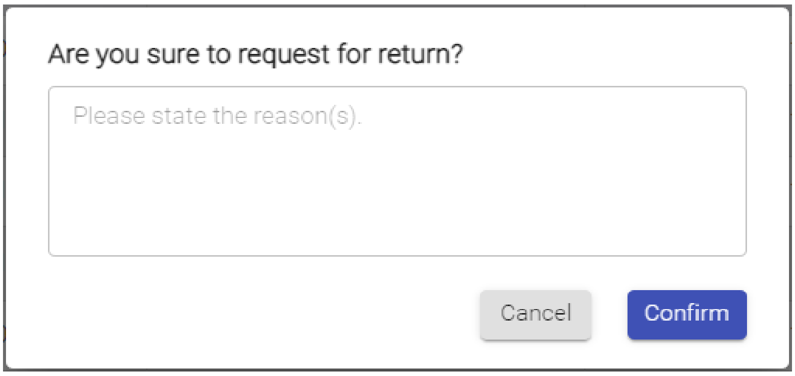


Figure 5.5.1.2 Pop-up dialog to proceed "Request for Return"

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;

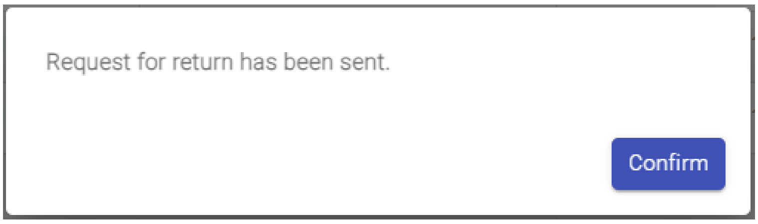


Figure 5.5.1.3 Pop-up dialog after "Request for Return"

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

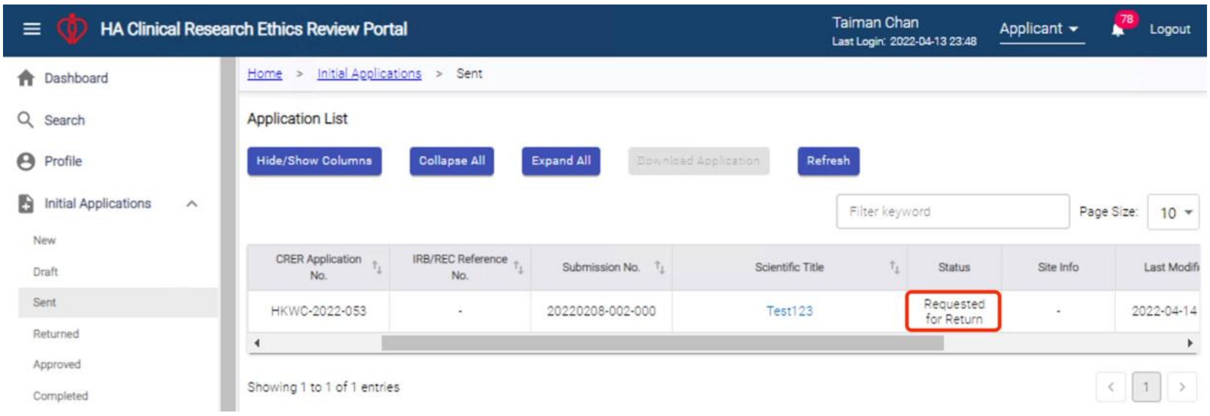


Figure 5.5.1.4 "Requested for Return" Status of the Initial Application

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 Returned Initial Application and Re-submit Initial Application

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

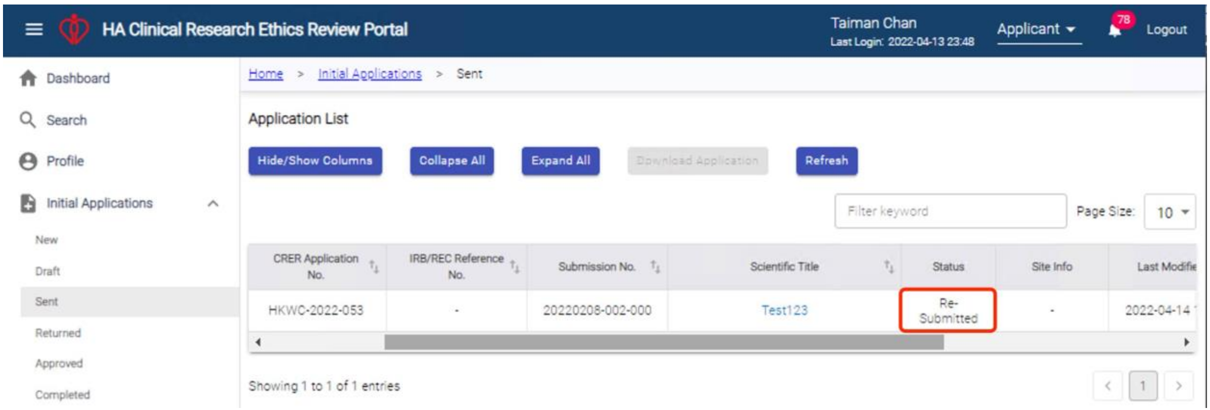


Figure 5.5.1.5 Screen of “Reject Request for Return” Initial Application in Sent Application List

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

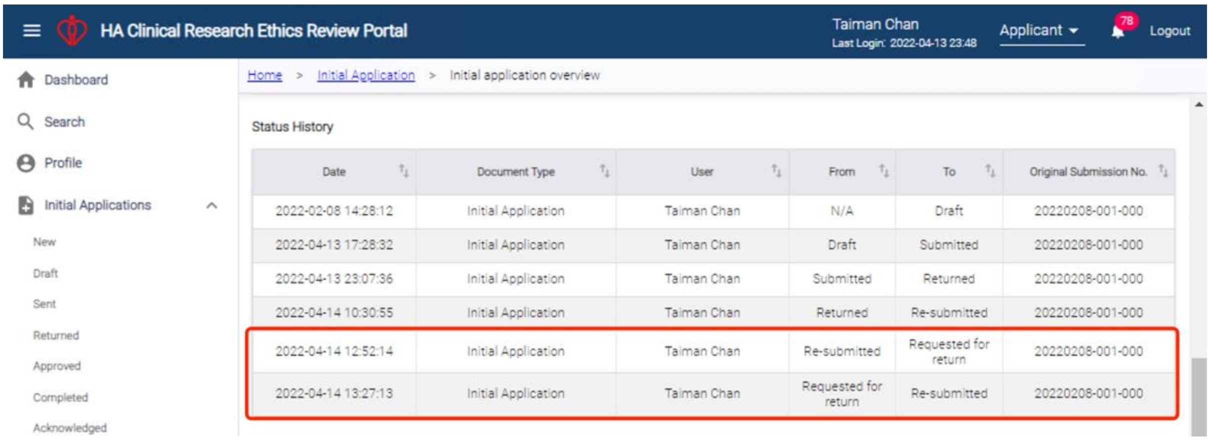


Figure 5.5.1.6 View the Status changes in Status History of Initial Application Overview

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.

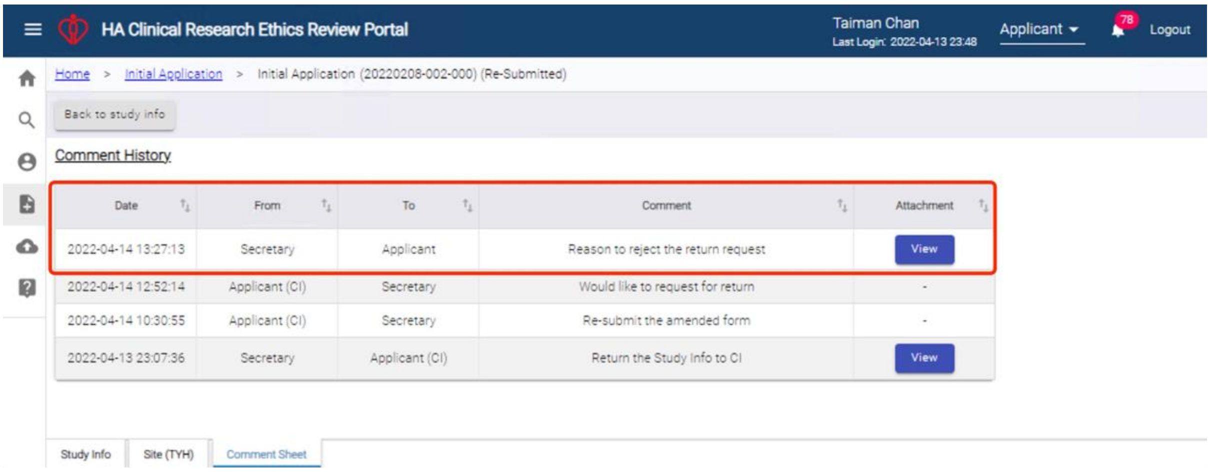


Figure 5.5.1.7 Comment tab of the Initial Application

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.

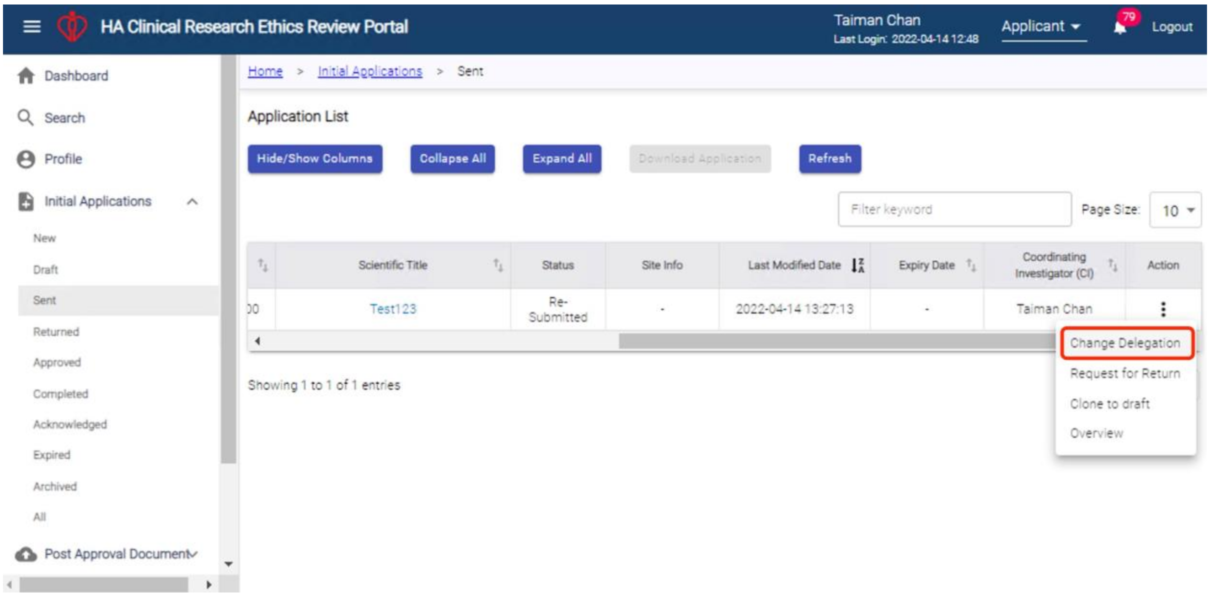


Figure 5.5.2.1 Screen of "Change Delegation" button in Application List

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. CI'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.

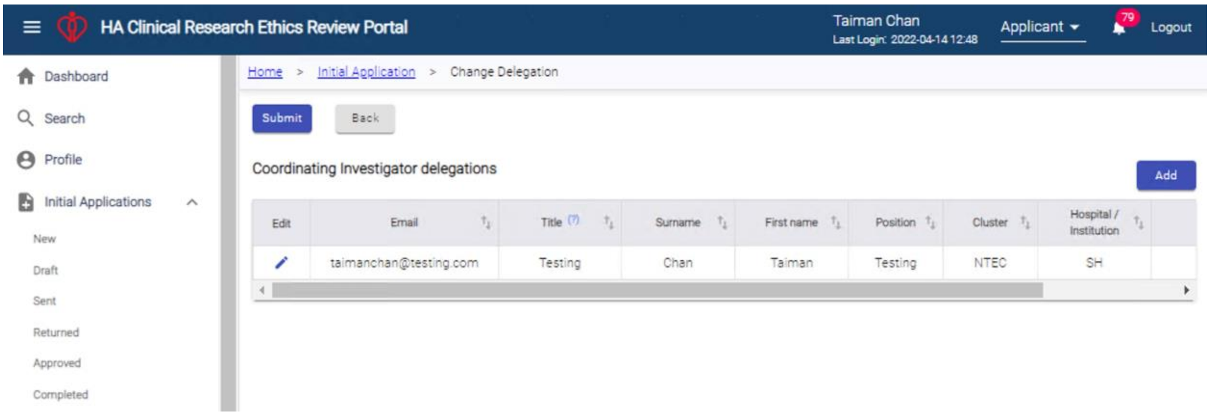


Figure 5.5.2.2 Page of "Change Delegation"

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

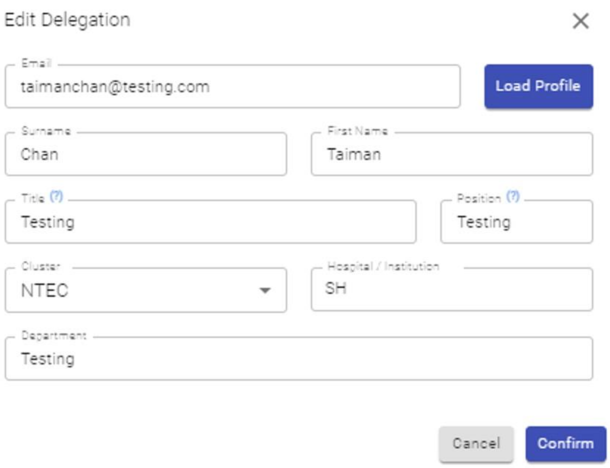


Figure 5.5.2.3 Pop-up Dialog for Editing CI's delegation

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

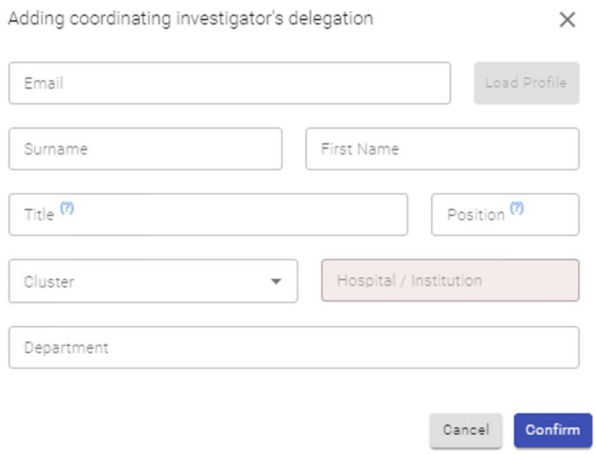


Figure 5.5.2.4 Pop-up Dialog for Adding CI's delegation

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;

