

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

*Date: December 14, 2016*

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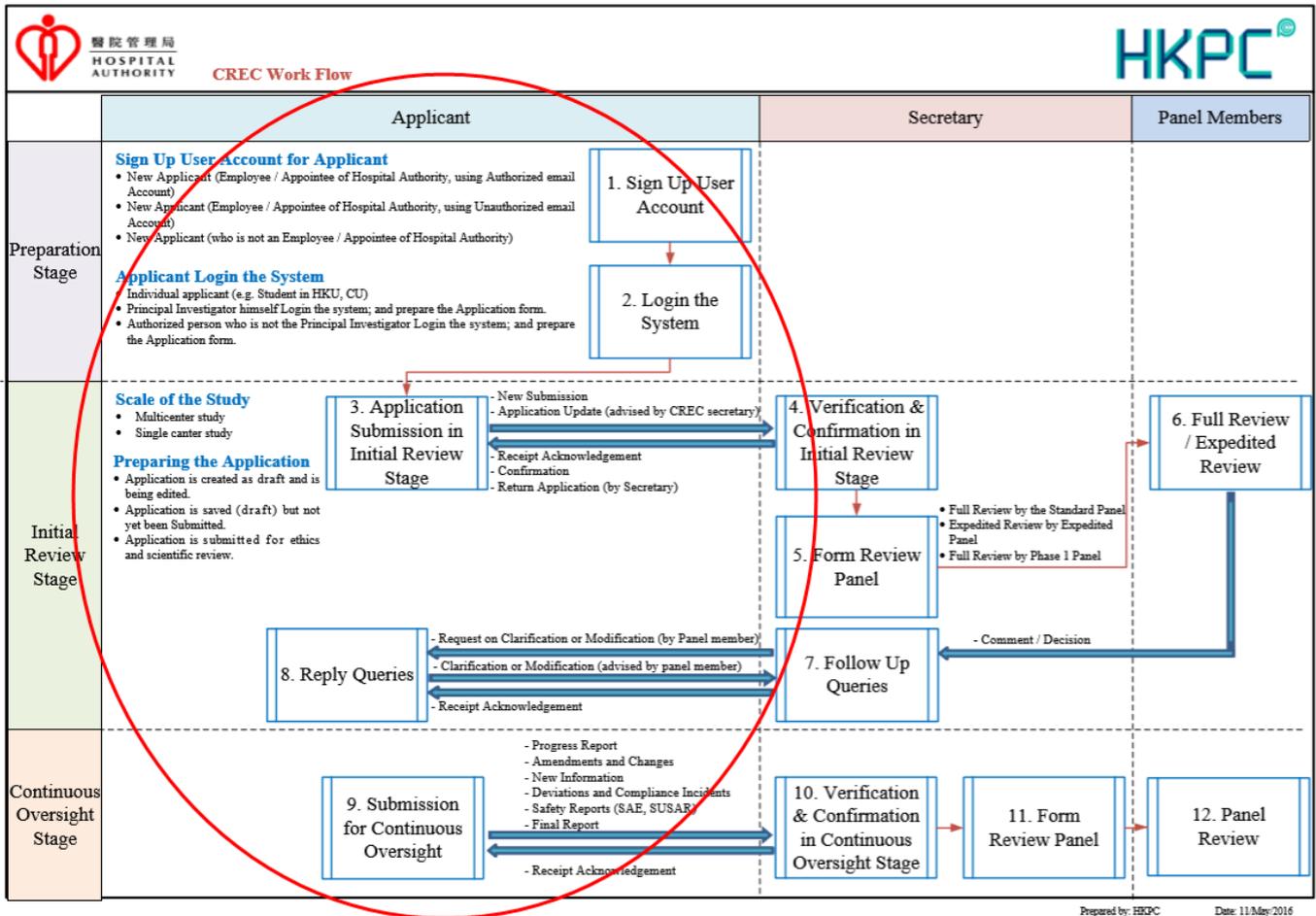
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# 1. Introduction

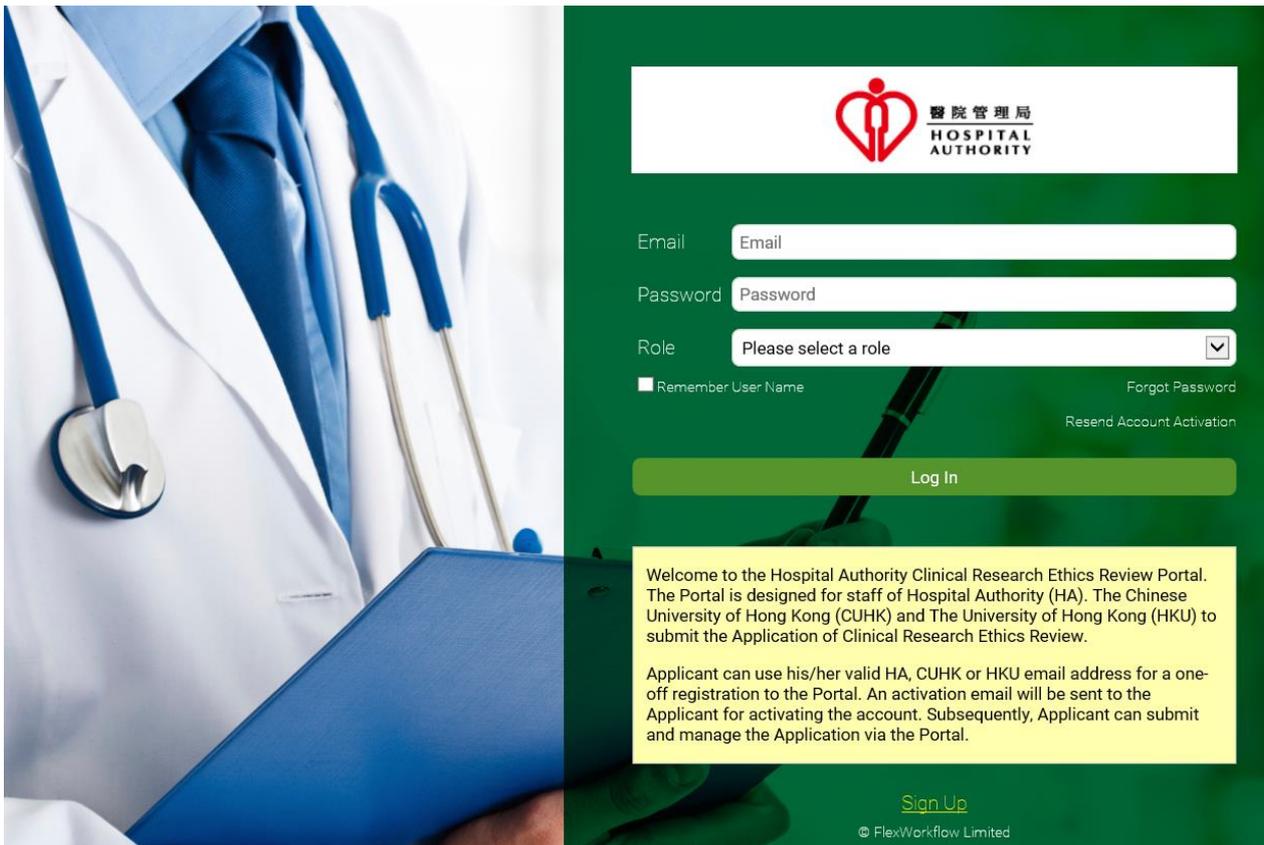
This user guide is to provide guidance for Applicant to use the new CRER Portal. In the coming chapters, we will go through the functions from the “initial review stage” and “continuous oversight stage” processes.



## 2. System Prerequisite

**Important!** Please ensure you have read and followed the “[HA CRER Portal Client Machine Configuration Instruction manual](#)” to install or configure the system components before you start to use the new CRER Portal.

Please type the URL ( <https://harec.ha.org.hk/Portal> ) in the address bar of Microsoft Internet Explorer to go to the login page of the portal.



Login page of HACRER Portal

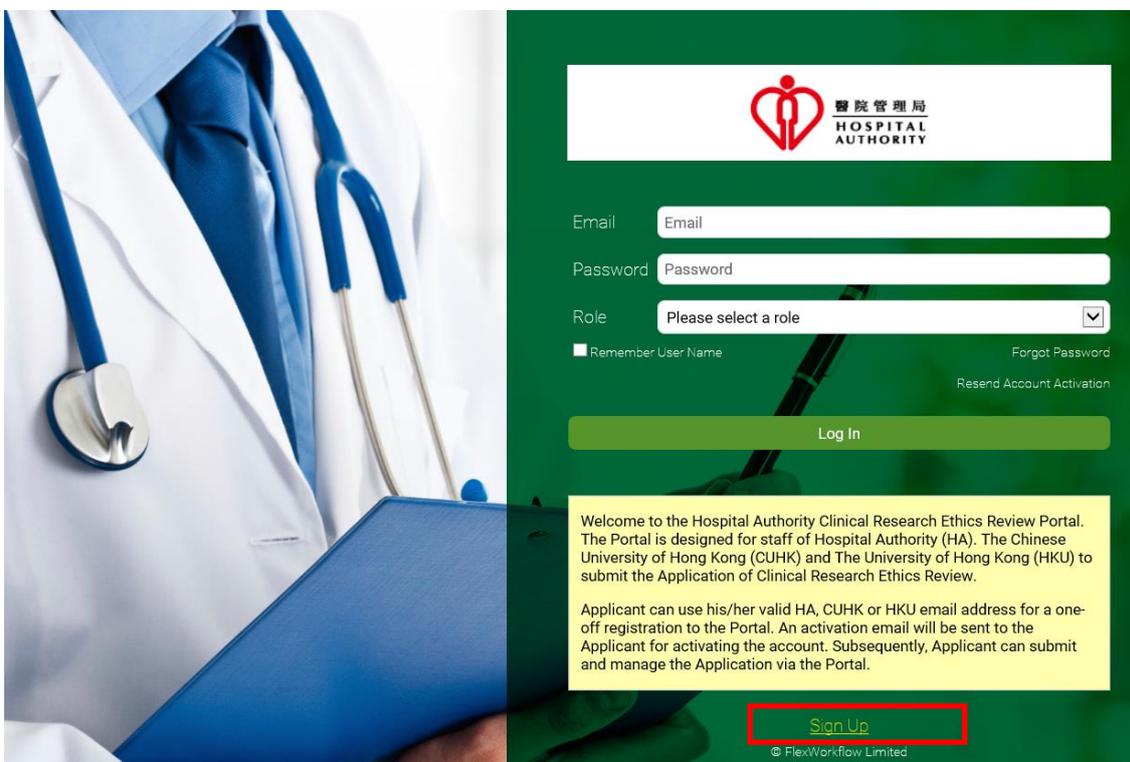
### 3. Preparation Stage

#### 3.1. Sign Up User Account for Applicant

Applicant users are required to create an applicant account on the new Hospital Authority Clinical Research Ethics Review Portal (HACRER Portal) before they can submit an application for a research.

##### 3.1.1. New Applicant (Employee / Appointee of Hospital Authority, using an authorized email account)

Click the **[Sign Up]** button:



A sign up form will appear.

Sign up page of system authorized email

Please follow the below steps to register an account on the portal.