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

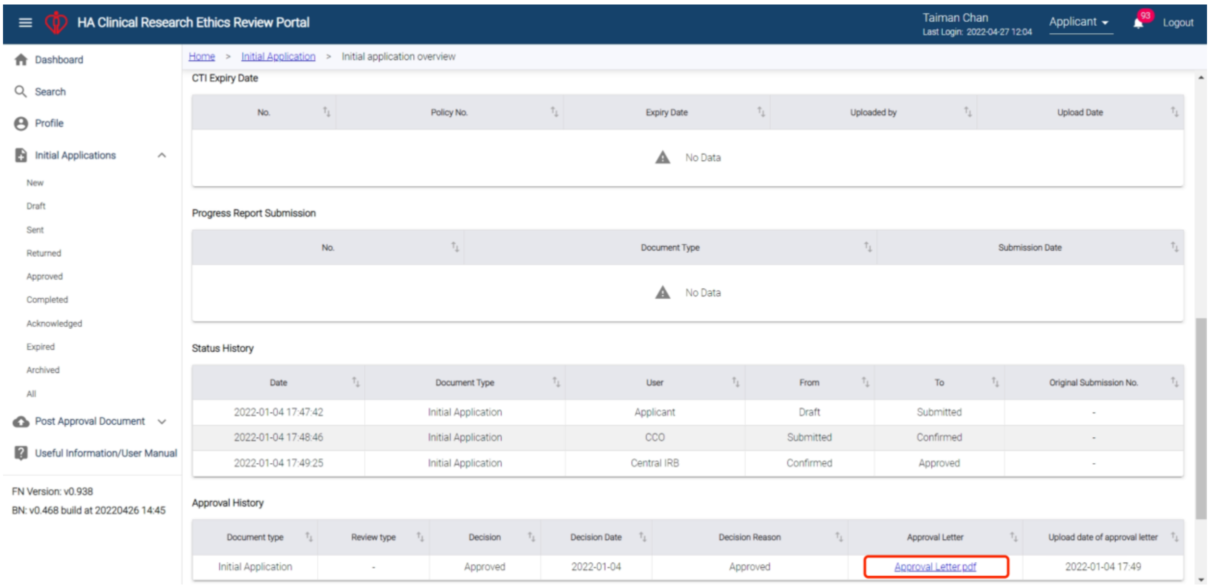


Figure 5.6.1 Approval Letter in Overview of Initial Application

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;

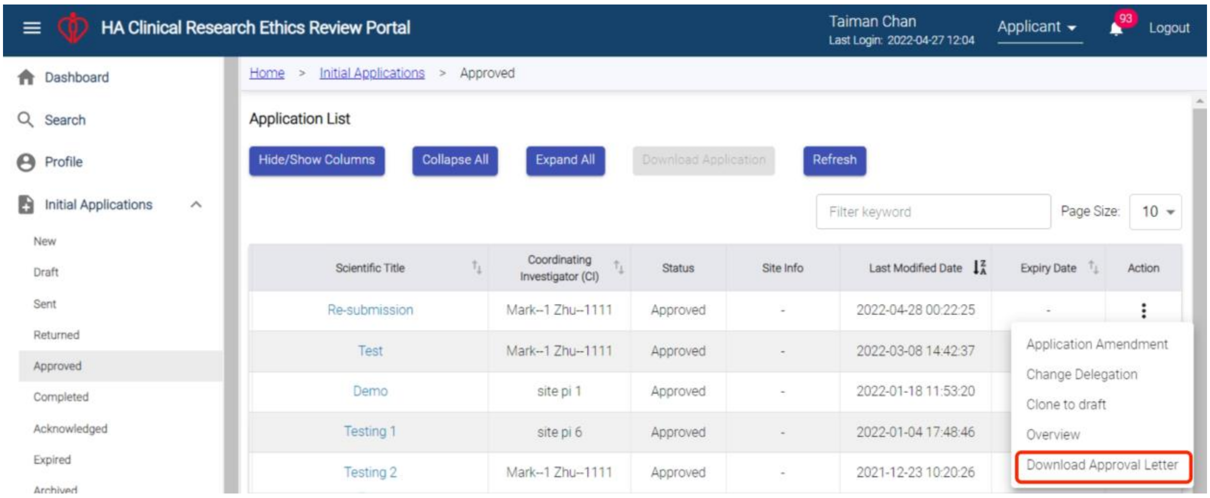


Figure 5.6.2 Screen of "Download Approval Letter" in Action Menu

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

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>.

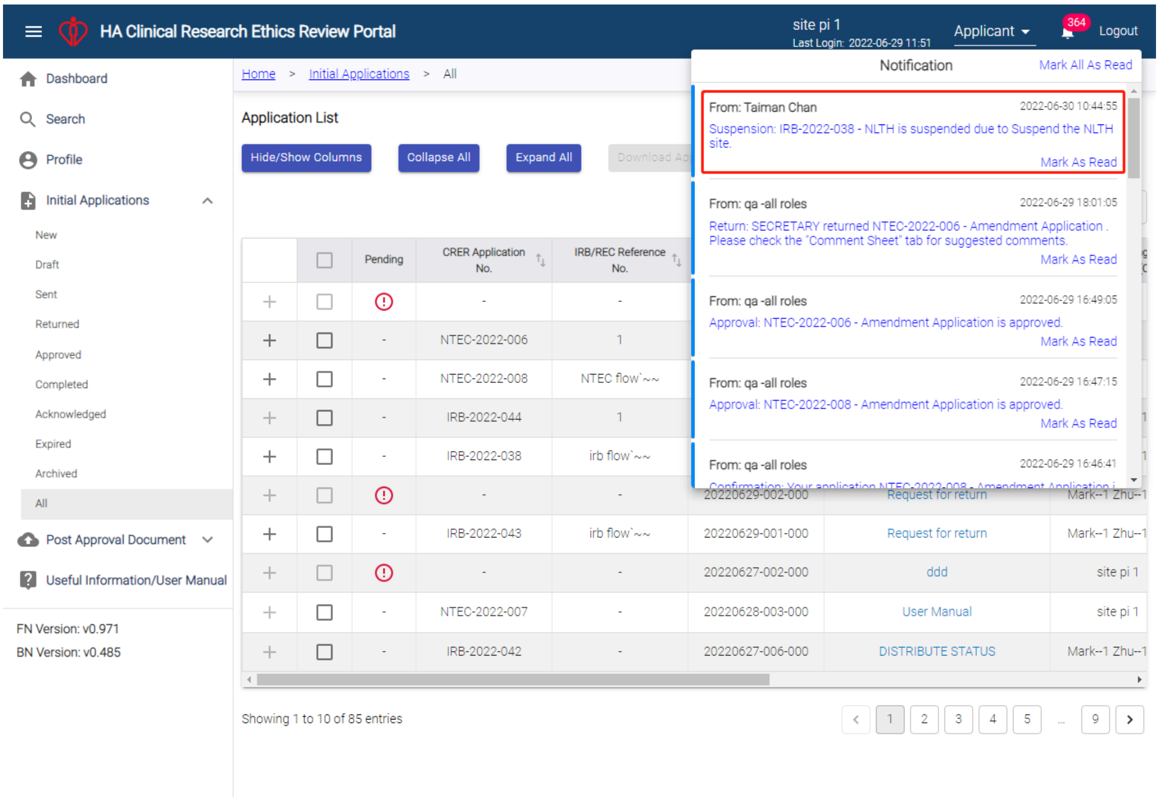


Figure 5.7.1 Notification of Suspending Study Site

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.

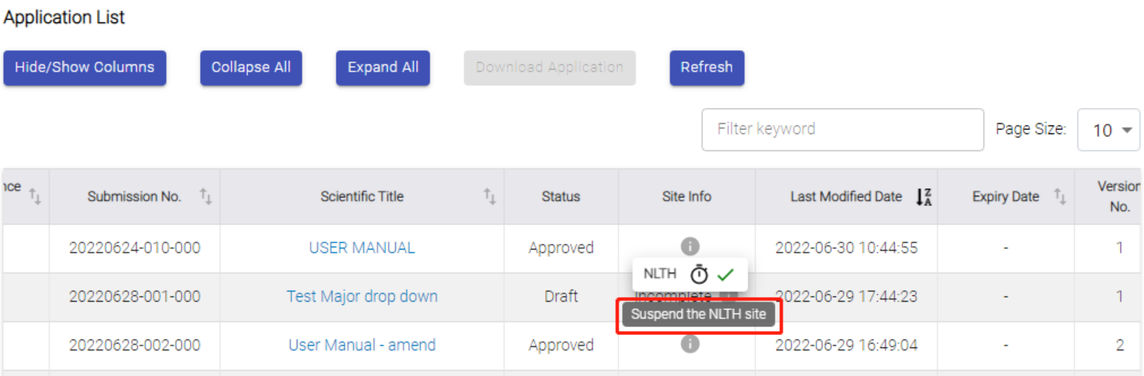
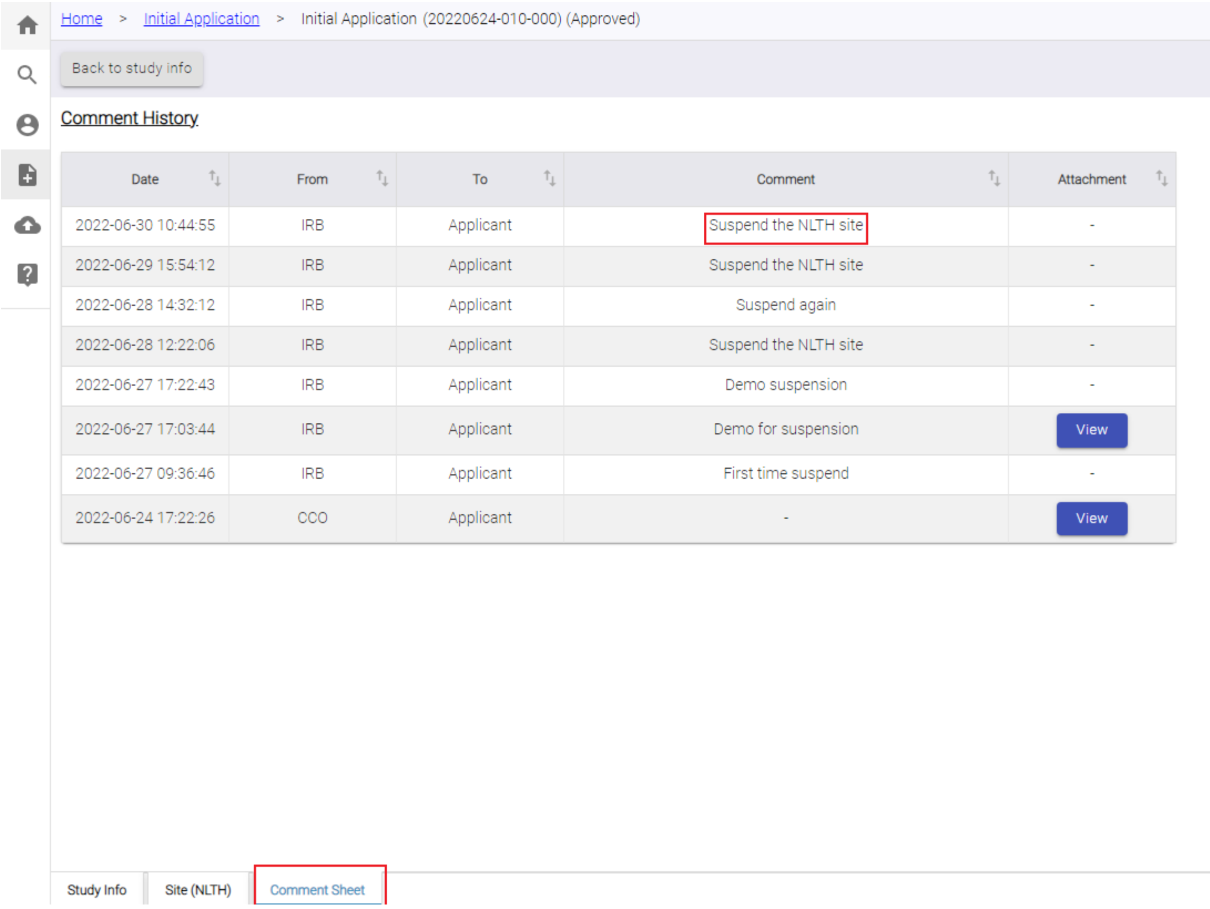


Figure 5.7.2 Tooltips of Suspension

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.



Date	From	To	Comment	Attachment
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.

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

<table>
<tr><th>Study/Site Base</th><th>Form/Report</th><th>CI/Delegate(s)</th><th>Site PI/Delegate(s)</th></tr>
<tr><td rowspan="5">Study Base (Study Info)</td><td>SUSAR Report</td><td rowspan="5">Create, Edit and Submit</td><td rowspan="5">View only</td></tr>
<tr><td>Miscellaneous Report</td></tr>
<tr><td>Amendment Application</td></tr>
<tr><td>Final Report</td></tr>
<tr><td>CTC/CTI Submission</td></tr>
<tr><td rowspan="5">Site Base (Site Info)</td><td>Progress Report</td><td rowspan="5">View only</td><td rowspan="5">Create, Edit and Submit</td></tr>
<tr><td>Local SAE Report</td></tr>
<tr><td>Miscellaneous Report</td></tr>
<tr><td>Protocol Deviation Report</td></tr>
<tr><td>Amendment Application</td></tr>
</table>

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);

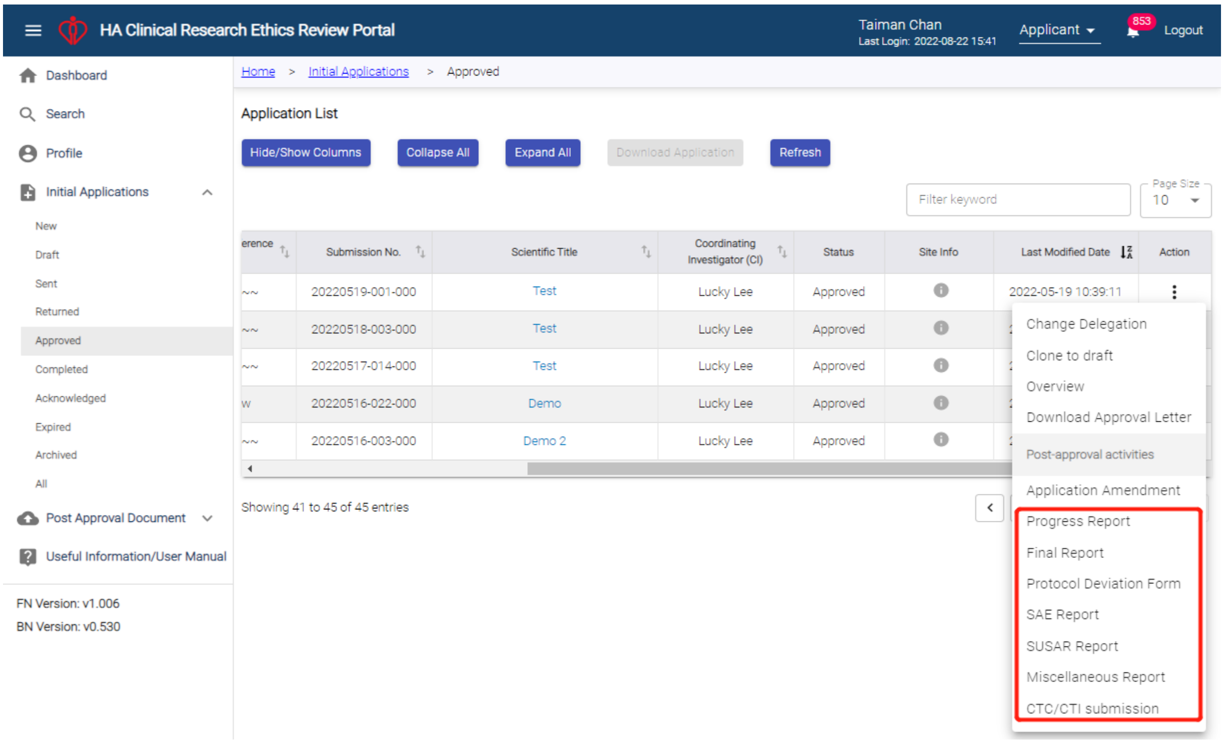


Figure 6.1.1.1.1 Post Approval Activities buttons of "Approved" Application List

3. 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;