1. Fill in the required information:

- Email address

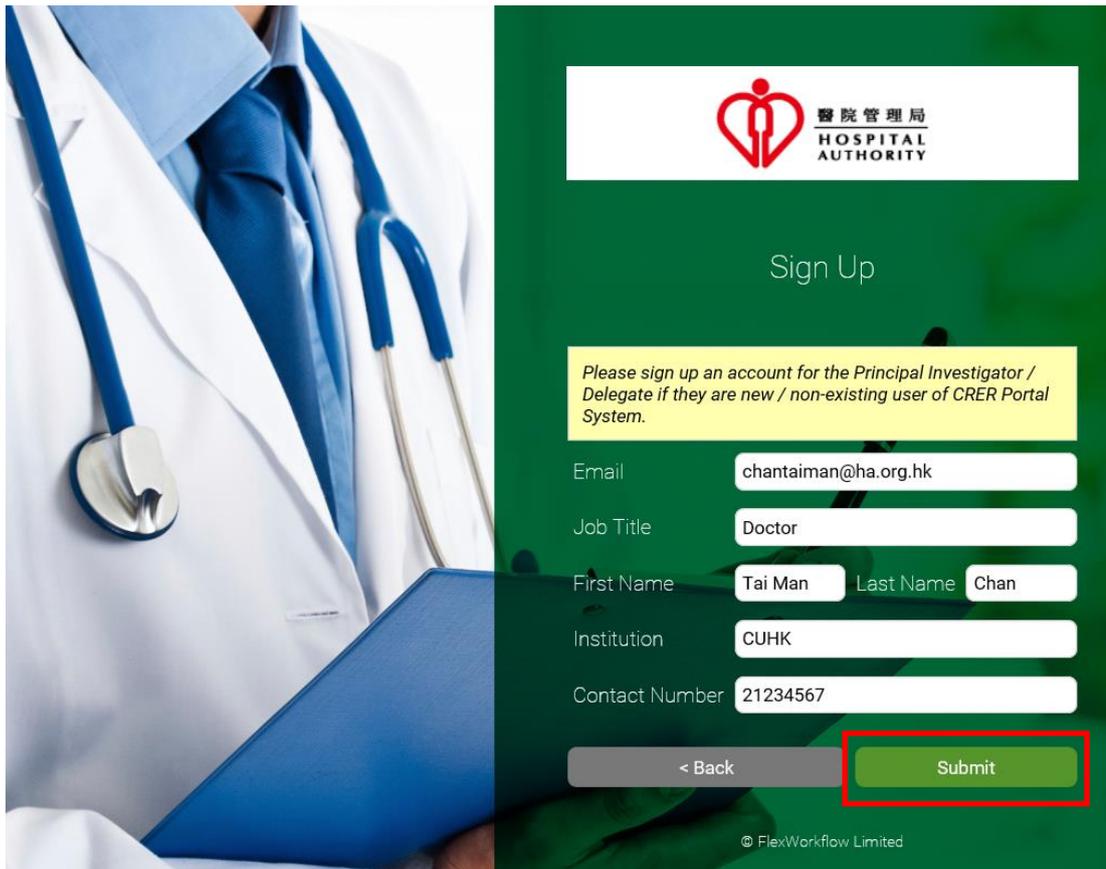
*Note: System is able to recognize whether your input email address is authorized or not. Currently, all email addresses ending with the following domains are authorized as of writing:*

- *ha.org.hk*
- *hku.hk*
- *hkucc.hku.hk*
- *pathology.hku.hk*
- *cuhk.edu.hk*

- Basic Personal Information

- Job Title
- First Name & Last Name
- Institution
- Contact Number

2. Click the **[Submit]** button.



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AUTHORITY

### Sign Up

*Please sign up an account for the Principal Investigator / Delegate if they are new / non-existing user of CRER Portal System.*

Email

Job Title

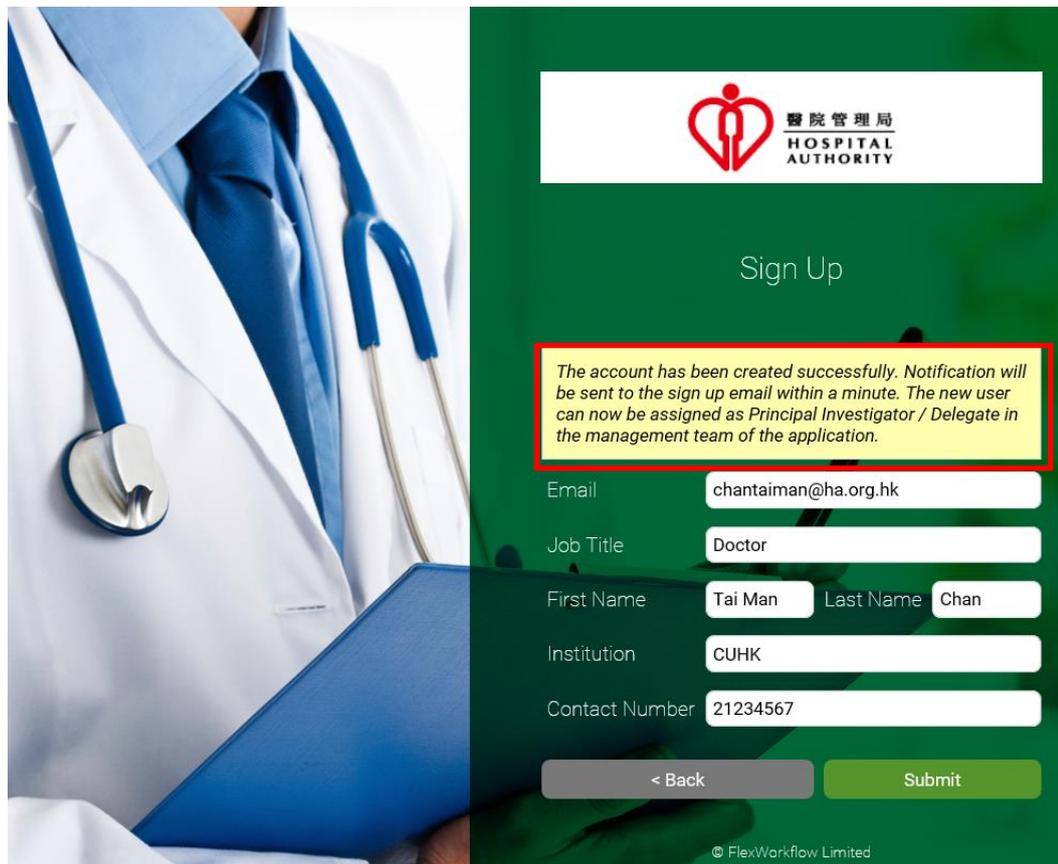
First Name  Last Name

Institution

Contact Number

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3. Wait until this highlighted message is shown:



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### Sign Up

*The account has been created successfully. Notification will be sent to the sign up email within a minute. The new user can now be assigned as Principal Investigator / Delegate in the management team of the application.*

Email

Job Title

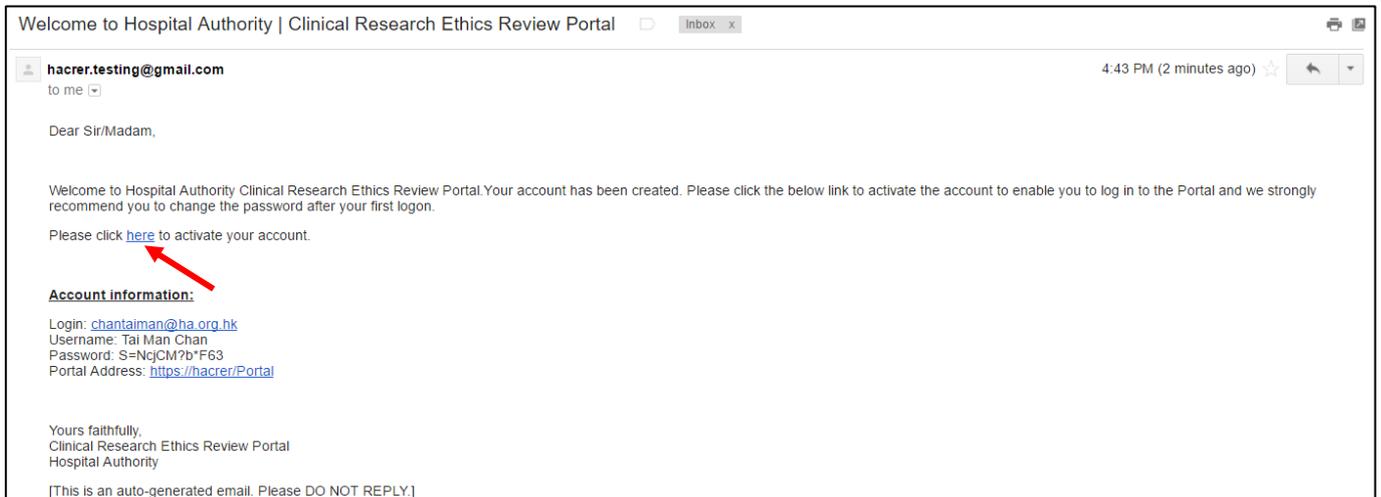
First Name  Last Name

Institution

Contact Number

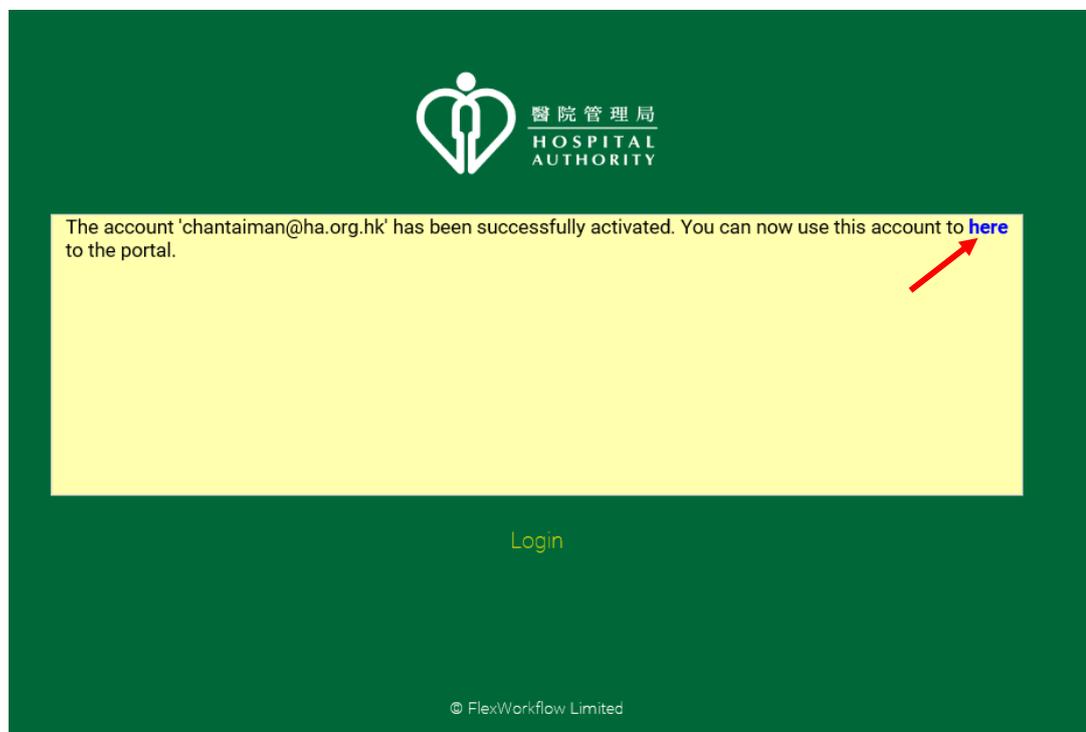
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4. You will receive an auto-generated email **after registration**. Please do the following:
  - Check if your account information is correct
  - Click the hyperlink "[here](#)" to activate your account (a **MUST**; you will not be able to log in without activation)



Confirmation email after registration

5. After clicking the activation link, you will be directed to the following page if account activation is successful.
6. You have now completed the account registration. Click the "[here](#)" link to go to the login page.



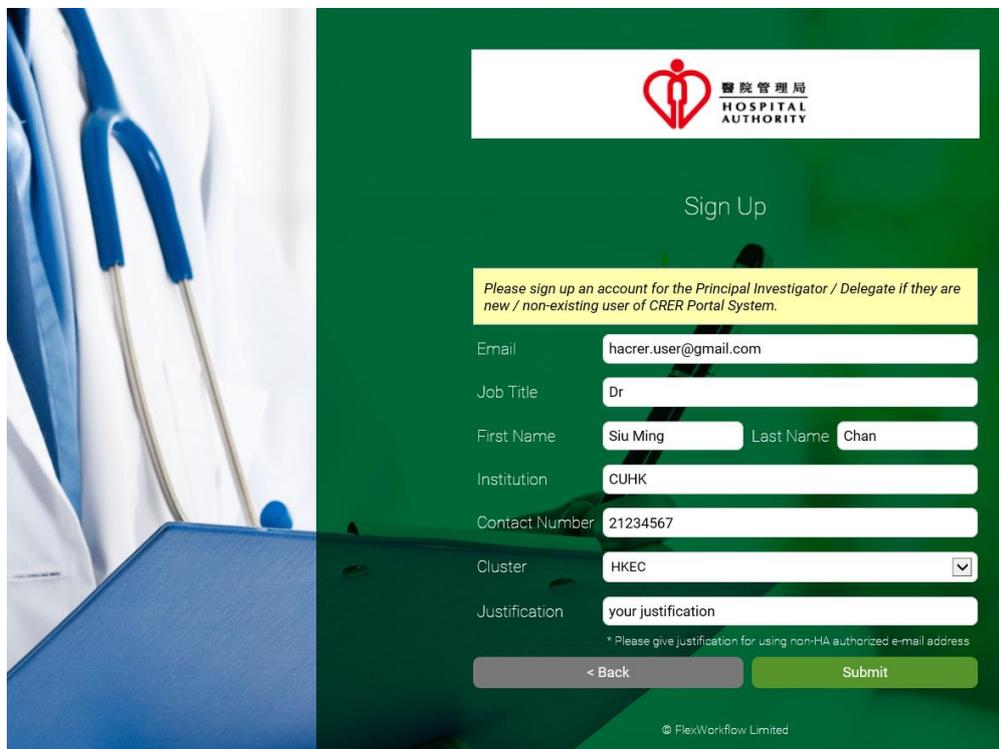
Page showing successful activation

### 3.1.2. New Applicant (Employee / Appointee of Hospital Authority, using an unauthorized email account)

If you do not have a “System Authorized Email Account”, you can still register a portal account through the portal. Please click the **[Sign Up]** button and a sign up form will appear.

1. Fill in the required information:

- Email address
  
- Basic Personal Information
  - Job Title
  - First Name & Last Name
  - Institution
  - Contact Number
  
- Cluster  
Choose the cluster that you belong to.
  
- Justification  
The justification will be sent to your cluster secretary for approval.



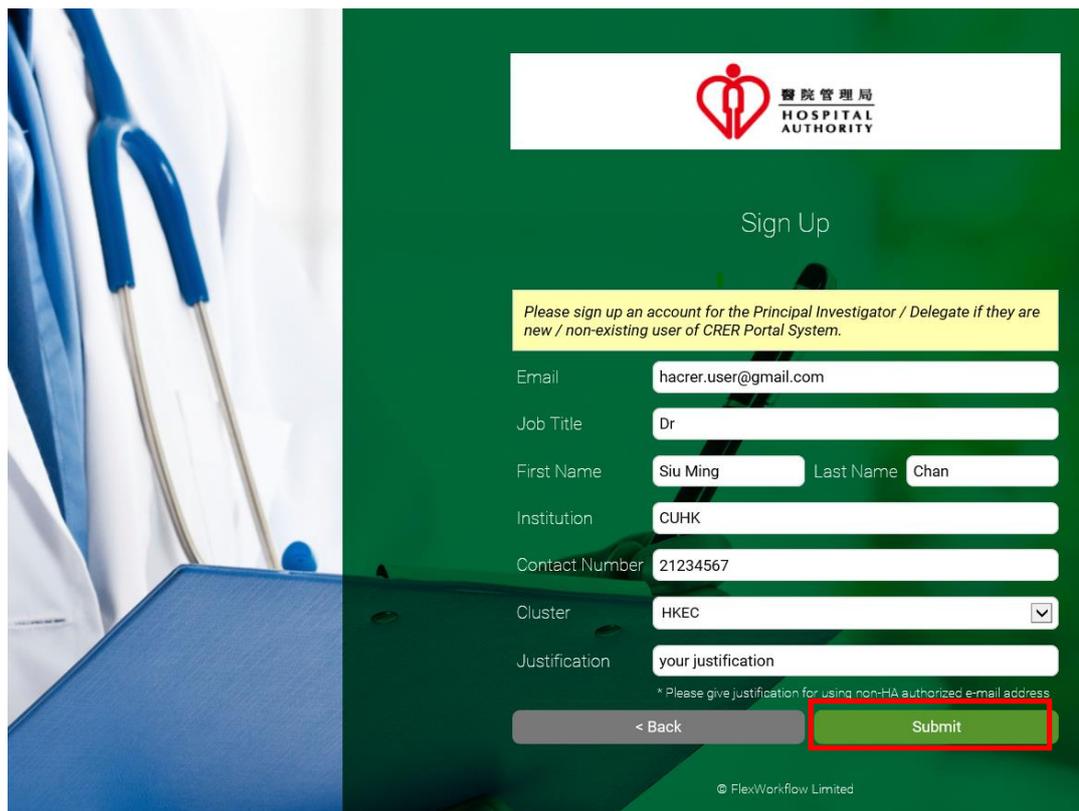
The image shows a screenshot of a web form titled "Sign Up" for the Hospital Authority. The form is set against a green background with a white sidebar on the left showing a stethoscope and a clipboard. The form fields are as follows:

- Email:** hacrer.user@gmail.com
- Job Title:** Dr
- First Name:** Siu Ming
- Last Name:** Chan
- Institution:** CUHK
- Contact Number:** 21234567
- Cluster:** HKEC (selected from a dropdown menu)
- Justification:** your justification

Below the justification field, there is a small asterisk and the text: "\* Please give justification for using non-HA authorized e-mail address". At the bottom of the form, there are two buttons: "< Back" (grey) and "Submit" (green). The Hospital Authority logo is at the top right, and the text "© FlexWorkflow Limited" is at the bottom right.

Sign up page of non-system authorized email

2. Click the **[Submit]** button



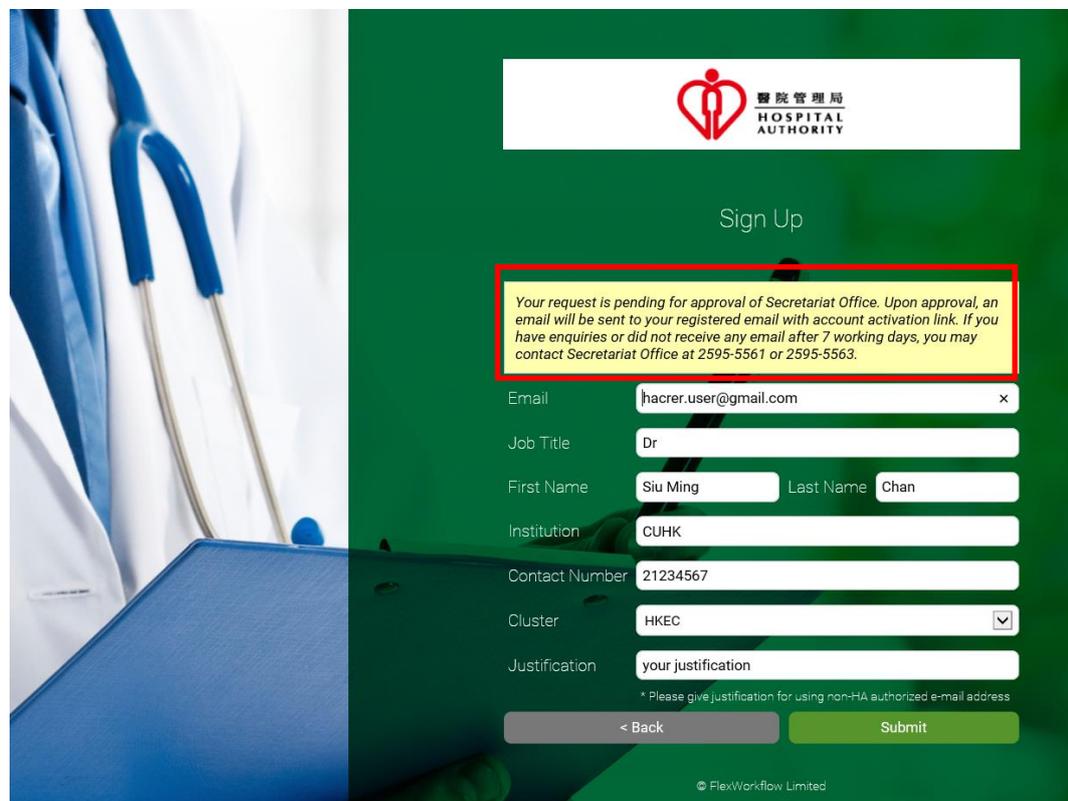
The screenshot shows the Hospital Authority Sign Up form. The form fields are filled with the following information:

- Email: hacrer.user@gmail.com
- Job Title: Dr
- First Name: Siu Ming, Last Name: Chan
- Institution: CUHK
- Contact Number: 21234567
- Cluster: HKEC
- Justification: your justification

A yellow message box at the top of the form reads: "Please sign up an account for the Principal Investigator / Delegate if they are new / non-existing user of CRER Portal System." The "Submit" button is highlighted with a red box.

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3. Wait until the highlighted message is shown:



The screenshot shows the Hospital Authority Sign Up form after submission. A yellow message box at the top of the form reads: "Your request is pending for approval of Secretariat Office. Upon approval, an email will be sent to your registered email with account activation link. If you have enquiries or did not receive any email after 7 working days, you may contact Secretariat Office at 2595-5561 or 2595-5563." The message box is highlighted with a red border.

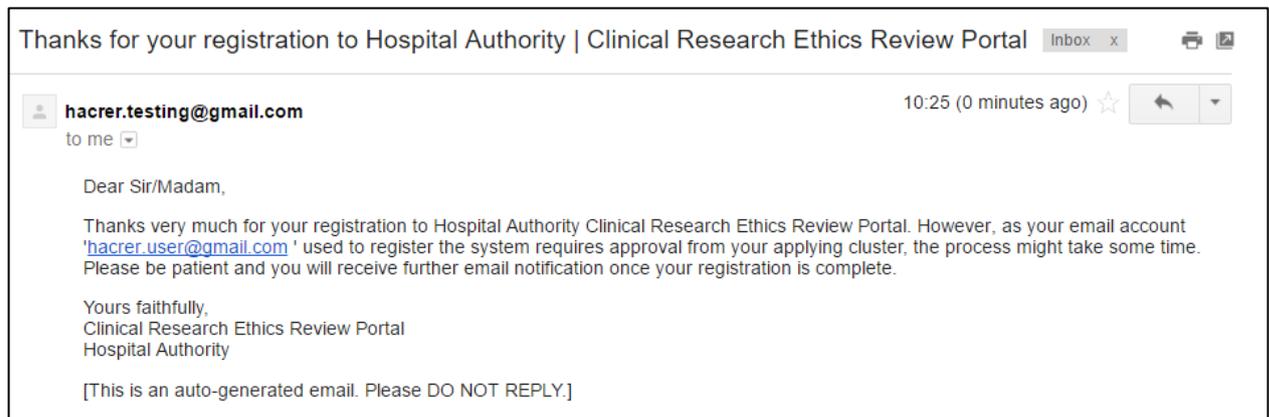
The form fields are filled with the following information:

- Email: hacrer.user@gmail.com
- Job Title: Dr
- First Name: Siu Ming, Last Name: Chan
- Institution: CUHK
- Contact Number: 21234567
- Cluster: HKEC
- Justification: your justification

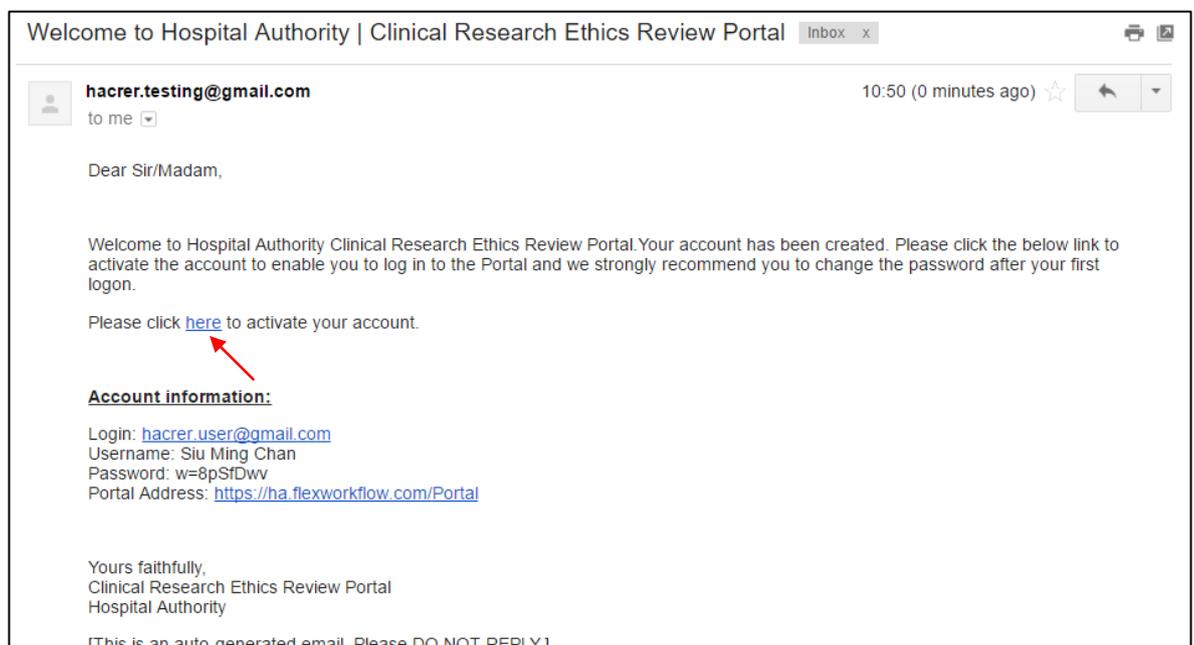
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- 
4. You will receive an auto-generated email sending to **the e-mail address you have entered** as the first notification of account application.