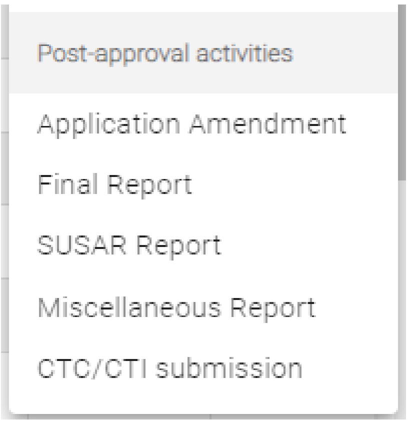


Figure 6.1.1.1.2 Post Approval Document Type button displayed for CI/Delegate(s)

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;

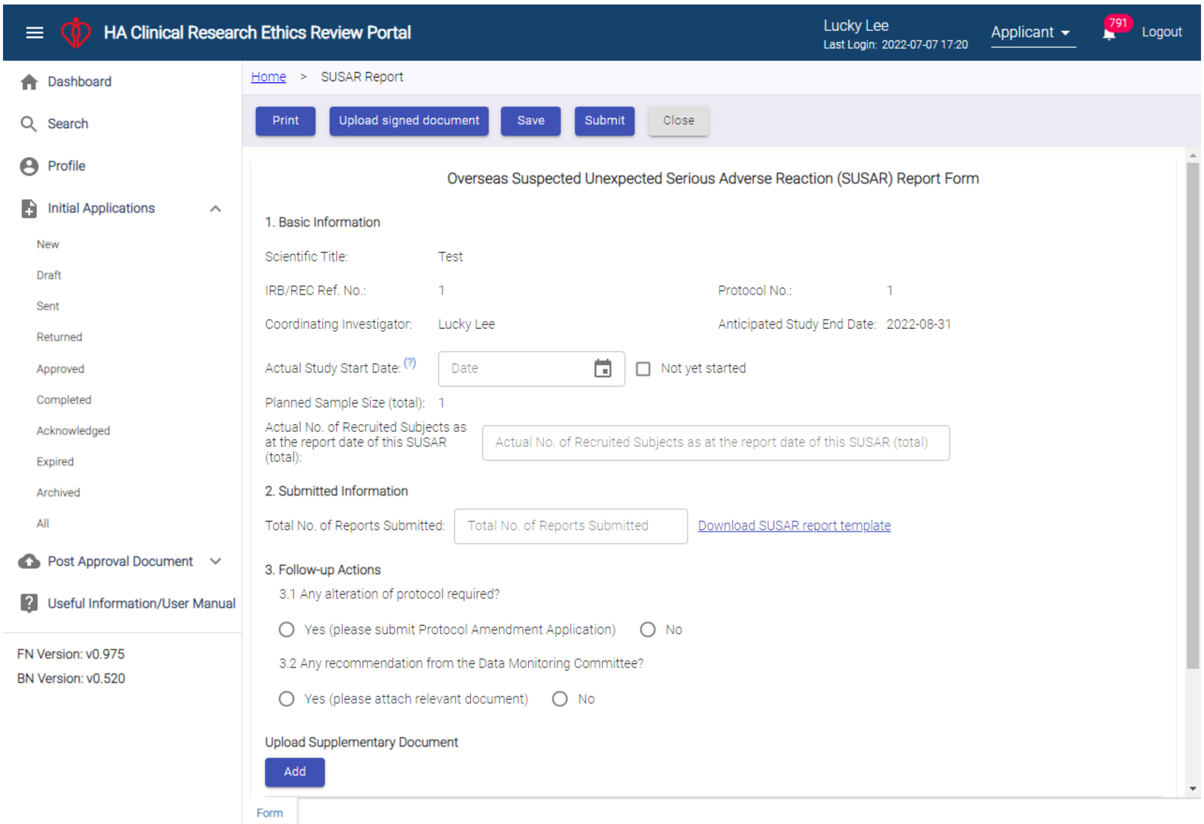


Figure 6.1.1.1.3 Report page of Study Base Post Approval Document

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

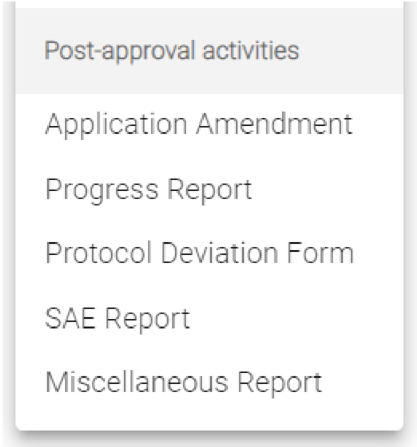


Figure 6.1.1.1.4 Post Approval Document Type button displayed for Site PI/Delegate(s)

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;

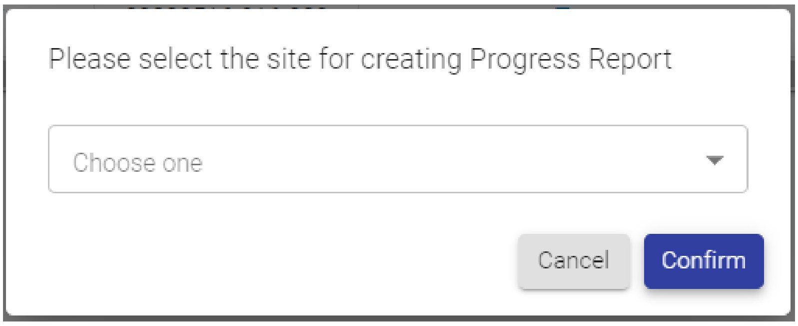


Figure 6.1.1.1.5 Dialog for choosing Site of Site Base Post Approval Document

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.

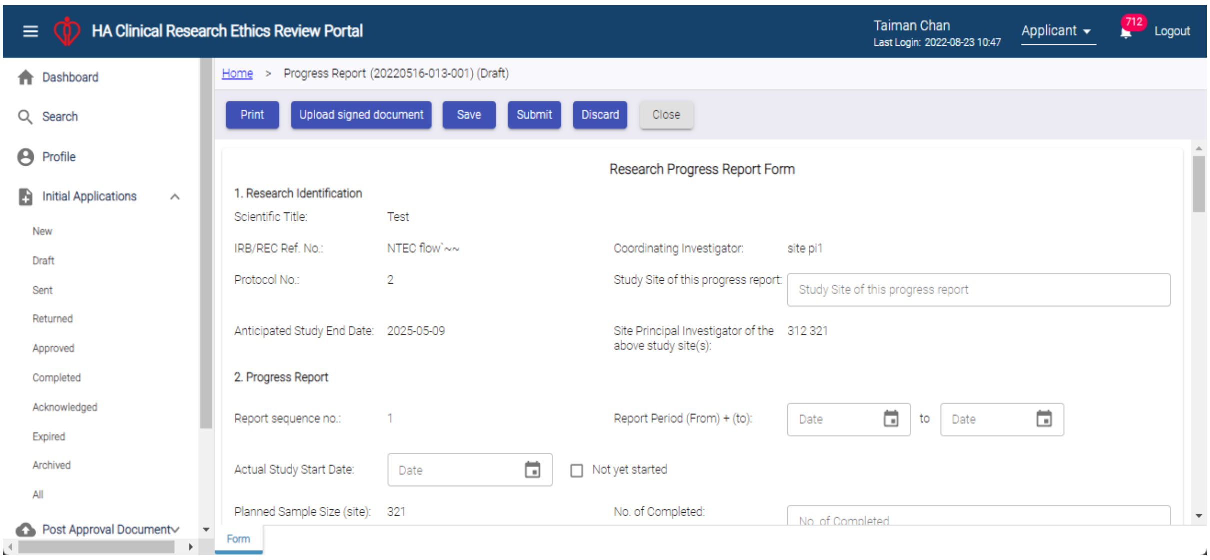


Figure 6.1.1.1.6 Report page of Site Base Post Approval Document

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.

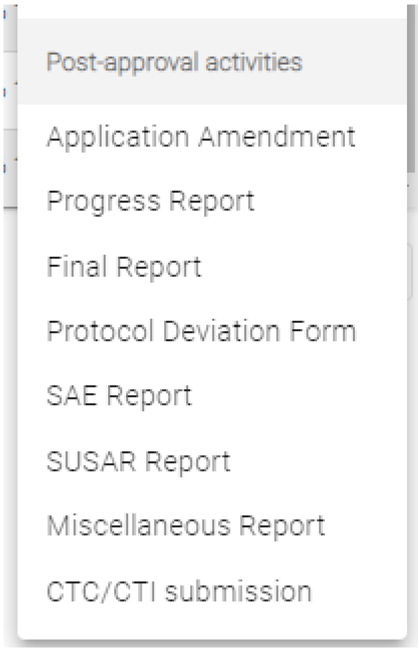


Figure 6.1.1.1.7 Post Approval Document Type button for both CI/Site PI and Delegate(s) of Site PI/CI

9. 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;

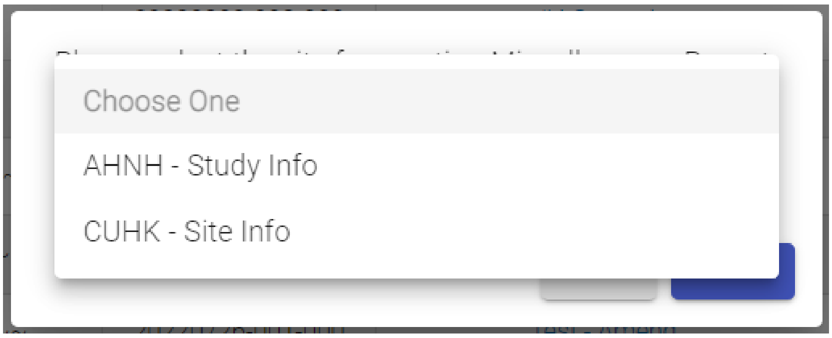


Figure 6.1.1.1.8 Dialog for choosing Site of Miscellaneous for both CI/Site PI and Delegate(s) of Site PI/CI

10. If other Study-based or Site-based reports are selected, it will follow the behaviour of <u>Step 3 – Step 4</u> or <u>Step 5 – Step 7</u> 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.

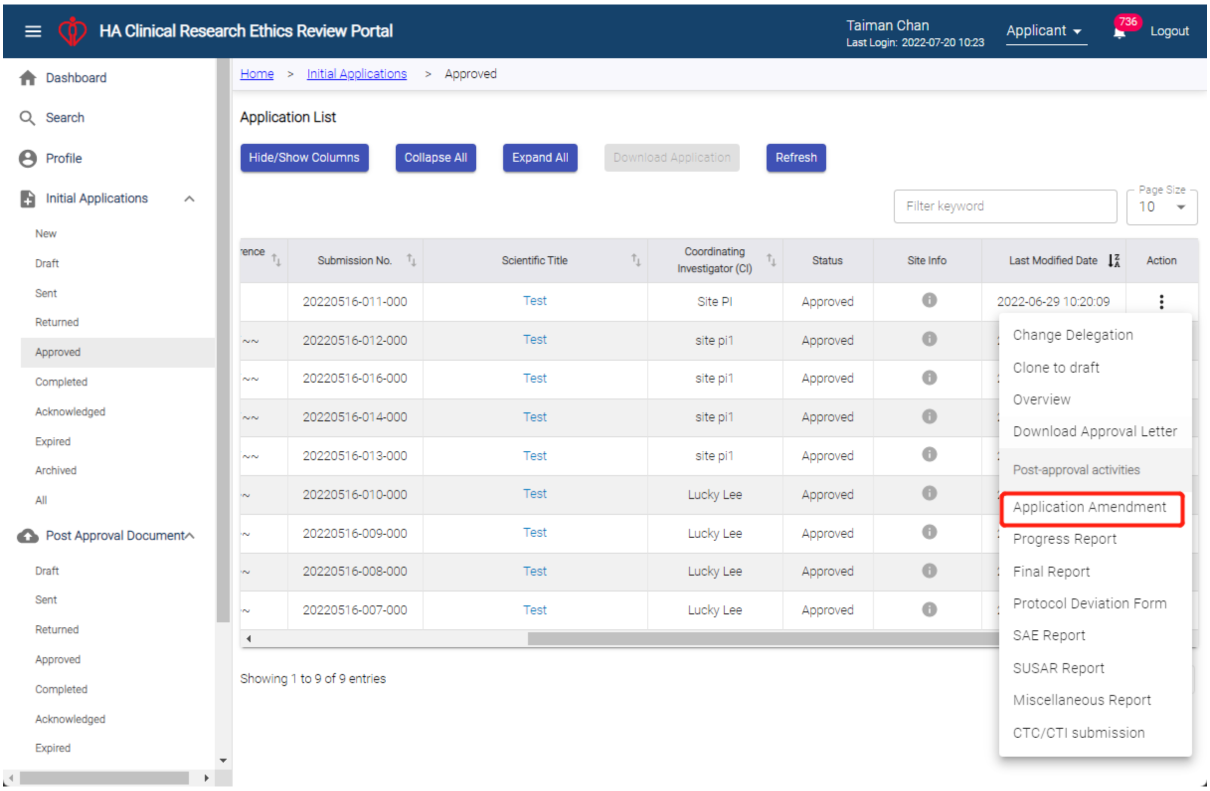


Figure 6.1.1.2.1 Application Amendment button of "Approved" Application List

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;

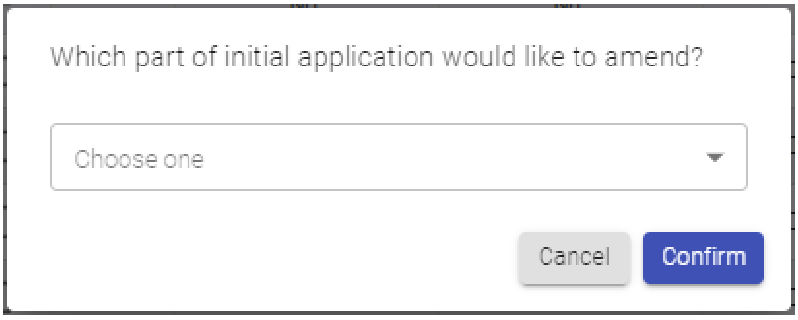


Figure 6.1.1.2.2 Pop-up dialog of choosing which part to amend

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;