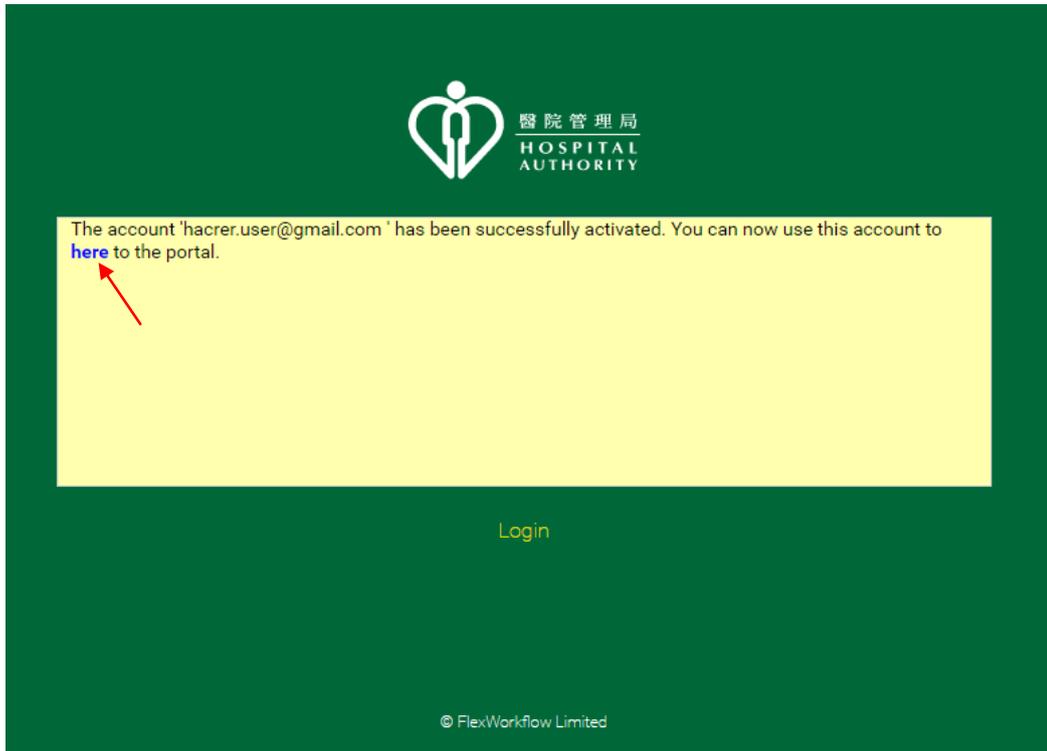
But still you have to wait for the cluster secretary to approve your registration before you can login to the portal.



5. You will receive an auto-generated e-mail **once the secretary approves the account registration request**. Please do the following:
- Check if your account information in the email is correct
  - Click the hyperlink "[here](#)" to activate your account (*a **MUST**; you will not be able to log in without activation*)



6. After clicking the activation link, you will be directed to the following page if account activation is successful.
7. You have now completed the account registration. Click the "[here](#)" link to go to the login page.

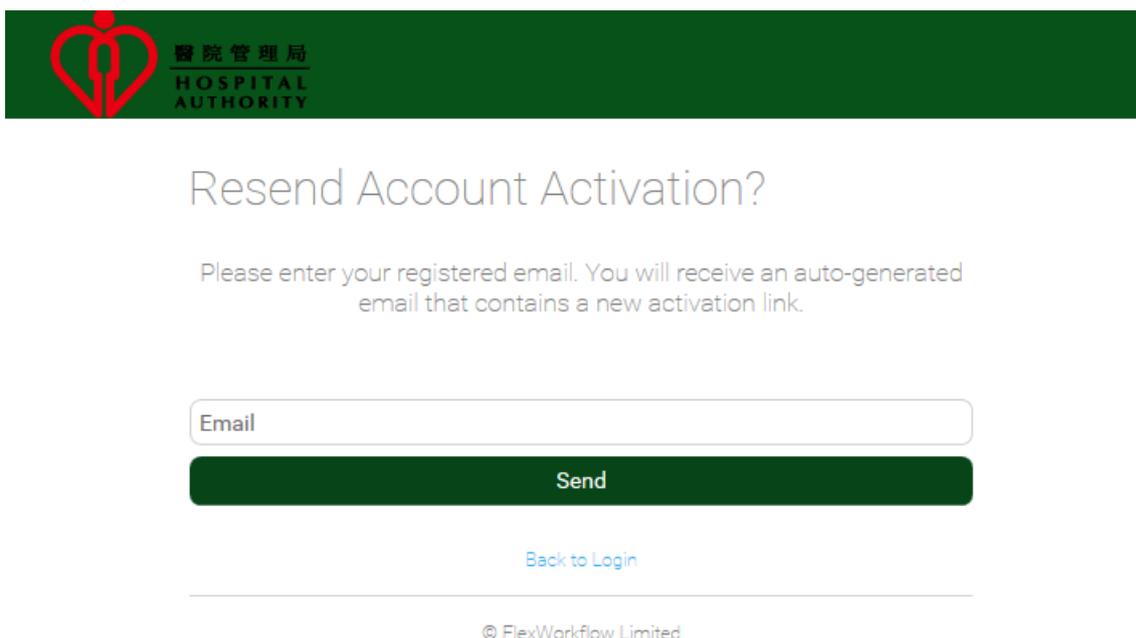


## 3.2. Resend Account Activation

If you cannot receive the account activation email, you can click “Resend Account Activation” on the login page of the portal.



It should bring you to the resend account activation page. Type the email you registered your account with and click **[Send]**. You should receive another auto-generated email that contains a new activation link.



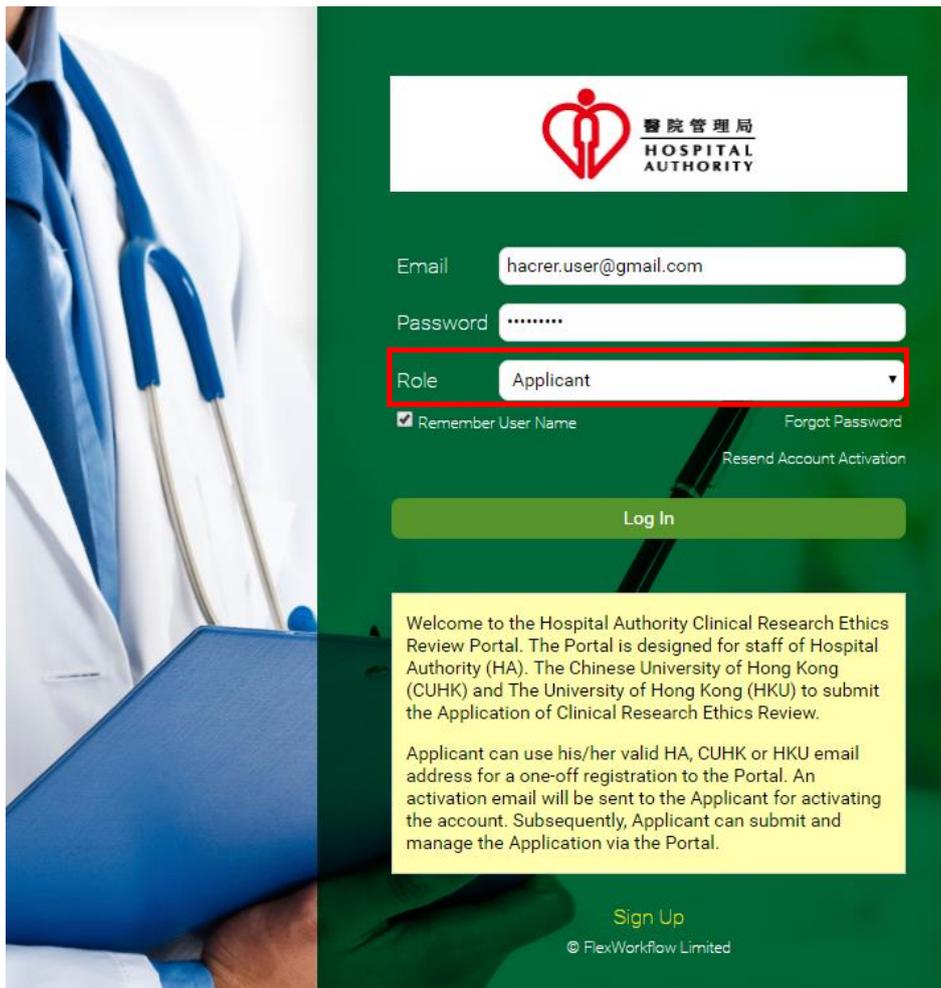
### 3.3. Login

Now you can log into the system if your account registration is completed successfully.

If you have forgotten your password, please refer to section 7.2 Forgot Password Handling.

Please follow below steps:

1. Enter the email address you registered your account with and the password.
2. Select the Role **“Applicant”**.
3. Click the **[Log In]** button to proceed.



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Email hacrer.user@gmail.com

Password .....

Role Applicant

Remember User Name [Forgot Password](#)

[Resend Account Activation](#)

Log In

Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong (CUHK) and The University of Hong Kong (HKU) to submit the Application of Clinical Research Ethics Review.

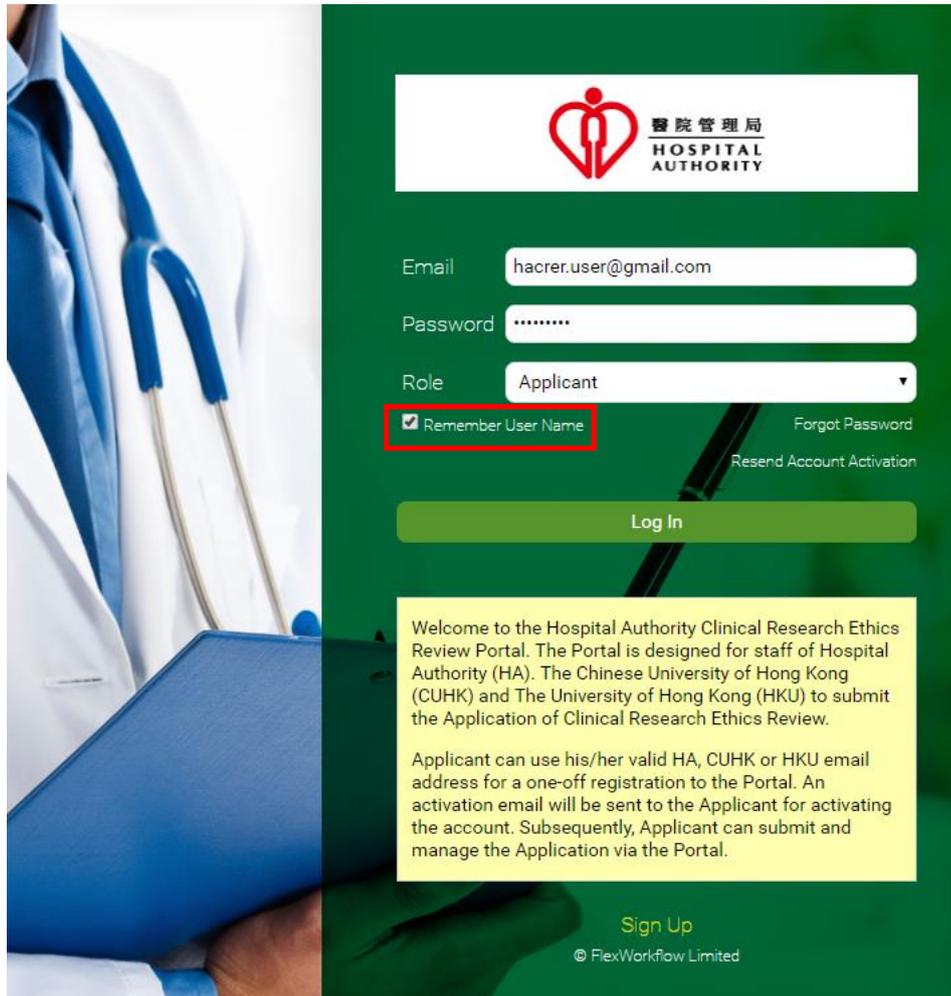
Applicant can use his/her valid HA, CUHK or HKU email address for a one-off registration to the Portal. An activation email will be sent to the Applicant for activating the account. Subsequently, Applicant can submit and manage the Application via the Portal.