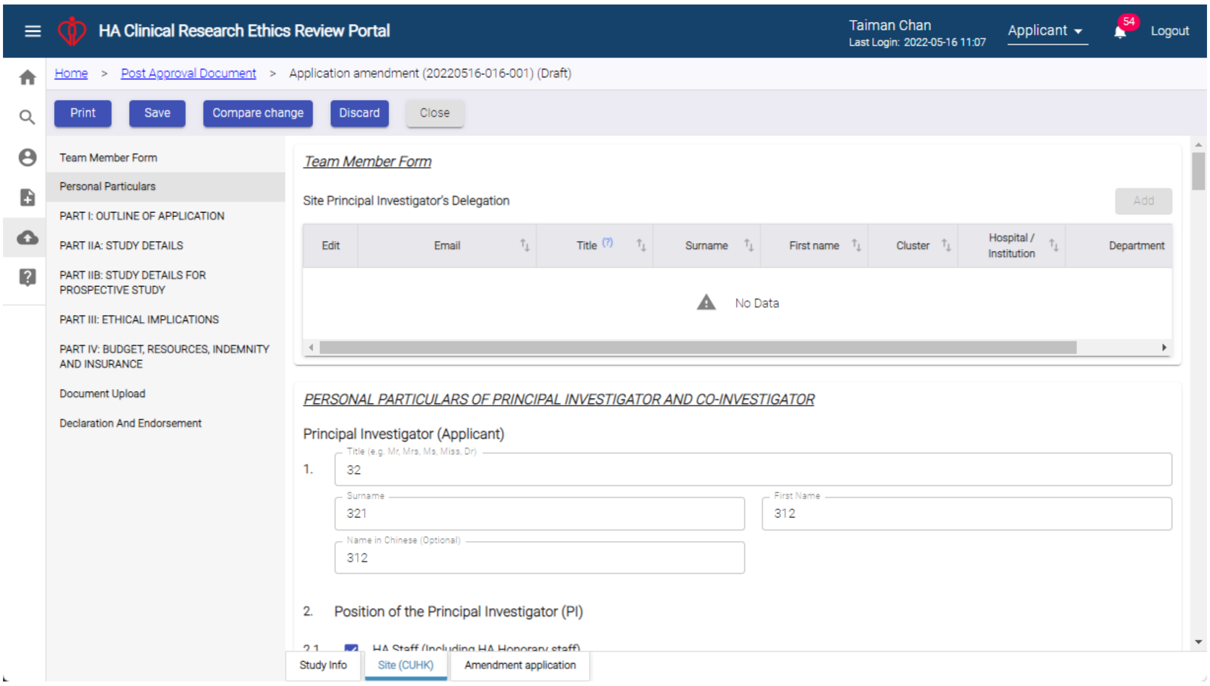


Figure 6.1.1.2.4 Editable tab of Application Amendment Form

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;

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.)

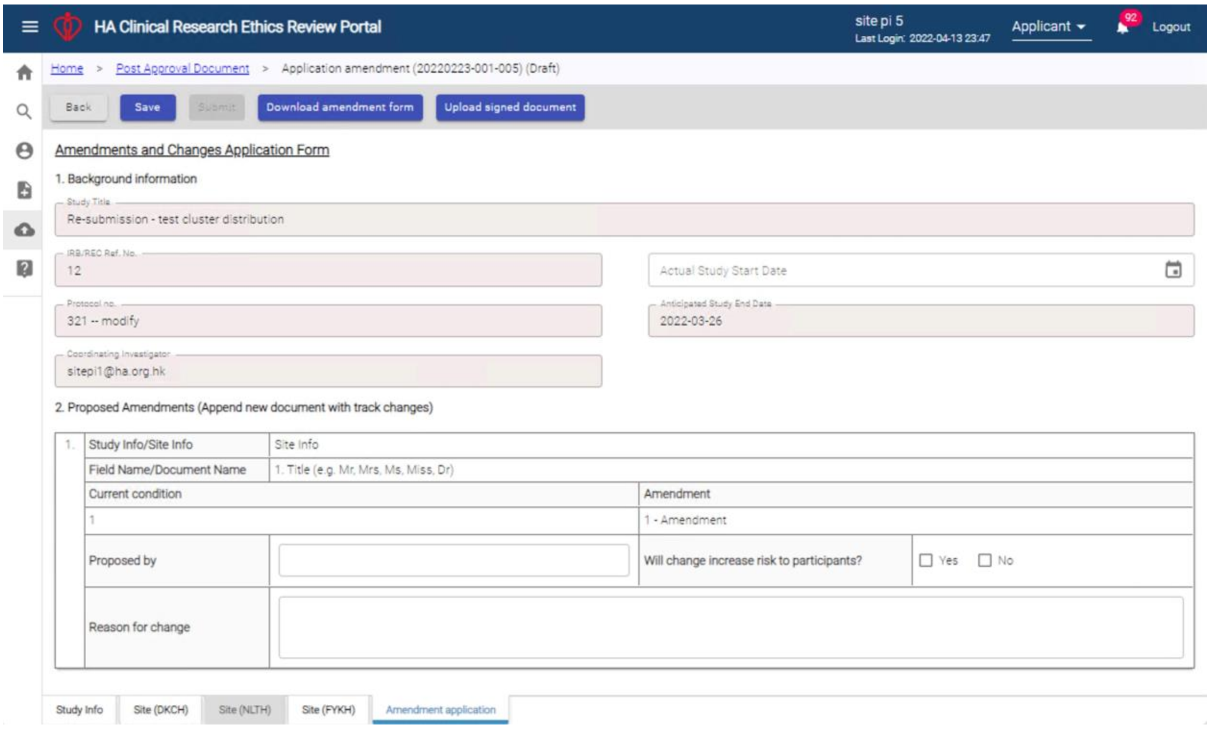


Figure 6.1.1.2.6 Amendments and Changes Application Form

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 "Compare" next to "Amendment" of 2. Proposed Amendments table to view changes in pop-up dialog as Figure 6.1.1.2.7 if needed;

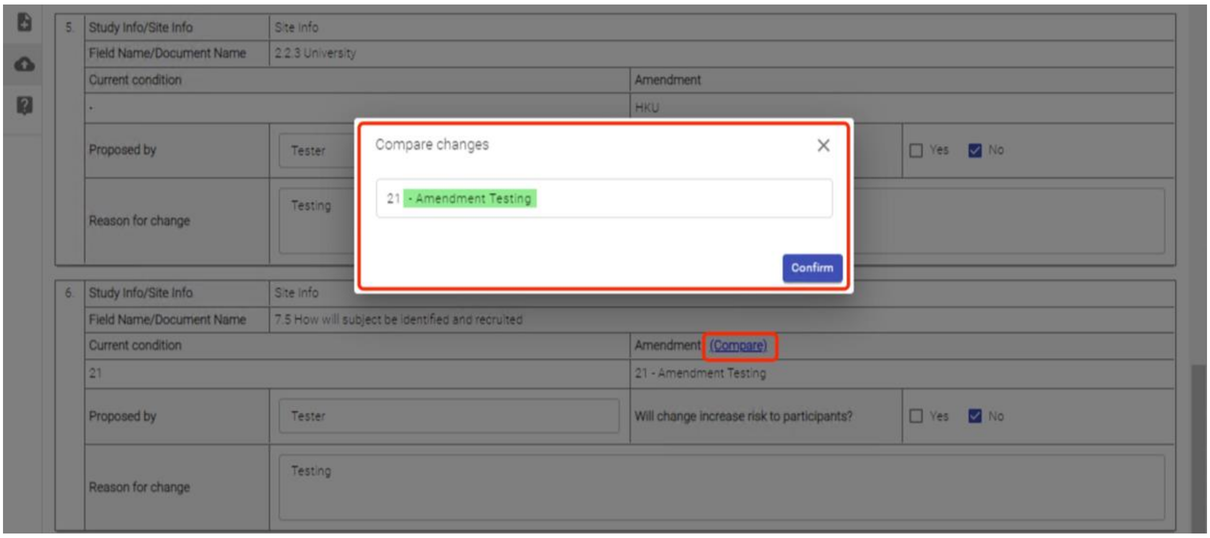


Figure 6.1.1.2.7 Pop-up dialogs of "Compare Changes"

13. Input the Proposed Person in "Proposed by" and Reason in "Reason for change" in the textbox;
14. 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.

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;

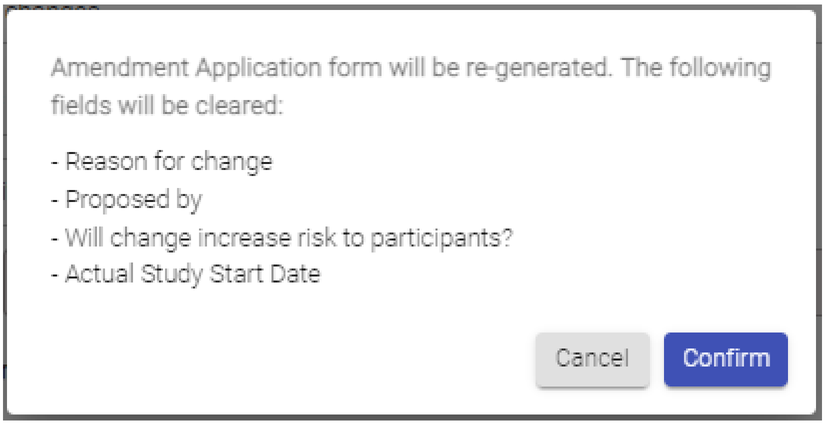


Figure 6.1.1.2.9 Dialog of regenerating the Amendment Application Form

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;

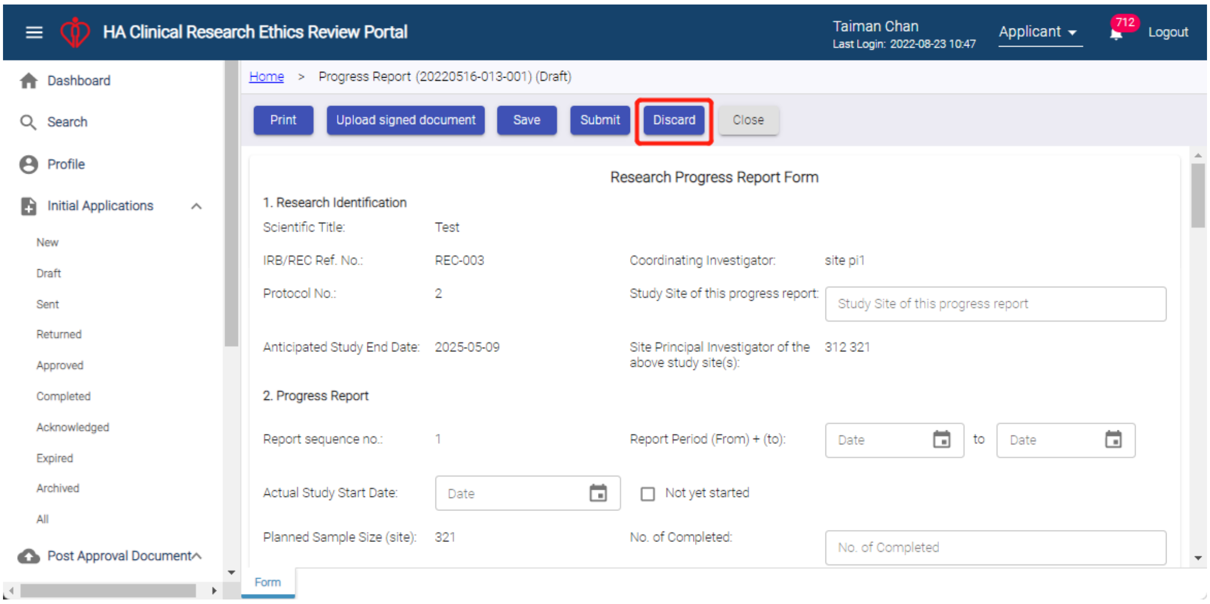


Figure 6.1.2.1 Discard button in the Draft Post Approval Document

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

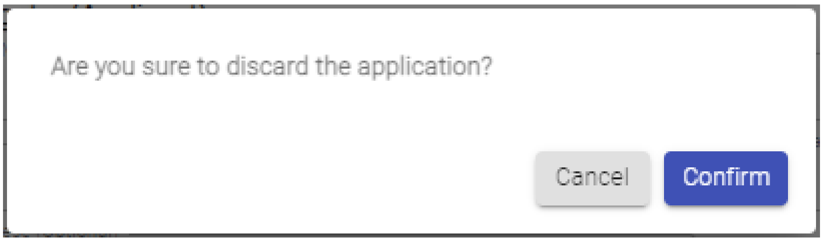


Figure 6.1.2.2 Popup dialog before discarding Post Approval Document

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;

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;

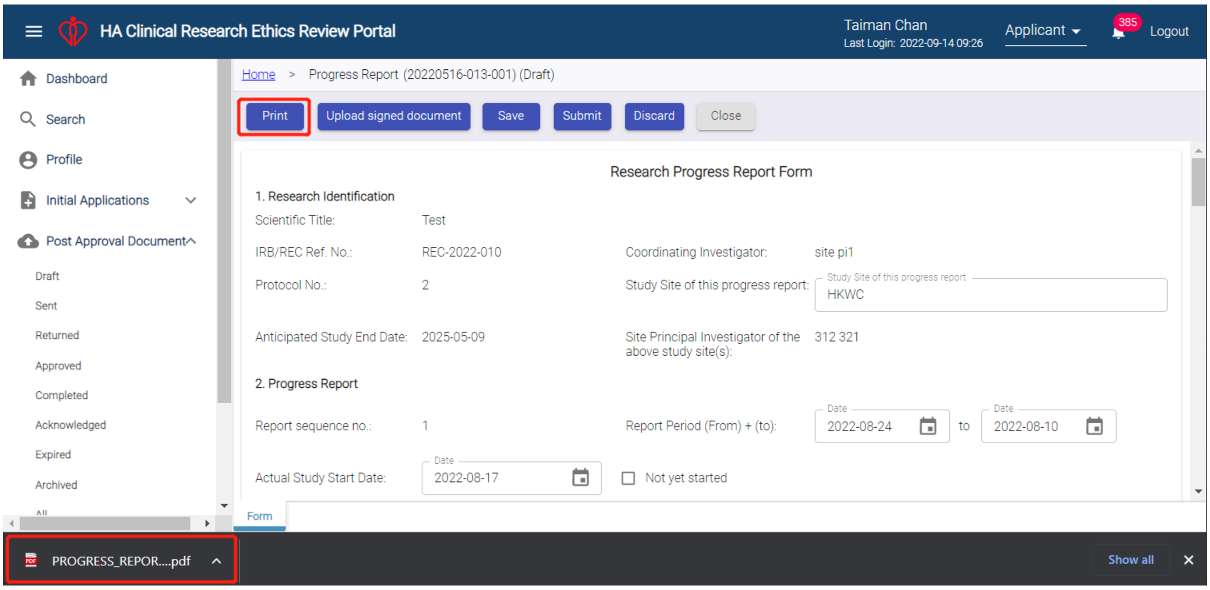


Figure 6.1.3.1.1 Download report in PDF format for signature

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;