Sign Up

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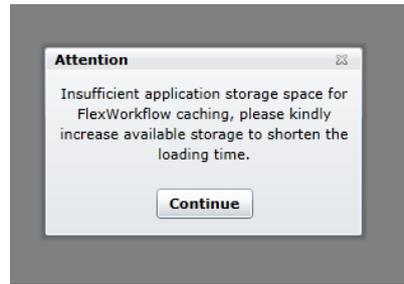
Select your role

In the login page, there is an option “**Remember my username**”, which allows you to save your username in the login page.



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You may see the following dialog if you create or open an application for the first time. If so, click "Continue" followed by "Yes" to proceed.



## 4. Introduction of Applicant's Home Page

The screenshot shows the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the Hospital Authority logo. The main header area displays a welcome message "Welcome, SIU MING CHAN!" in a blue box, with the user's role "Applicant" shown in a dropdown menu and the last successful login time "0001/01/01 00:00:00". A green sidebar menu on the left contains options: Home, Profile, Application, Function, Help, and Logout. A yellow banner below the header reads: "Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong (CUHK) and The University of Hong Kong (HKU) to submit the Application for Clinical Research Ethics Review."

User name is shown at the top of welcome page

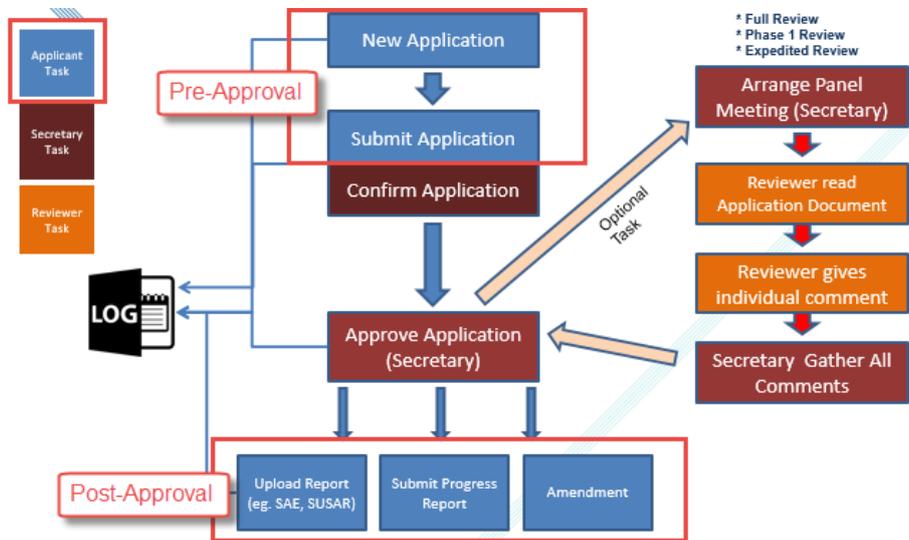
| <u>Function Menu</u> | <u>Description</u>  |
|----------------------|---|
| <b>Home</b>          | The welcome page  |
| <b>Profile</b>       | Profile page of the login user. Please refer to Section 7 Maintain User Profile for more information.   |
| <b>Application</b>   | Allows you to create an application and view past or ongoing applications. Please refer to Section 5 Manage an Application (Pre-Approval) for more information. |
| <b>Function</b>      | Allows you to perform " <b>Application search</b> " and " <b>Document Search</b> ". Please refer to Section 8.2 Search of Application by Filter                 |
| <b>Help</b>          | Useful tips and reminders about the portal.   |
| <b>Logout</b>        | Allows you to log out from the current user account.  |
| <b>Role</b>          | Allows you to swap your roles quickly.<br><i>(Applicable only if you have both Applicant and Reviewer roles)</i>  |

The HACRER Portal allows a single account to contain different roles. You can choose any assigned role **before or after logging in** and change the role at the top right corner of the portal.



## 5. Manage an Application (Pre-Approval)

### Overview of the Pre-Approval stage



The submission of new applications involves two steps:

1. Fill in a **Member Form** of the new application
2. Fill in the detailed **Application Form** of the new application

## 5.1. Creation of New Application

*(Strongly recommend to strictly follow and read for your first application)*

Navigate to **[Application]** -> **[New]** to create a new application. An application Management Team Member Form should be opened.

The screenshot displays the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the Hospital Authority logo. The main header area shows a welcome message for Peter Chan, his role as 'Applicant', and his last successful login time. A yellow banner provides a welcome message and explains the portal's purpose for staff at Hospital Authority (HA), CUHK, and HKU. On the left, a dark green navigation sidebar is visible, with the 'Application' menu item and its sub-menu 'New' highlighted by a red box. Other menu items include Home, Profile, Function, Help, and Logout. The footer contains the copyright notice for FlexWorkflow Limited.

### 5.1.1. Fill in Member Form

**Application Management Team Member Form** allows you to assign roles to your team members for the new application.

**Application Management Team Member Form** Refresh

**Note to Investigator**

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

**Scientific Title (<500 characters)\***

**Principal Investigator :**

|  | Email | Name | Existing Account         | Please sign up             |
|--|-------|------|--------------------------|----------------------------|
|  |       |      | <input type="checkbox"/> | <a href="#">Click here</a> |

*Assign Principal Investigator who will be responsible for the Application.*

Add New RowDelete Selected Row(s)

**Delegates :**

|  | Email | Name | Existing Account | Please sign up |
|--|-------|------|------------------|----------------|
|  |       |      |                  |                |

*Please assign Delegates who will help manage and edit the application forms before research ethics approval.*

Add New RowDelete Selected Row(s)

**Application Follow Up Users :**

|  | Email | Name | Existing Account | Please sign up |
|--|-------|------|------------------|----------------|
|  |       |      |                  |                |

*Please assign Follow-up Users who will help manage and follow up the post-approval activities.*

Please follow the instructions below:

1. Scientific Title

Input the scientific title, which should be within 500 characters.

|  |
|--|
| Scientific Title (<500 characters)*      |
| <br><br><br><br><br><br><br><br><br><br> |

2. Principal Investigator (PI)

- Principal Investigator is a **MANDATORY** field;
- Principal Investigator is the one responsible for the application.
- In the “Email” column, input the **login email address** of the Principal Investigator.

|                          |                     |
|--------------------------|---------------------|
| Principal Investigator : | Email               |
|                          | app01.kwc@gmail.com |

The “Name” and checkbox of “Existing Account” will be auto-filled by the system if he/she is recognized as an existing account.

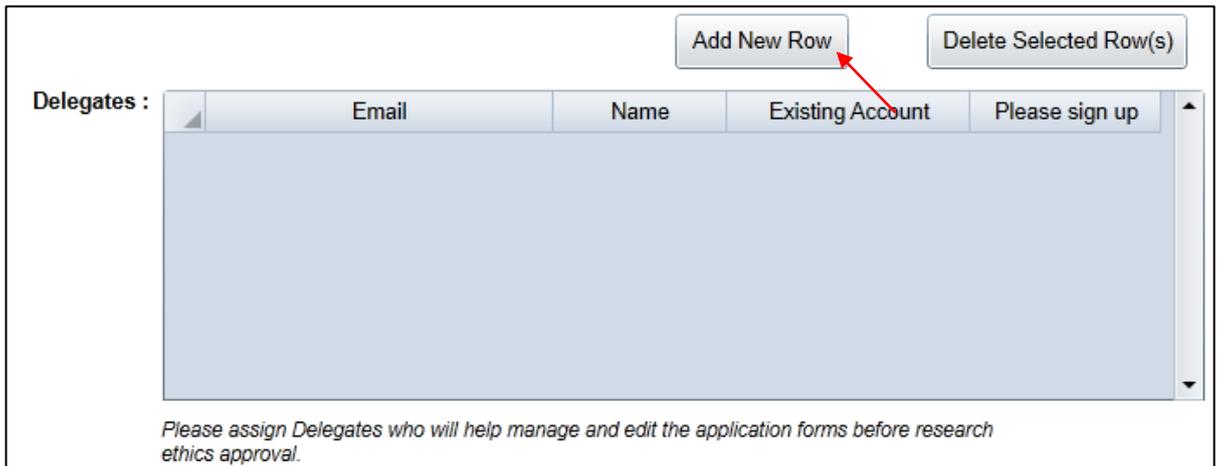
| Email               | Name      | Existing Account                    | Please sign up |
|---------------------|-----------|-------------------------------------|----------------|
| app01.kwc@gmail.com | KWC APP01 | <input checked="" type="checkbox"/> |                |

- On the contrary, the “Name” and checkbox of “Existing Account” will not be auto-filled by the system if he/she is not recognized as an existing account, which means your Principal Investigator does not have an account yet. Press “**Click here**” to sign up the account first.

| Email               | Name | Existing Account         | Please sign up             |
|---------------------|------|--------------------------|----------------------------|
| app11.kwc@gmail.com |      | <input type="checkbox"/> | <a href="#">Click here</a> |

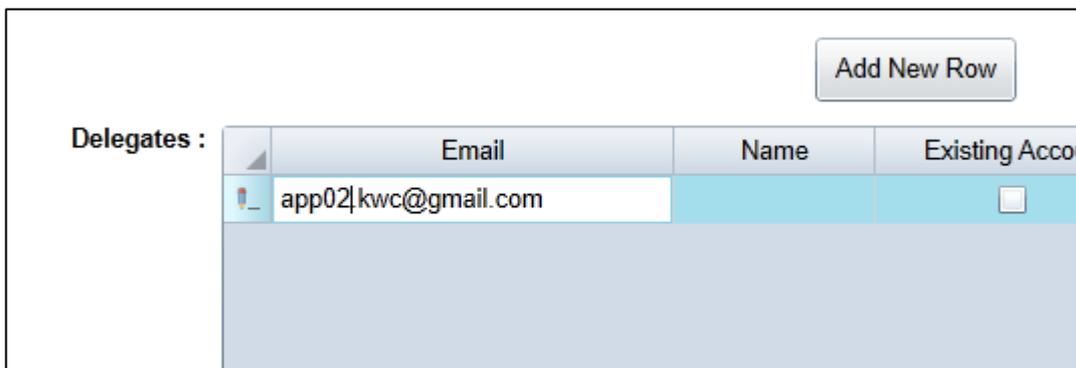
### 3. Delegates

- Please assign Delegates who will help manage and edit the application forms before research ethics approval.
- Click the “Add New Row” button to add a new row.



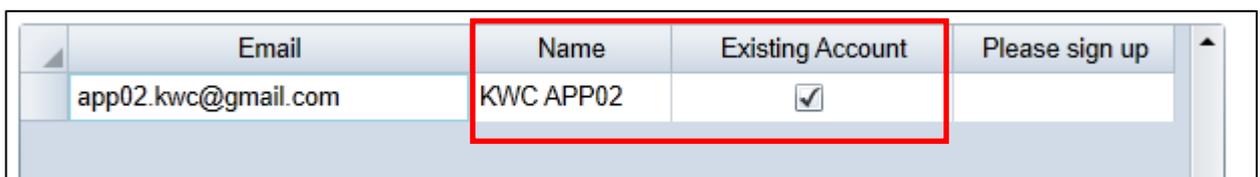
The screenshot shows a table titled "Delegates :". The table has four columns: "Email", "Name", "Existing Account", and "Please sign up". Above the table are two buttons: "Add New Row" and "Delete Selected Row(s)". A red arrow points to the "Add New Row" button. Below the table, there is a note: "Please assign Delegates who will help manage and edit the application forms before research ethics approval."

- In the “Email” column, input the **login email address** of the delegates.



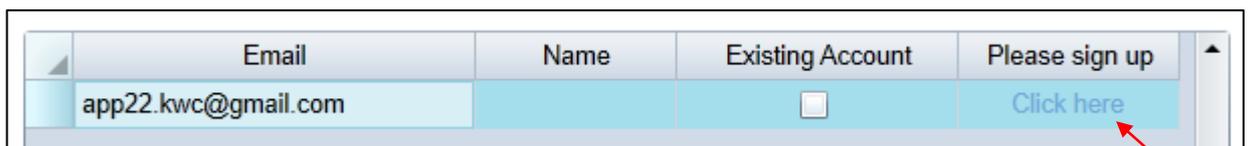
The screenshot shows the "Delegates :" table with the "Email" column containing the text "app02.kwc@gmail.com". The "Add New Row" button is visible above the table.

- The “Name” and checkbox of “Existing Account” will be auto-filled by the system if he/she is recognized as an existing account.



The screenshot shows the "Delegates :" table with the "Email" column containing "app02.kwc@gmail.com". The "Name" column is filled with "KWC APP02" and the "Existing Account" column has a checked checkbox. A red box highlights the "Name" and "Existing Account" columns.

- On the contrary, the “Name” and checkbox of “Existing Account” will not be auto-filled by the system if he/she is not recognized as an existing account, which means your delegate does not have an account yet. Press “**Click here**” to sign up the account first.



The screenshot shows the "Delegates :" table with the "Email" column containing "app22.kwc@gmail.com". The "Name" and "Existing Account" columns are empty. The "Please sign up" column contains a blue link that says "Click here". A red arrow points to the "Click here" link.

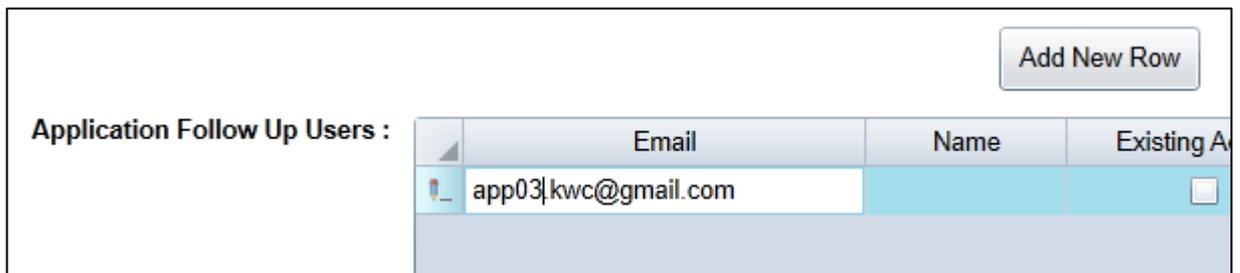
#### 4. Application Follow Up Users

- Please assign Follow-Up Users who will help manage and follow up the post-approval activities:
  - Upload Progress Report
  - Upload Final Report
  - Upload SAE Report
  - Upload SUSAR Report
  - Submit Protocol Deviation Form
  - Submit New/Renewed CTC
  - Submit New/Renewed CTI
  - Submit Amendment Application Form

- Click the “Add New Row” button to add a new row.



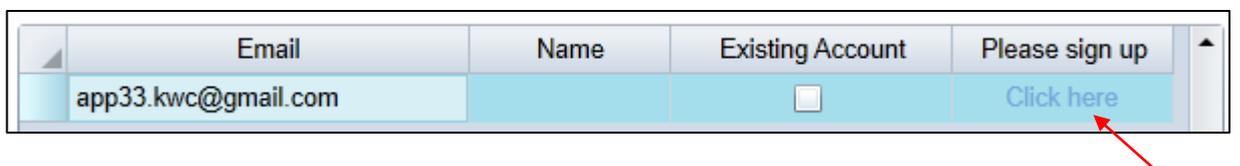
- In the “Email” column, input the **login email address** of the application follow up users.



- The “Name” and checkbox of “Existing Account” will be auto-filled by the system if he/she is recognized as an existing account.



- On the contrary, the “Name” and checkbox of “Existing Account” will not be auto-filled by the system if he/she is not recognized as an existing account, which means your follow up user does not have an account yet. Press “**Click here**” to sign up the account first.



5. Click the **[Create]** button to submit the Management Team Member Form:

**Welcome, Peter Chan** Role: Applicant

Print **Create** Close

### Application Management Team Member Form

**Note to Investigator**

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

**Scientific Title (<500 characters)\***

[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

**Principal Investigator :**

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app1@gmail.com | ntec.app1@gma | <input checked="" type="checkbox"/> |                |

*Assign Principal Investigator who will be responsible for the Application.*

Add New Row Delete Selected Row(s)

**Delegates :**

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app2@gmail.com | ntec.app2@gma | <input checked="" type="checkbox"/> |                |

Logout

© FlexWorkflow Limited Application Management Team Member Form

6. You will get the following message dialog prompted. Click [Yes] to proceed.

The screenshot shows a web application interface for the 'Application Management Team Member Form'. At the top, it says 'Welcome, Peter Chan' and 'Role: Applicant'. The form contains a 'Note to Investigator' section with instructions to complete the form before opening a new Application Form. Below this is a 'Scientific Title (<500 characters)\*' field containing the text: '[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial'. A confirmation dialog box is displayed in the center, asking 'Please confirm to create a new application for clinical research ethics review.' with 'Yes' and 'No' buttons. The 'Yes' button is highlighted with a red box. Below the dialog is a 'Principal Investigator' table with one row: ntec.app1@gmail.com, ntec.app1@gma, and a checked checkbox. Below that is a 'Delegates' table with one row: ntec.app2@gmail.com, ntec.app2@gma, and a checked checkbox. The interface includes a sidebar with navigation icons and a 'Logout' button. The footer shows '© FlexWorkflow Limited' and 'Application Management Team Member Form'.

**Application Management Team Member Form**

**Note to Investigator**

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

**Scientific Title (<500 characters)\***

[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

**Message**

Please confirm to create a new application for clinical research ethics review.

**Principal Investigator :**

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app1@gmail.com | ntec.app1@gma | <input checked="" type="checkbox"/> |                |

Assign Principal Investigator who will be responsible for the Application.

**Delegates :**

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app2@gmail.com | ntec.app2@gma | <input checked="" type="checkbox"/> |                |

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7. Click **[OK]** in the promoted dialog.

**Welcome, Peter Chan** Role: Applicant

**Application Management Team Member Form**

**Note to Investigator**

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

**Scientific Title (<500 characters)\***

[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

**Information**

The task is being processed.

**Principal Investigator :**

ntec.app1@gmail.com ntec.app1@gmail.com Please sign up

Assign Principal Investigator who will be responsible for the Application.

Add New Row Delete Selected Row(s)

**Delegates :**

| Email               | Name                | Existing Account                    | Please sign up |
|---------------------|---------------------|-------------------------------------|----------------|
| ntec.app2@gmail.com | ntec.app2@gmail.com | <input checked="" type="checkbox"/> |                |

Logout

© FlexWorkflow Limited

Application Management Team Member Form

## 5.1.2. Fill in Application Form

After Management Team Member Form submission, you need to fill in the Application Form.

1. Go to **[Application]** ->**[Draft]**

The screenshot displays the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the Hospital Authority logo and name in Chinese and English. The main header area says "Welcome, Peter Chan" and shows the user's role as "Applicant" and the last successful login time as "2016/11/13 20:47:28". A yellow banner below the header reads "Welcome to the Hospital Authority Clinical Research Ethics Review Portal." and provides a brief description of the portal's purpose. On the left, a dark green navigation sidebar is visible, with the "Application" menu item highlighted in red. A sub-menu is open for "Application", showing options: "New", "Draft", "Sent", "Returned", "Approved", "Completed", "Withdrawn", and "All". The "Draft" option is also highlighted in red. At the bottom of the sidebar, there is a "Logout" button and the copyright notice "© FlexWorkflow Limited".

2. In the “Task” column, choose your application and click “Initial Application Approval” to open the Application Form.

**醫院管理局**  
HOSPITAL  
AUTHORITY

Welcome, Peter Chan

Role: Applicant

Last Successful Log In: 2016/11/13 20:47:28

**Draft** Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title  | PI Hospital | PI University | Status | Action(s)                                   |
|---------------|---------------------|------------------|--|---|-------------|---------------|--------|---|
|               |                     | 2016/11/13 22:38 | <a href="#">Initial Application Approval</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial |             |               | Draft  | <a href="#">Export</a> <a href="#">More</a> |

Click to open

Logout

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3. In the toolbar, buttons are available for operation:

**Welcome, Peter Chan** Role: Applicant

Save Print Submit Delete Application Summary Close

Submission Ref No.(For Office Use)

Status

醫院管理局  
HOSPITAL AUTHORITY

**Hospital Authority**

**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

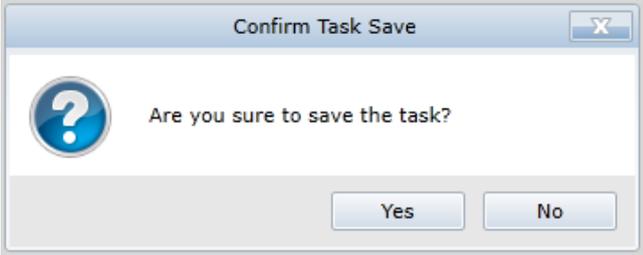
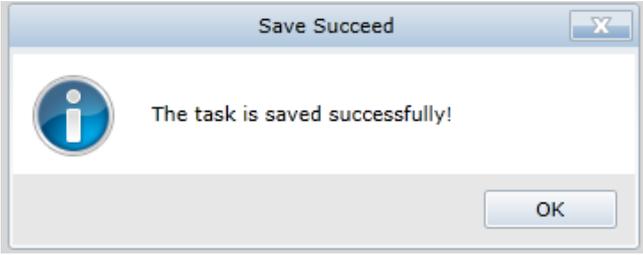
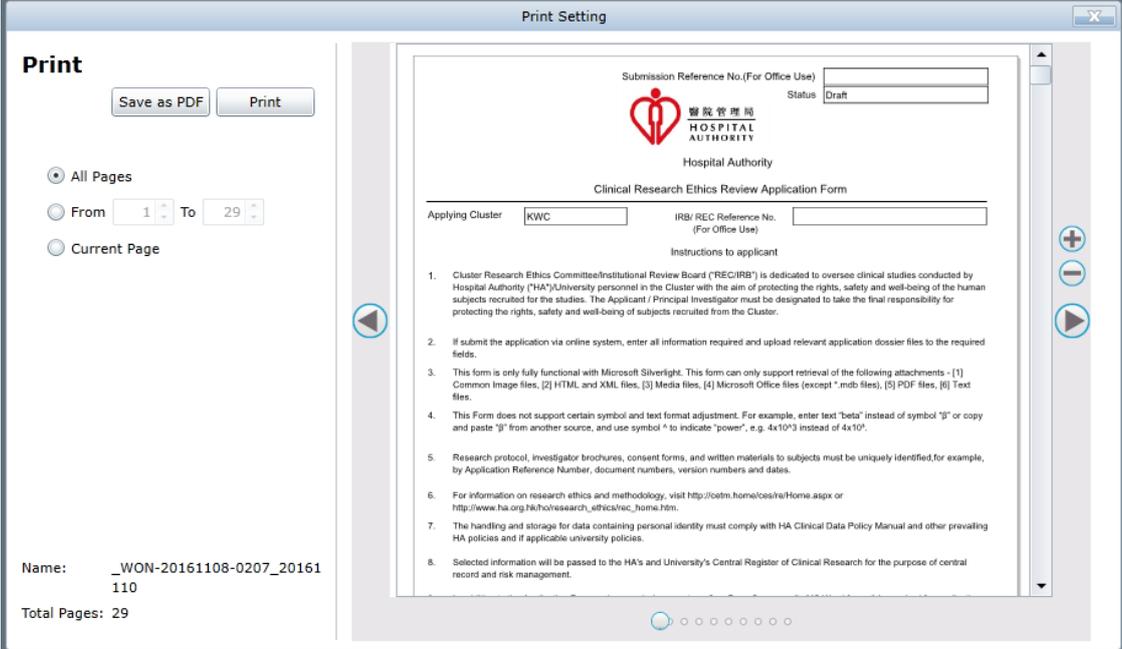
1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10<sup>β</sup>.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.