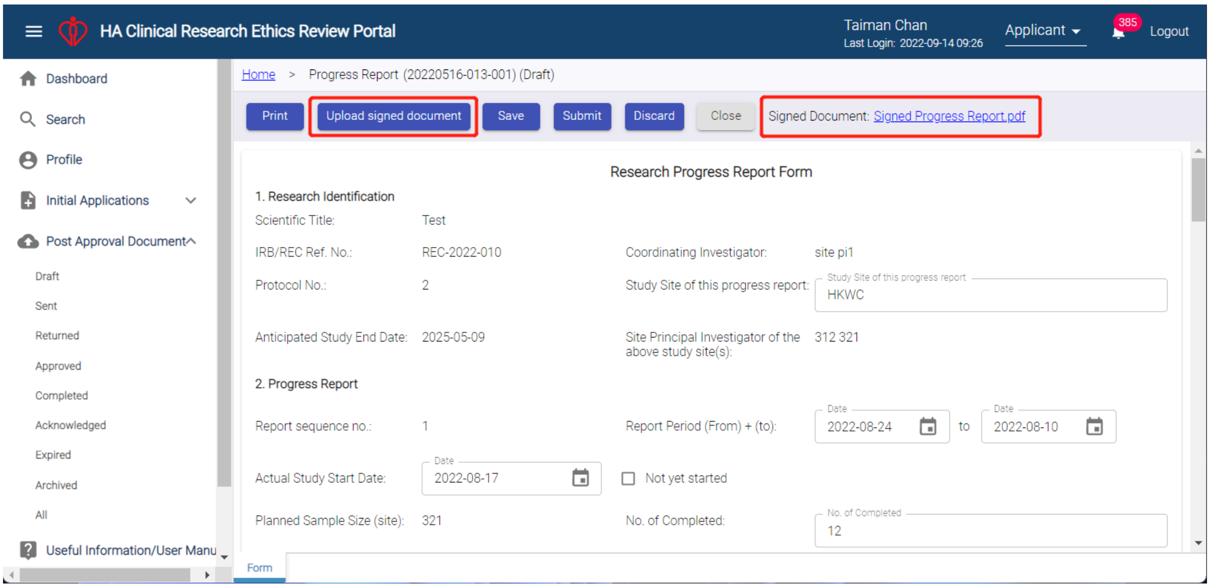


Figure 6.1.3.1.2 Screen of the uploaded signed file

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.

1. 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;

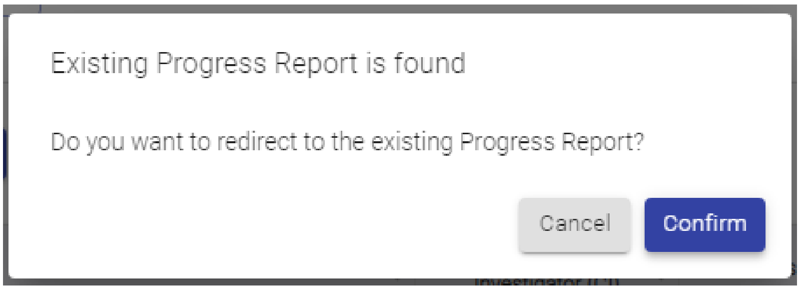


Figure 6.1.3.2.5 Pop-up dialog of redirecting to the existing report

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;

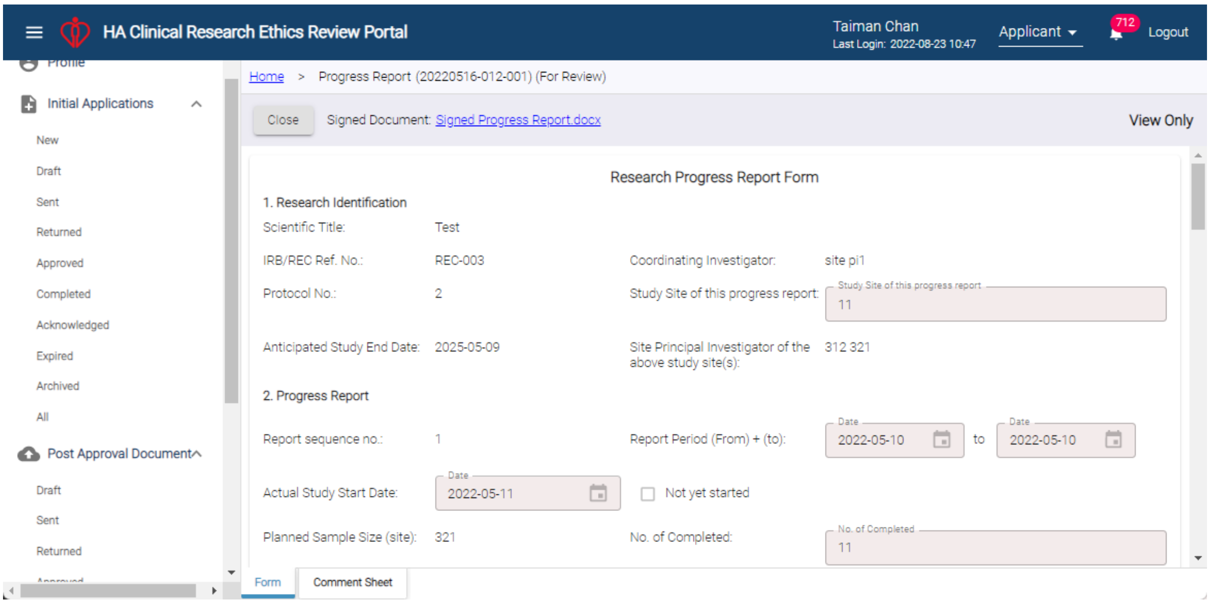


Figure 6.1.3.2.6 View-only mode of the submitted report

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 Request for Return of Post Approval Document.

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;

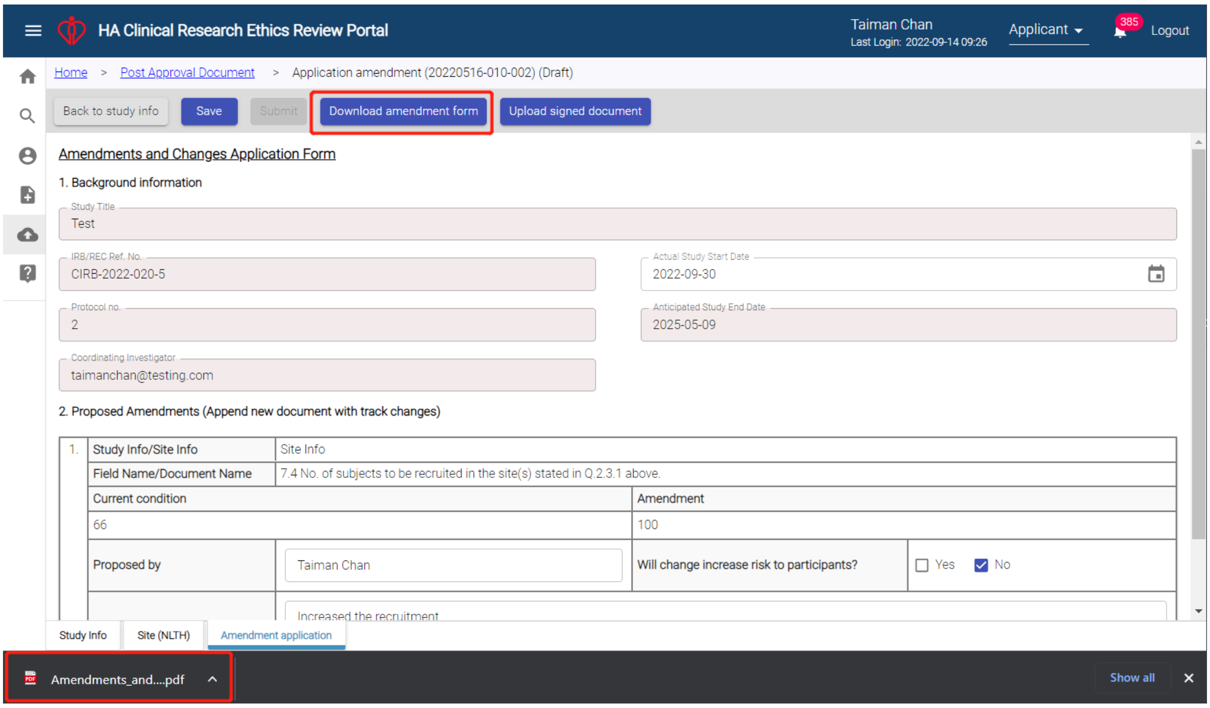


Figure 6.1.3.2.1 Screen of downloading Amendment form in PDF format

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

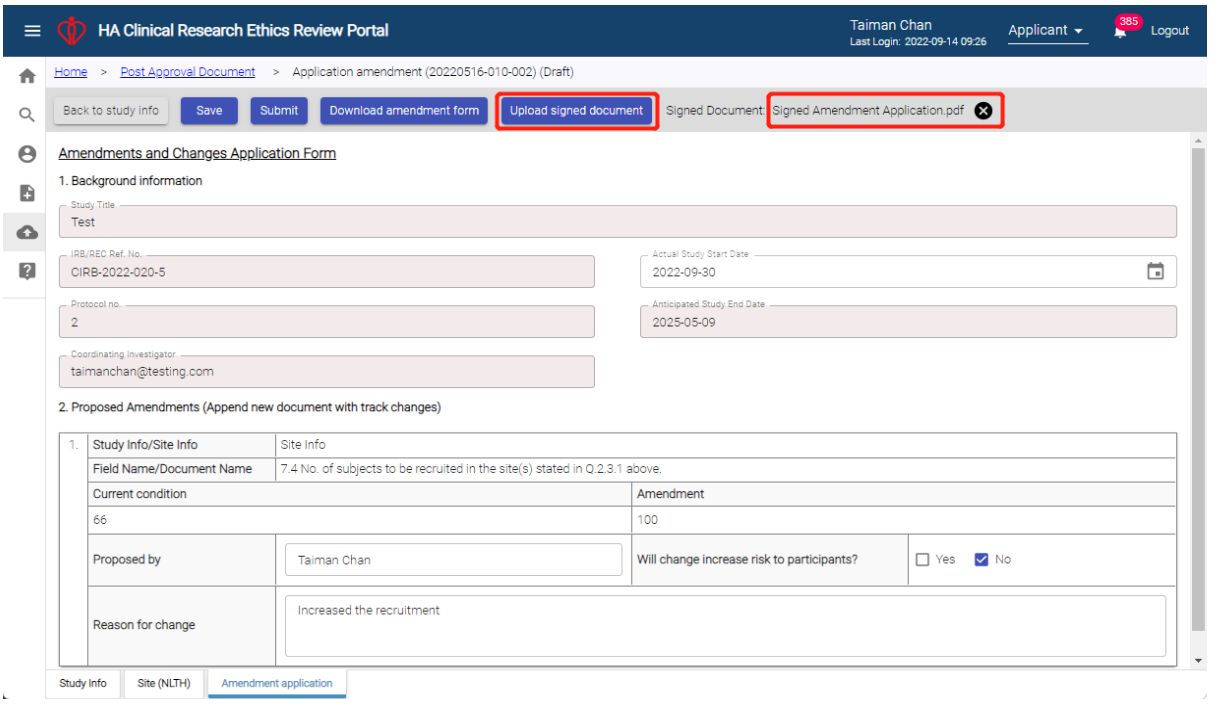


Figure 6.1.3.2.2 Screen of uploading Amendment form before pressing Save button

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

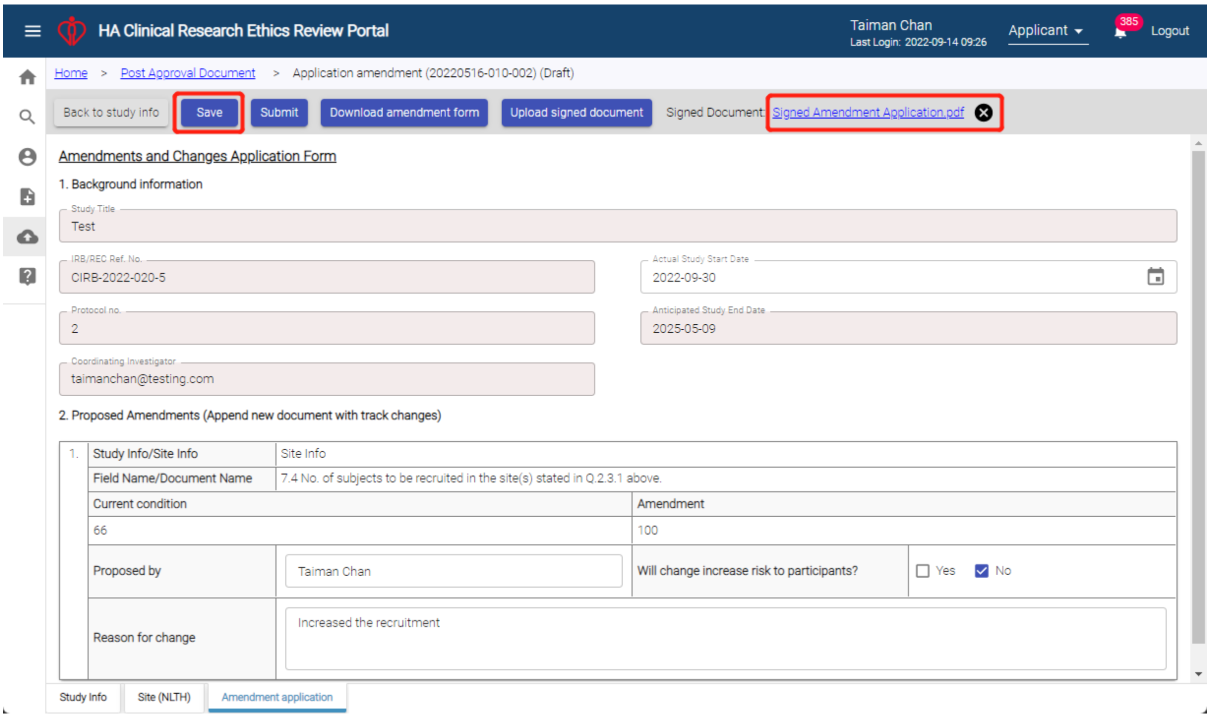


Figure 6.1.3.2.3 Hyperlink to download the Signed form after pressing Save button

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;

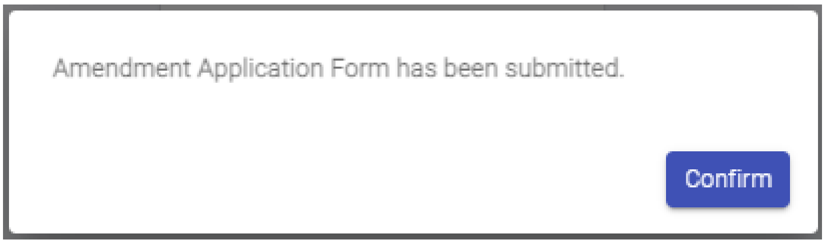


Figure 6.1.3.2.5 Dialog after Application Amendment is submitted

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;

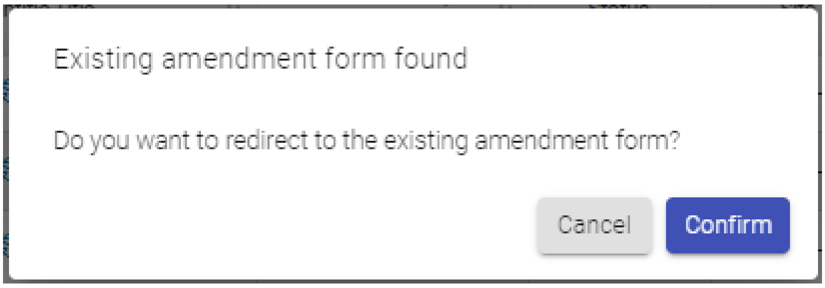


Figure 6.1.3.2.6 Pop-up dialog of redirecting to the existing amendment form

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;

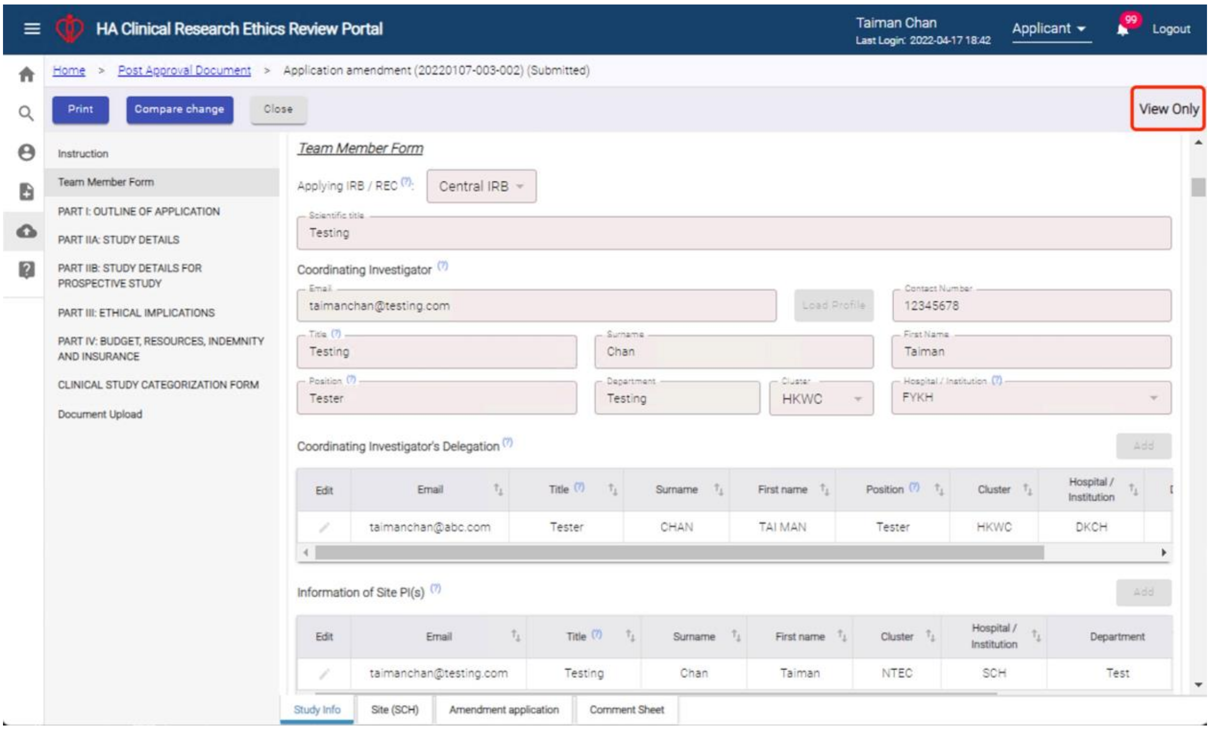


Figure 6.1.3.2.7 View-only mode of the Application Amendment

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 Request for Return of Application Amendment.

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.

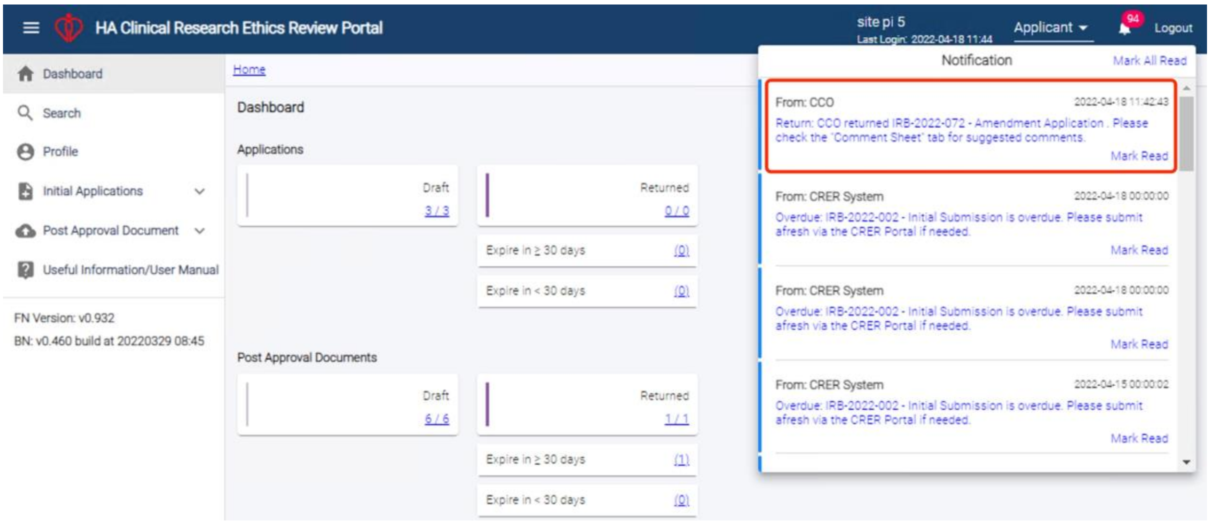


Figure 6.1.4.1 Notification for Returned Post Approval Document

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.

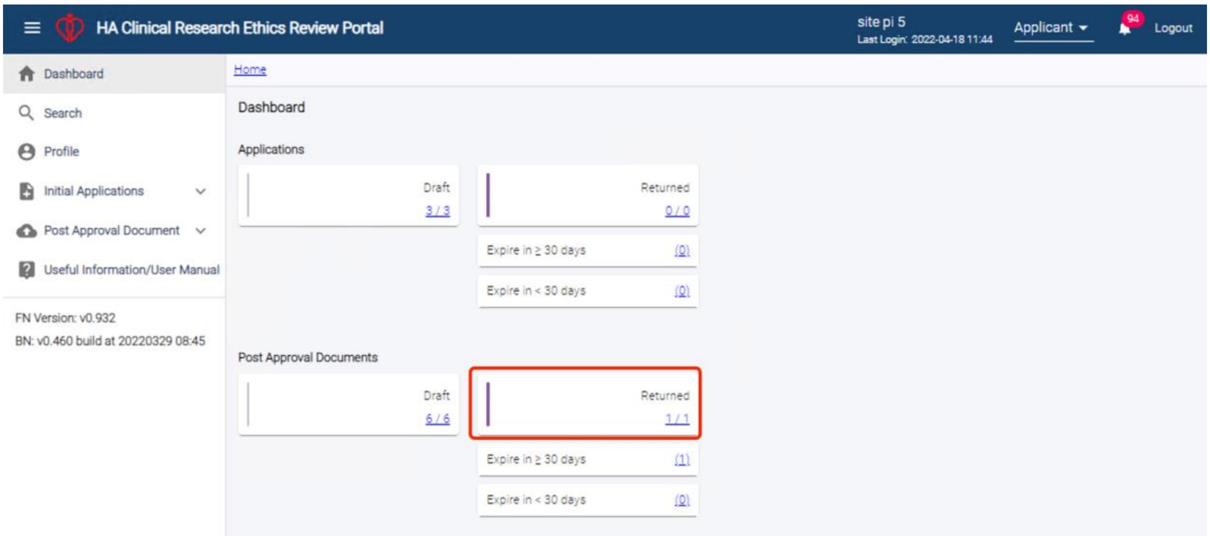


Figure 6.1.4.2 Changes on Dashboard for Returned Post Approval Document

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.

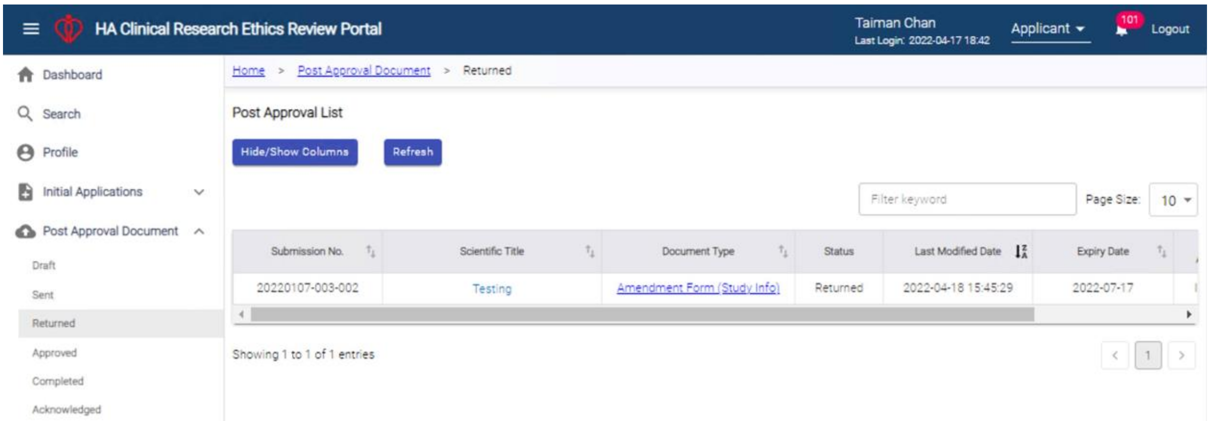


Figure 6.1.4.3 Returned Post Approval Document in "Returned" Post Approval List

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.

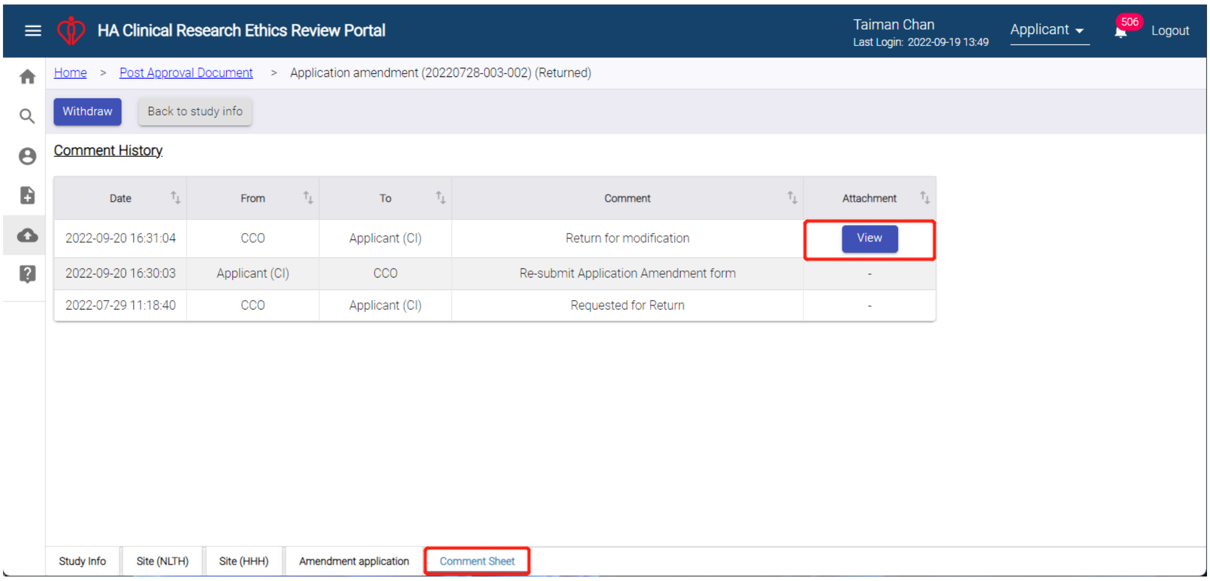


Figure 6.1.4.4 Comment tab of Post Approval Document

If the returned Post Approval Document has not yet been re-submitted, the number of the boxes “Expire ⩾ 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;

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;

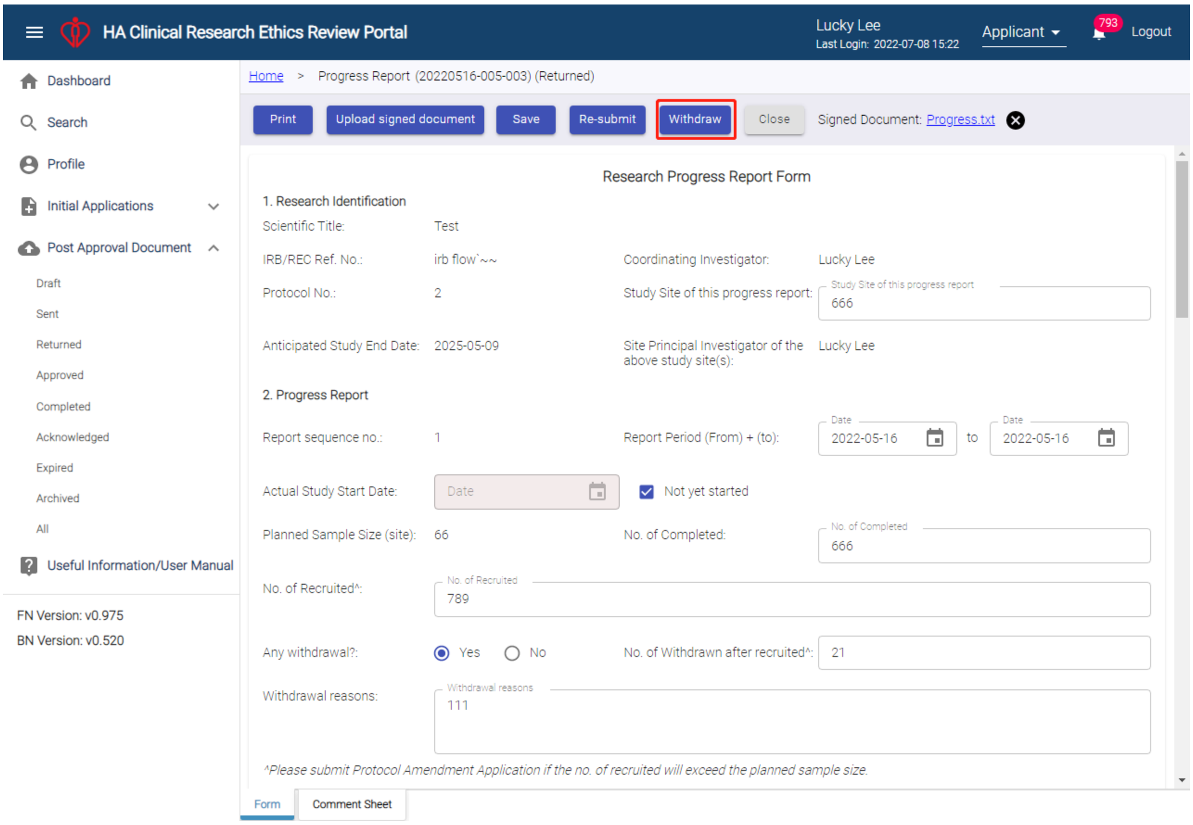


Figure 6.1.5.1.3 Screen of Withdraw button in Post Approval Document

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;