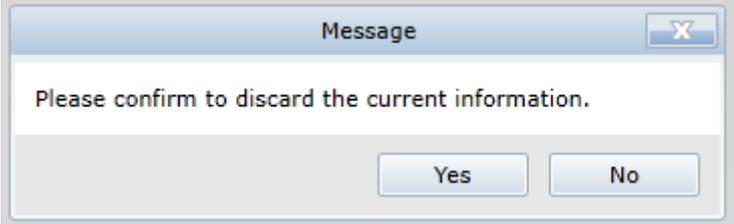
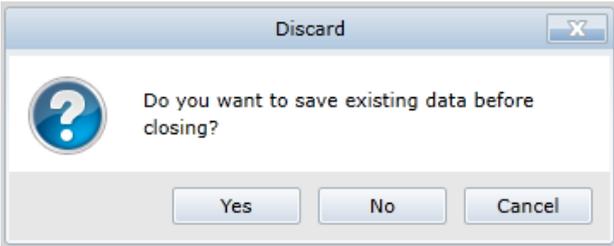
Logout

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Instructions PartI PartII PartIII PartIV PartV PartVI  
Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet  
Comment Box

Below is the description of each button:

| Button | Description   |
|--------|---|
| Save   | <p>Save your application. After clicking the “Save” button, the following dialog will be prompted. Click [Yes] if you confirm.</p>  <p>After that the following dialog will be prompted to inform you the task is saved.</p>  |
| Print  | <p>The following console will be prompted. There are two buttons:</p> <p>“Save as PDF” is to save the application form as a PDF file.</p> <p>“Print” is to print your application form. You can choose to print all pages, the current page or a page range that you specify.</p>                           |
| Submit | Submit your application form. For details, please refer to the section 5.1.3 Submit Initial Application Form  |
| Delete | Delete your application. Click [Yes] to confirm in the following prompted dialog.   |

|       |   |
|-------|---|
|       |  <p>For details, please refer to the section 5.2.4 Delete Initial Application</p>   |
| Close | <p>Close the application form. The following dialog will be prompted to ask you whether to save the existing data before closing.</p>  |

4. The application form contains multiple pages.

At the bottom, click the tabs to open the corresponding pages of the application form.

**Welcome, Peter Chan** Role: Applicant

Save Print Submit Delete Application Summary Close

Instructions

**Submission Ref No.(For Office Use)**

**Status**

 **醫院管理局**  
**HOSPITAL AUTHORITY**

**Hospital Authority**

**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10<sup>3</sup>.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.

Logout

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**Instructions** | PartI | PartII | PartIII | PartIV | PartV | PartVI

Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet

Comment Box

5. The application form requires you to input information. Below are some instructions:

**The mandatory fields are marked with an asterisk (\*).**

**Welcome, Peter Chan** Role: Applicant

**Clinical Research Ethics Review Application Form**

Fields mark with asterisk (\*) are mandatory fields

IRB/ REC Reference No. (For Office Use)

**PART I: OUTLINE OF APPLICATION**

**1. Name of Study**

1.1 Scientific Title (<500 characters)\*

[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

1.1.1 Research protocol number

1.2 Short Title (for lay public / easy quote)\*

1.3 Key Words (for searching purpose, e.g. disease name, drug name, etc.)\*

**2. Applicant (Principal Investigator)**

2.1 Title \* (e.g. Mr, Mrs, Ms, Miss, Dr) Surname \* First name \*

Name in Chinese

Logout

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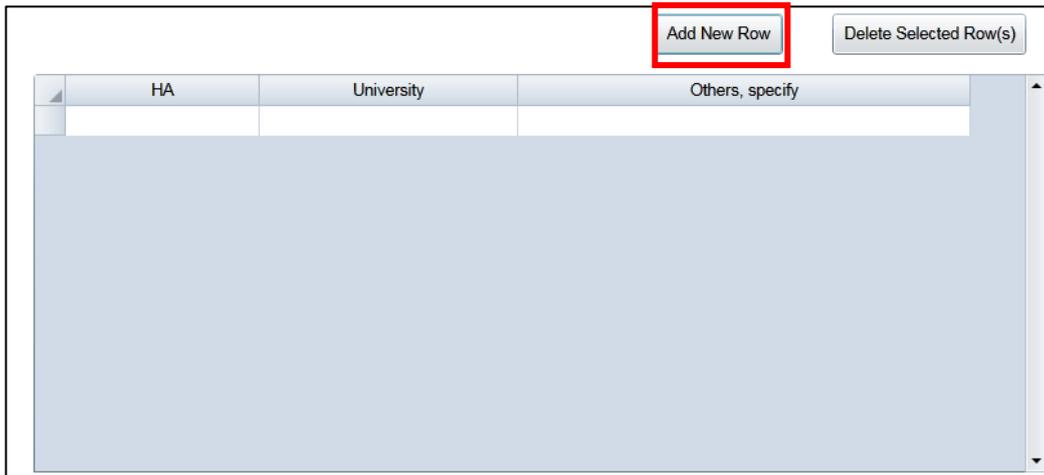
Instructions PartI PartII PartIII PartIV PartV PartVI

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

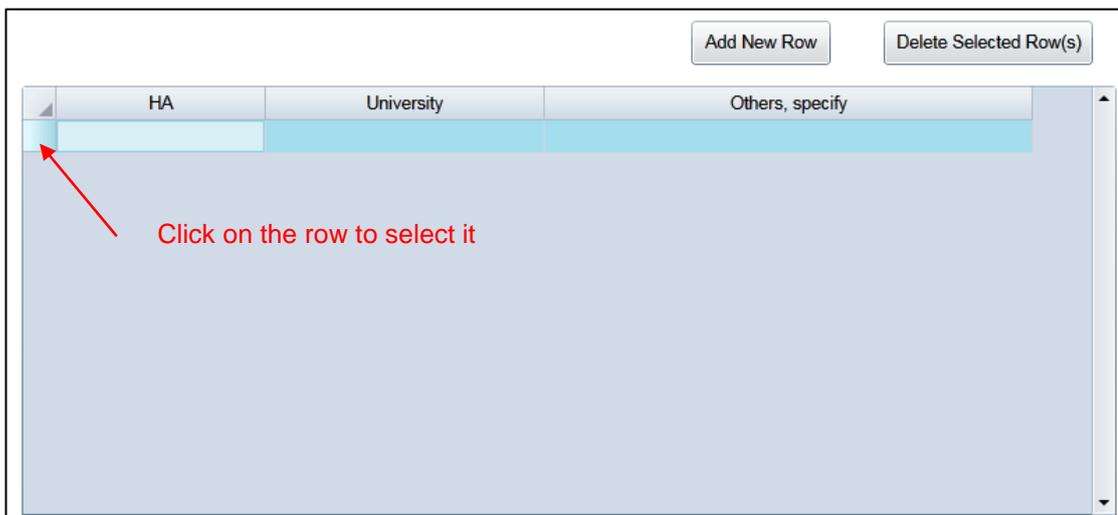
Comment Box

## How to Add Row / Delete Row

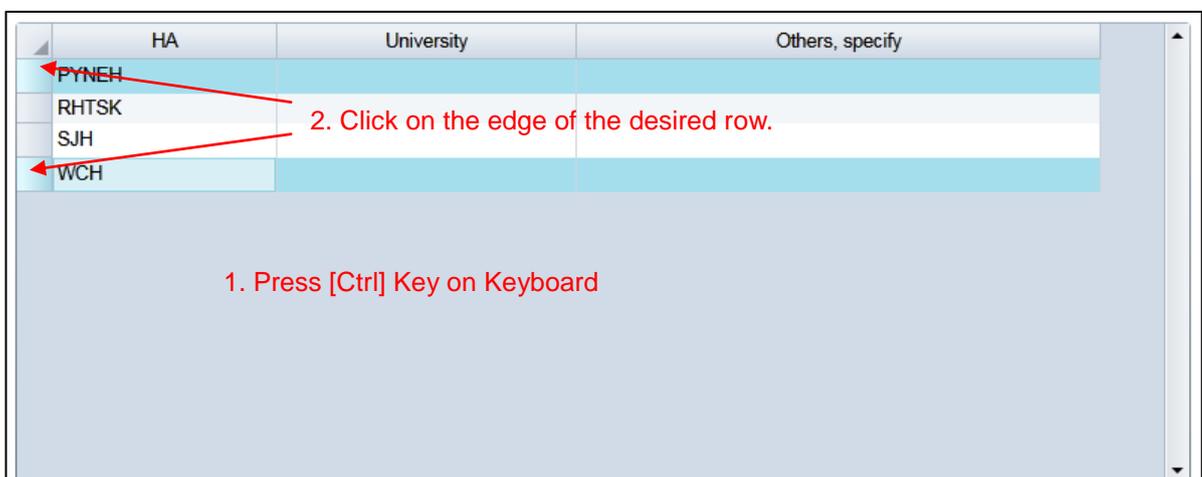
- In some fields, you may need to add or delete a row.
- Click **[Add New Row]** to insert the information row;



- Select the row by clicking it. After selection, it will be highlighted in blue.



- To select multiple rows, hold the [Ctrl] key on the keyboard and click on the edges of your desired rows one by one.



- To select consecutive rows, hold the [Shift] key on the keyboard. Click on the edge of the starting row and then the last row.

A screenshot of a table with three columns: HA, University, and Others, specify. The rows are CCH, PYNEH, RHTSK, SJH, TWEH, and WCH. The rows RHTSK, SJH, and TWEH are highlighted in light blue. Red arrows point to the left edge of the RHTSK row and the left edge of the TWEH row. Red text annotations are present: '2. Click on the edge of the start row' pointing to the RHTSK row, '3. Click on the edge of the last row' pointing to the TWEH row, and '1. Press [Shift] Key on Keyboard' centered below the table.

| HA    | University | Others, specify |
|-------|------------|-----------------|
| CCH   |            |                 |
| PYNEH |            |                 |
| RHTSK |            |                 |
| SJH   |            |                 |
| TWEH  |            |                 |
| WCH   |            |                 |

- Click **[Delete Selected Rows(s)]** to remove the selected row(s).

A screenshot of a table with three columns: HA, University, and Others, specify. The first row is highlighted in light blue. Above the table are two buttons: 'Add New Row' and 'Delete Selected Row(s)'. The 'Delete Selected Row(s)' button is highlighted with a red rectangular border.

| HA | University | Others, specify |
|----|------------|-----------------|
|    |            |                 |

### Enabled / Disabled Field

- Disabled fields are dimmed:

2.2 Position of the Principal Investigator (PI)

2.2.1  HA staff

Position

Department/Unit

Hospital (1)

Hospital (2)

Site Coordinator (If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination.)

2.2.2  University staff

Position

Department/School/Faculty

University

2.2.3  HA Employee  University Employee

### Radio Button

- If you need to cancel the checked option, click on the checked option again:

Yes  No

Yes  No

## Upload Document

- Supporting documents can be attached in Part VI:

28. Subject Informed Consent Form<sup>^</sup> (Supplementary) <sup>^</sup> Unless waived by Cluster REC

No. of attachments: 0

|  | Upload Date | Created By | Document Type | File Name | Suggested Print Name | Upload Times |
|--|-------------|------------|---------------|-----------|----------------------|--------------|
|  |             |            |               |           |                      |              |

Instructions    PartI    PartII    PartIII    PartIV    PartV    **PartVI**

Clinical Study Categorization Form    Application Log    Document Log    Application Management Team Member Form    Comment Sheet

Comment Box

Below are some important notes when filling in each part:

### 5.1.2.1. Instructions

- The instruction page lists out the basic instructions of the application.