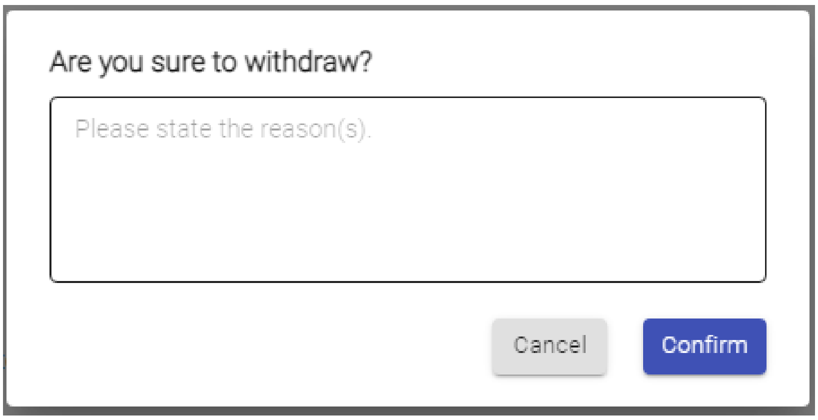


Figure 6.1.5.1.4 Pop-up dialog of Reason Statement when withdrawing Post Approval Document

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;

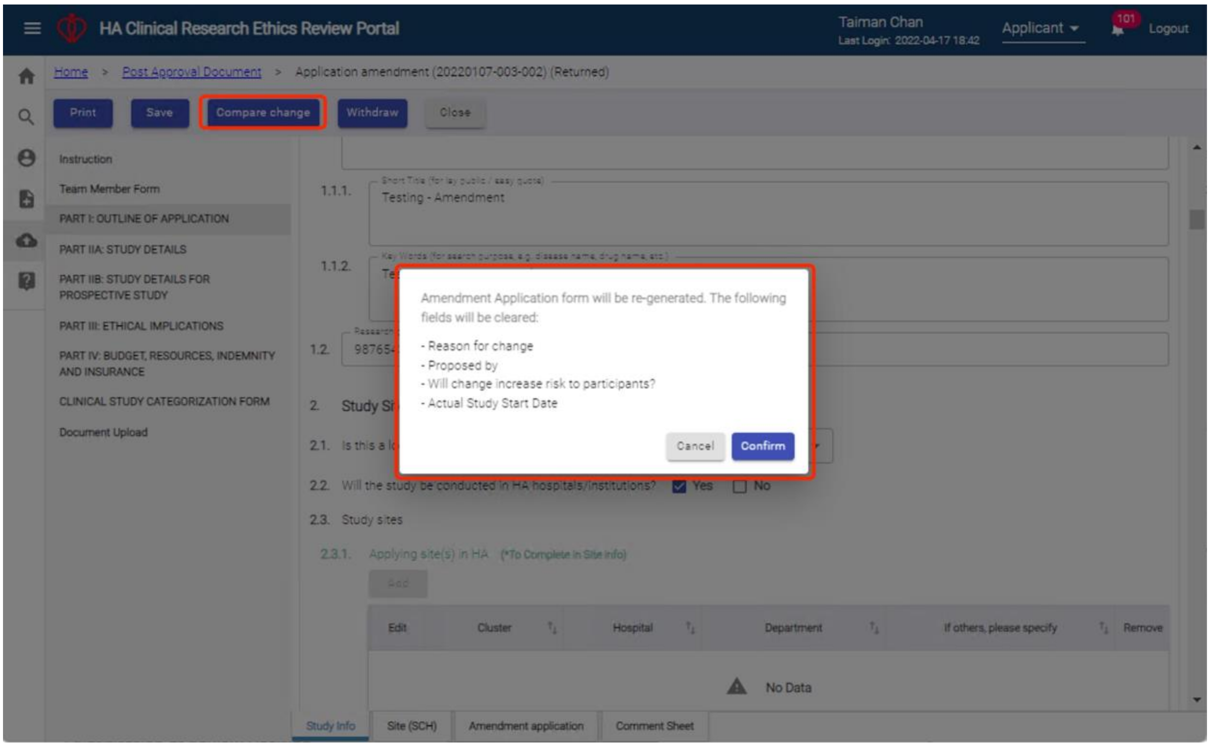


Figure 6.1.5.2.1 Dialog of regenerating the Amendment Application Form

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;

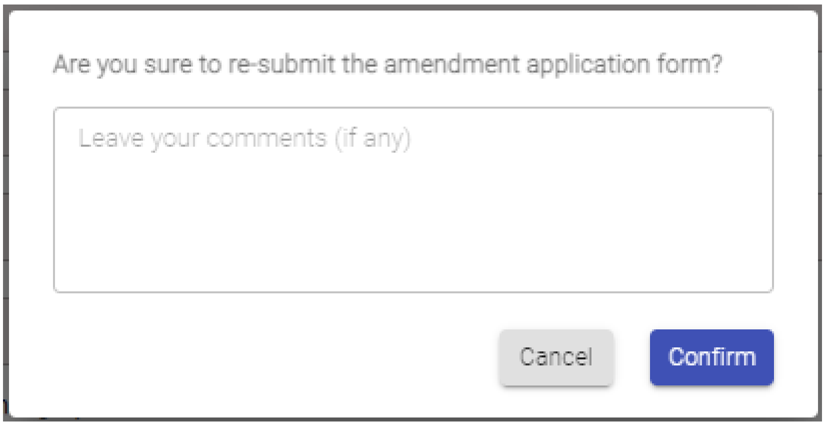


Figure 6.1.5.2.2 Pop-up dialog before re-submission

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

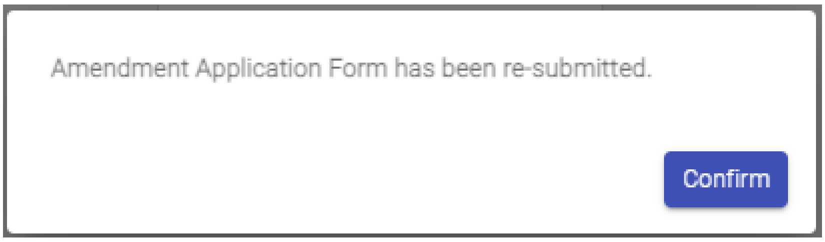


Figure 6.1.5.2.3 Pop-up dialog after re-submission

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;

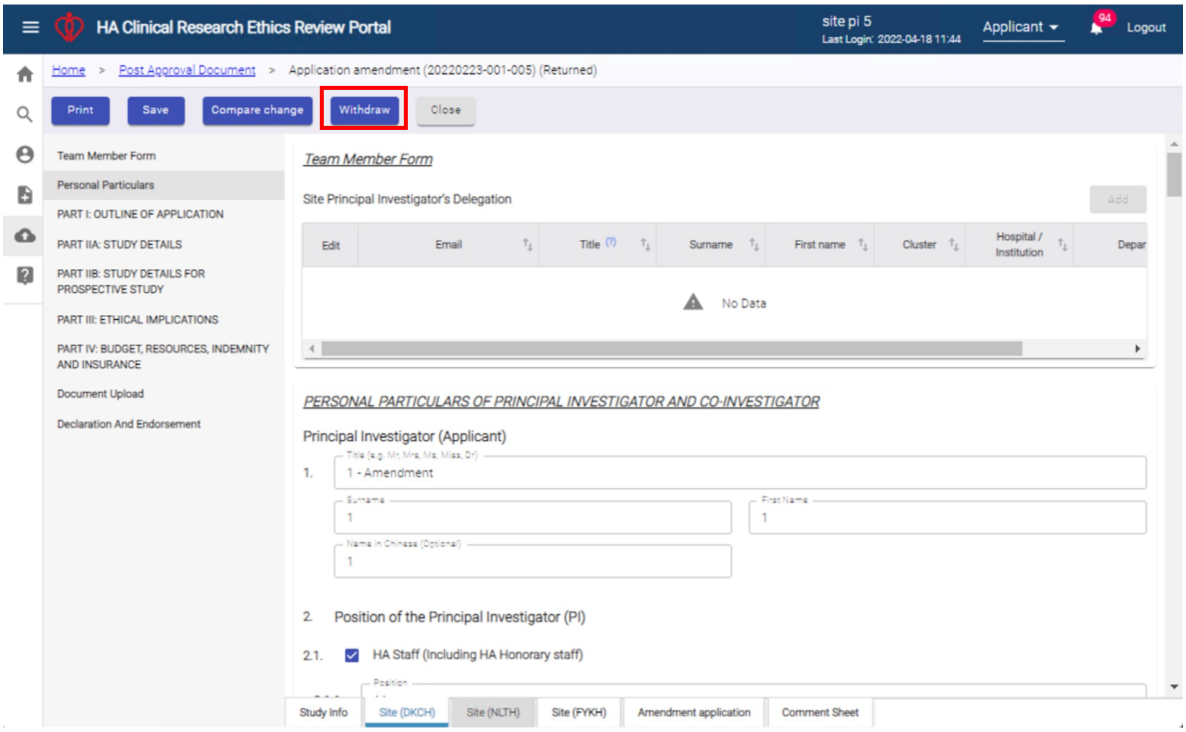


Figure 6.1.5.2.4 Screen of Withdraw button in Application amendment

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;

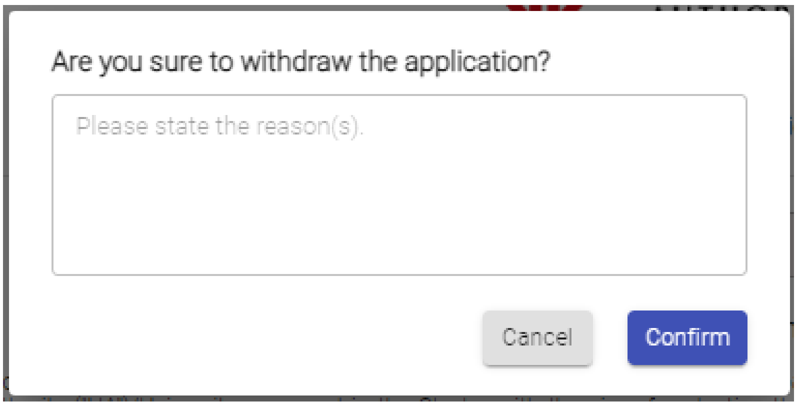


Figure 6.1.5.2.5 Pop-up dialog of Reason Statement when withdrawing the Amendment Form

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.

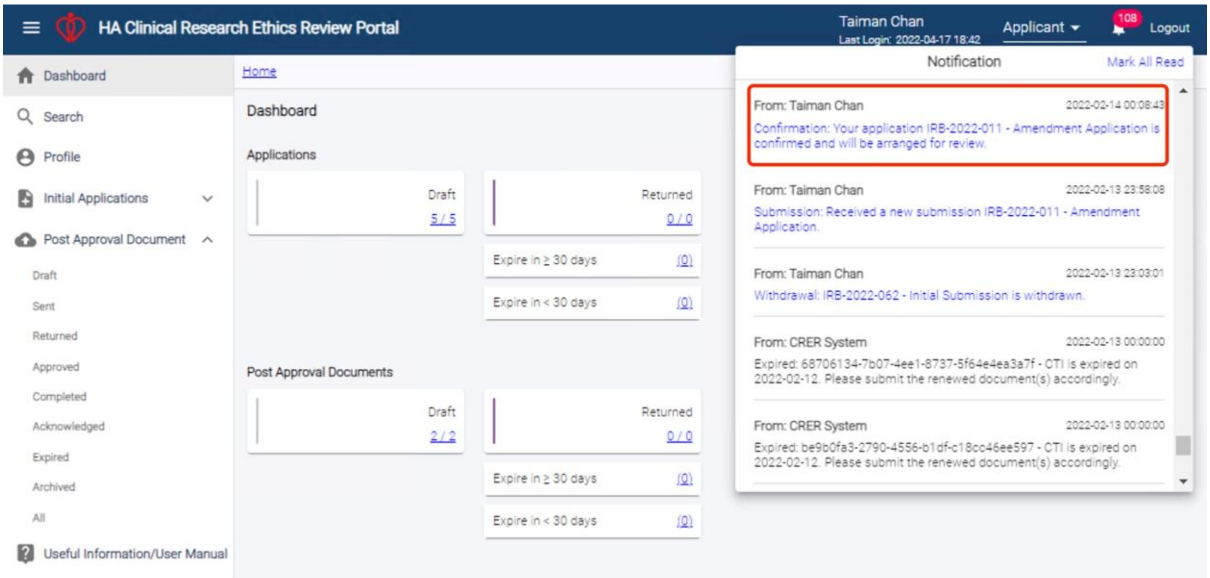


Figure 6.1.6.1 Notification of Confirmed Post Approval Document

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
2. 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.

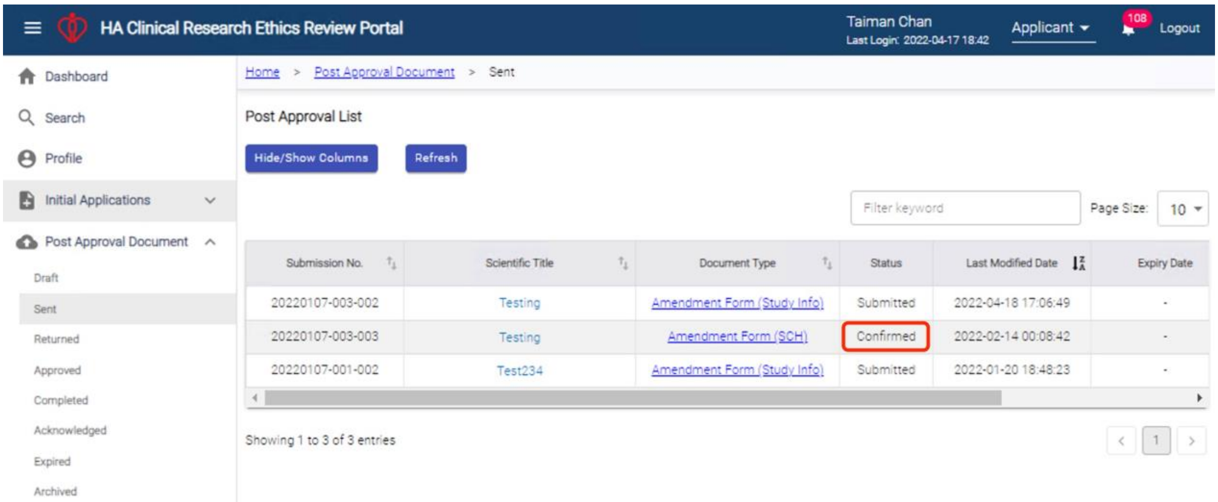


Figure 6.1.6.2 Confirmed Status of Post Approval Document

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

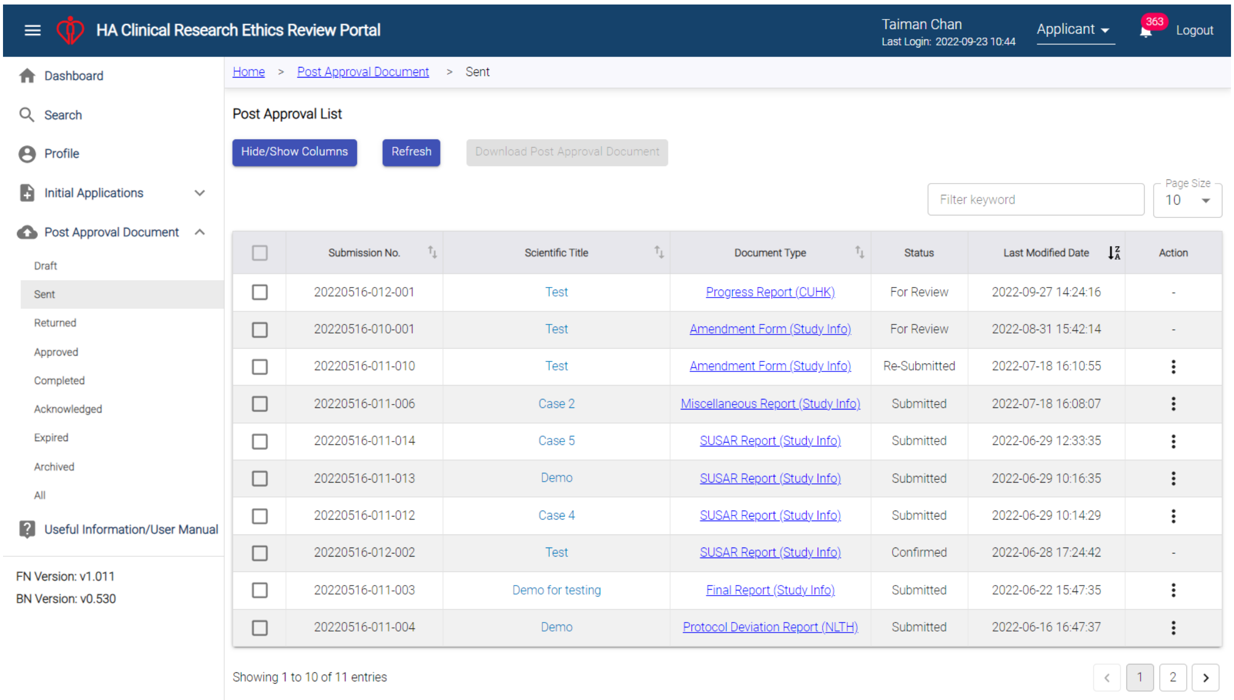


Figure 6.1.7.1 For Review Post Approval Documents in “Sent” Post Approval List

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.

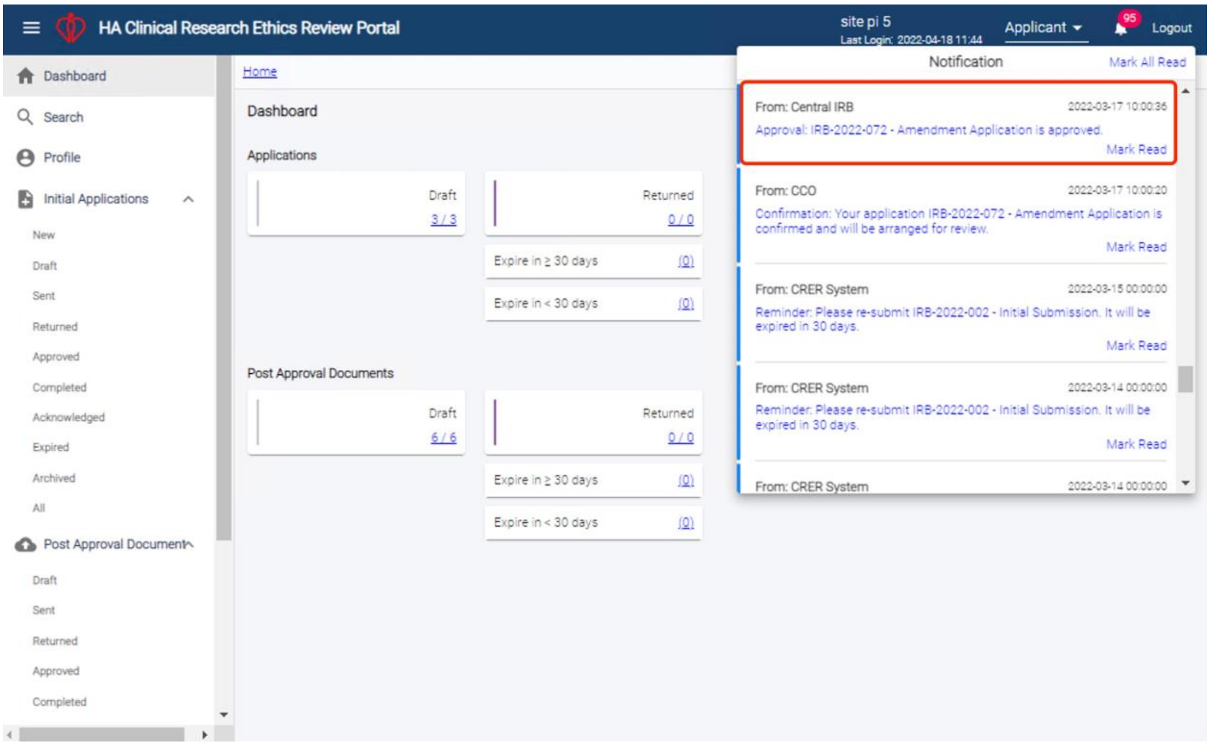


Figure 6.1.8.1 Notification of Approved Post Approval Document

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.

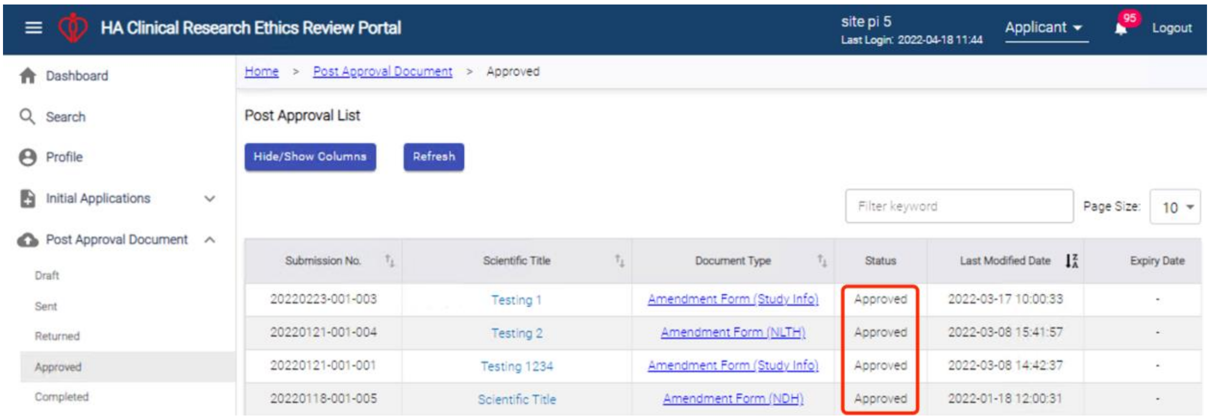


Figure 6.1.8.2 Approved Post Approval Document in "Approved" Post Approval List

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;

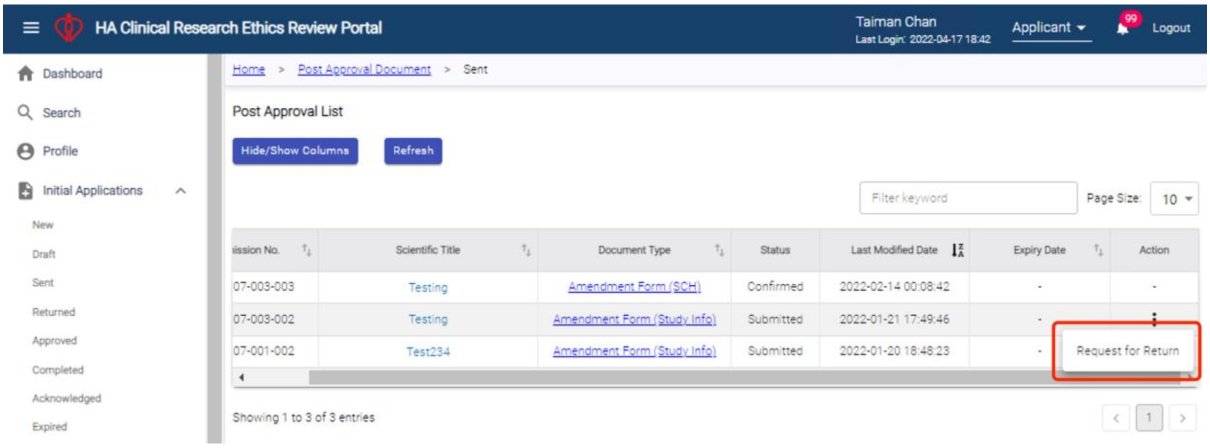


Figure 6.2.1.1 Screen of "Request for Return" button in "Sent" Post Approval List

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;

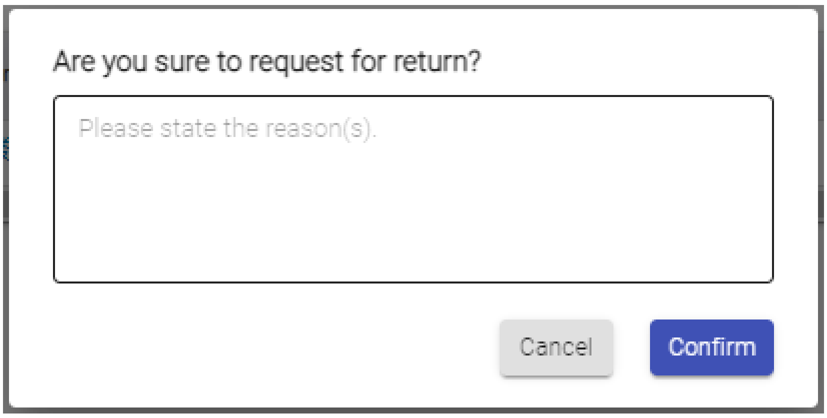


Figure 6.2.1.2 Pop-up dialog to confirm Request for Return

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.

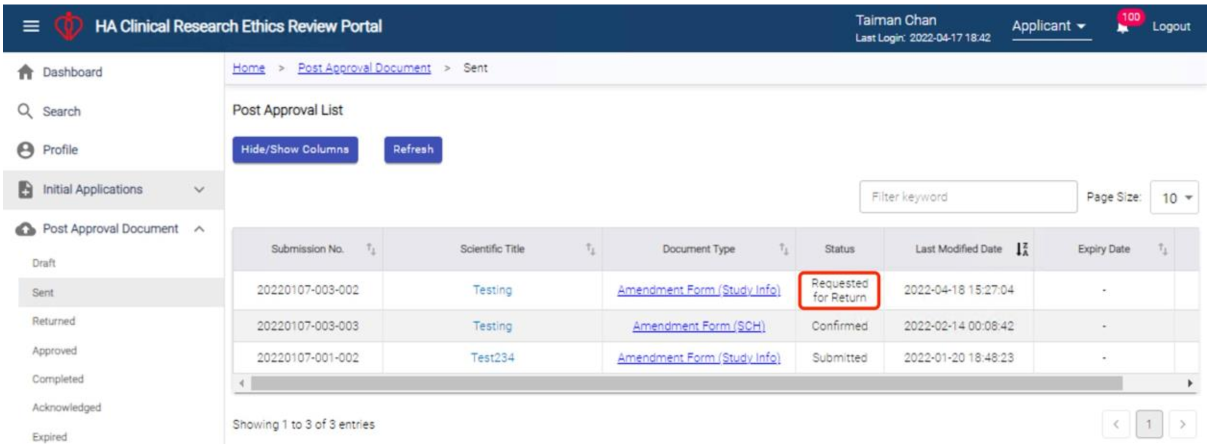


Figure 6.2.1.4 “Requested for Return” Status of the Application Amendment

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 Returned Application Amendment

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.

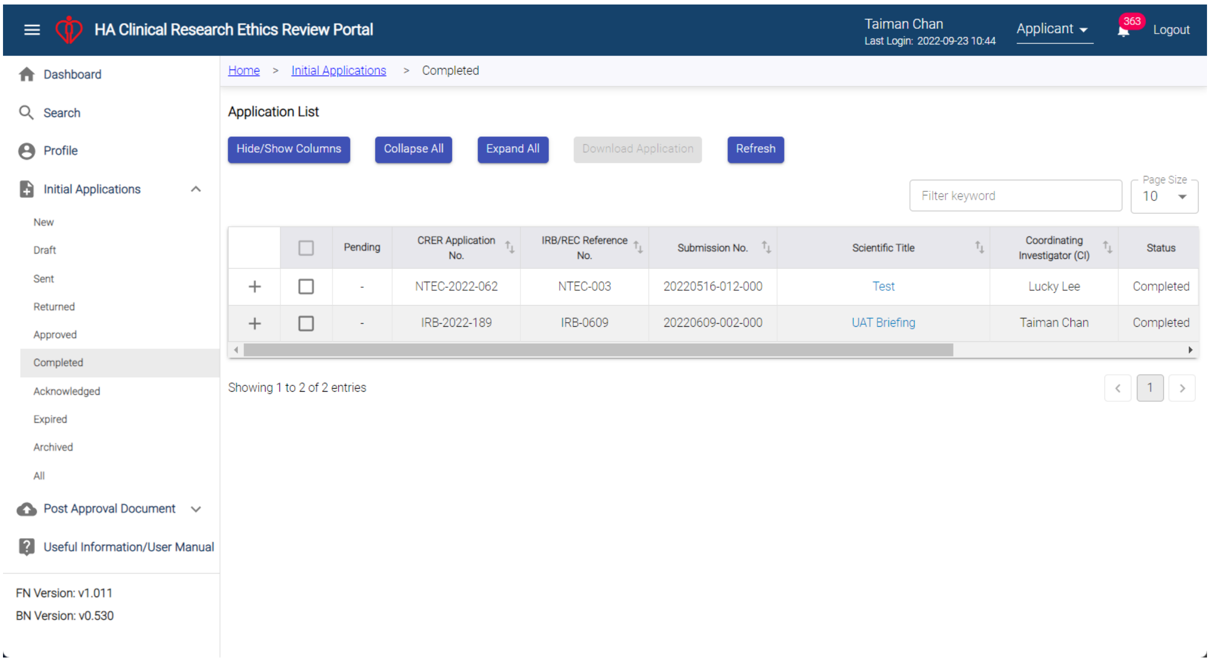


Figure 7.1 Completed Initial Application in “Completed” Folder