**Welcome, Peter Chan** Role: Applicant

Submission Ref No.(For Office Use)   
Status

**Hospital Authority**  
HOSPITAL AUTHORITY

**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10³.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.

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Logout | Instructions | PartI | PartII | PartIII | PartIV | PartV | PartVI

Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet

Comment Box

- Select your "Applying Cluster":

Submission Ref No.(For  
 醫院管理局  
 HOSPITAL  
 AUTHORITY  
 Hospital Authority  
 Clinical Research Ethics Review Appl  
 Applying Cluster: HKEC  
 Codevalue  
 HKEC  
 HKWC  
 KCC/KEC  
 KWC  
 NTEC  
 NTWC  
 IRB/ REC  
 (For Office  
 ons to applicant  
 Board ("REC/IRB") is dec  
 ter with the aim of protec  
 al Investigator must be d  
 ruitied from the Cluster.

- Tick the checkbox of "Acknowledge of the instruction" after fully understanding the instruction:

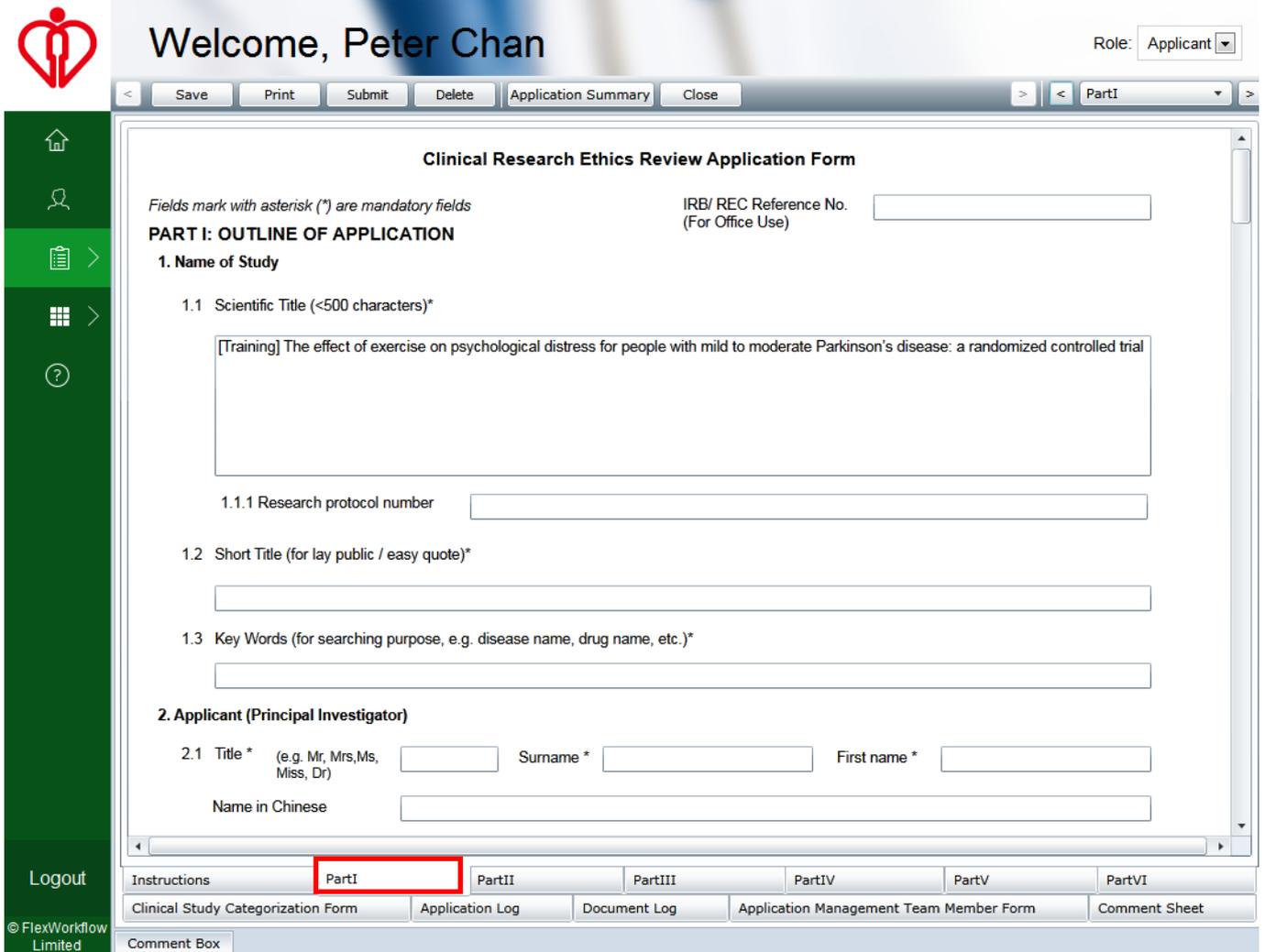
Reminder  
 1. Hospital Authority as a Research Institution  
 The HA is a body corporate established under the Hospital Authority Ordinance (Chapter 113 of the laws of Hong Kong). In addition to the primary responsibilities of establishing, managing, controlling and developing the public hospital system in Hong Kong and advising the Hong Kong government on healthcare policies and strategies, the HA also has the responsibility to promote, assist and take part in research relating to hospital services (Chapter 113, Section 4(f) (ii) of the laws of Hong Kong).  
 2. Local Regulation on Clinical Studies of Pharmaceutical Products  
 Clinical studies of pharmaceutical products are regulated in Hong Kong under the Pharmacy and Poisons Regulations (Chapter 138A Regulation 36B of the laws of Hong Kong). For the purpose of regulatory compliance, a Certificate for Clinical Trial ("CTC") shall be obtained before initiation of clinical study of pharmaceutical product.  
 Acknowledge of the instruction  
 Download Investigator's Conflict of Interest Declaration Form  
 Instructions: PartI, PartII, PartIII, PartIV, PartV, PartVI  
 Clinical Study Categorization Form, Application Log, Document Log, Application Management Team Member Form, Comment Sheet

- If necessary, press the [Download Investigator's Conflict of Interest Declaration Form] to **download** the declaration form. Fill in the declaration form, scan it and then upload it in Part VI:

Acknowledge of the instruction  
 Download Investigator's Conflict of Interest Declaration Form  
 Instructions: PartI, PartII, PartIII, PartIV, PartV, PartVI  
 Clinical Study Categorization Form, Application Log, Document Log, Application Management Team Member Form, Comment Sheet  
 Comment Box

## 5.1.2.2. Part I

- "Part I" is a page about the outline of your application.



 **Welcome, Peter Chan** Role: Applicant

> < PartI < >

### Clinical Research Ethics Review Application Form

*Fields mark with asterisk (\*) are mandatory fields* IRB/ REC Reference No.

#### PART I: OUTLINE OF APPLICATION

**1. Name of Study**

1.1 Scientific Title (<500 characters)\*

1.1.1 Research protocol number

1.2 Short Title (for lay public / easy quote)\*

1.3 Key Words (for searching purpose, e.g. disease name, drug name, etc.)\*

**2. Applicant (Principal Investigator)**

2.1 Title \* (e.g. Mr, Mrs, Ms, Miss, Dr)  Surname \*  First name \*

Name in Chinese

**Navigation:** Instructions | **PartI** | PartII | PartIII | PartIV | PartV | PartVI  
Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet

[Logout](#)

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- **Other Investigators**

To add other investigators, click the [Add New Row] button.

3. Other investigators

*(If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination)*

The screenshot shows a software interface for adding investigators. At the top, there are two buttons: 'Add New Row' (highlighted with a red box) and 'Delete Selected Row(s)'. Below these is a table with the following columns: No., Title, Surname, First name, Email, Relevant Qualifications, and Department. To the right of the table is a 'Responsibility' dropdown menu. The dropdown menu is open, showing a list of 14 responsibilities with checkboxes. The third option, 'Data/Sample Security', is currently selected.

Scroll sideways as shown below to view more columns

3. Other investigators

*(If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination)*

This screenshot illustrates how to view more columns in the table by scrolling horizontally. The 'Add New Row' and 'Delete Selected Row(s)' buttons are at the top. The table columns are Title, Surname, First name, Email, Relevant Qualifications, and Department. A red arrow points to the horizontal scrollbar at the bottom of the table. To the right, the 'Responsibility' dropdown menu is open, and the first option, 'Administration', is selected.

\*Please specify if there is a Lead PI in addition to the PI

Each of the filled “Other Investigators” requires the “Responsibility” information. Before adding a responsibility, input their “Email” first.

### 3. Other investigators

*(If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination)*

Add New Row    Delete Selected Row(s)

|  | Email           | Relevant Qualifications | Department | Responsibility |
|--|-----------------|-------------------------|------------|----------------|
|  | test@domain.com |                         |            |                |

<< Responsibility

| No. | ✓                        | Responsibility Description |
|-----|--------------------------|----------------------------|
| 1   | <input type="checkbox"/> | Administration             |
| 2   | <input type="checkbox"/> | Clinical Care              |
| 3   | <input type="checkbox"/> | Data/Sample Security       |
| 4   | <input type="checkbox"/> | Documentation              |
| 5   | <input type="checkbox"/> | Efficacy & Safety          |
| 6   | <input type="checkbox"/> | Expertise Advice           |
| 7   | <input type="checkbox"/> | Informed Consent           |
| 8   | <input type="checkbox"/> | Lead PI                    |
| 9   | <input type="checkbox"/> | Partners Coordinator       |
| 10  | <input type="checkbox"/> | Protection of Subject      |
| 11  | <input type="checkbox"/> | Site Coordinator           |
| 12  | <input type="checkbox"/> | Staff Safety               |
| 13  | <input type="checkbox"/> | Subject Recruitment        |
| 14  | <input type="checkbox"/> | Others                     |

\*Please specify if there is a Lead PI in addition to the PI

Make sure the row is highlighted (appear in blue color). Then select the responsibility in the right panel to assign it to the highlighted investigator.

### 3. Other investigators

*(If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination)*

Add New Row    Delete Selected Row(s)

|  | Email           | Relevant Qualifications | Department | Responsibility  |
|--|-----------------|-------------------------|------------|-----------------|
|  | test@domain.com |                         |            | test@domain.com |

<< Responsibility

| No. | ✓                                   | Responsibility Description |
|-----|-------------------------------------|----------------------------|
| 1   | <input type="checkbox"/>            | Administration             |
| 2   | <input checked="" type="checkbox"/> | Clinical Care              |
| 3   | <input type="checkbox"/>            | Data/Sample Security       |
| 4   | <input checked="" type="checkbox"/> | Documentation              |
| 5   | <input checked="" type="checkbox"/> | Efficacy & Safety          |
| 6   | <input type="checkbox"/>            | Expertise Advice           |
| 7   | <input type="checkbox"/>            | Informed Consent           |
| 8   | <input type="checkbox"/>            | Lead PI                    |
| 9   | <input type="checkbox"/>            | Partners Coordinator       |
| 10  | <input type="checkbox"/>            | Protection of Subject      |
| 11  | <input type="checkbox"/>            | Site Coordinator           |
| 12  | <input type="checkbox"/>            | Staff Safety               |
| 13  | <input type="checkbox"/>            | Subject Recruitment        |
| 14  | <input type="checkbox"/>            | Others                     |

\*Please specify if there is a Lead PI in addition to the PI

Click the  button to add the selected responsibilities.

**3. Other investigators**

*(If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination)*

|  | Email           | Relevant Qualifications | Department | Responsibility |
|--|-----------------|-------------------------|------------|----------------|
|  | test@domain.com |                         |            |                |



| No. | ✓                                   | Responsibility Description |
|-----|-------------------------------------|----------------------------|
| 1   | <input type="checkbox"/>            | Administration             |
| 2   | <input checked="" type="checkbox"/> | Clinical Care              |
| 3   | <input type="checkbox"/>            | Data/Sample Security       |
| 4   | <input checked="" type="checkbox"/> | Documentation              |
| 5   | <input checked="" type="checkbox"/> | Efficacy & Safety          |
| 6   | <input type="checkbox"/>            | Expertise Advice           |
| 7   | <input type="checkbox"/>            | Informed Consent           |
| 8   | <input type="checkbox"/>            | Lead PI                    |
| 9   | <input type="checkbox"/>            | Partners Coordinator       |
| 10  | <input type="checkbox"/>            | Protection of Subject      |
| 11  | <input type="checkbox"/>            | Site Coordinator           |
| 12  | <input type="checkbox"/>            | Staff Safety               |
| 13  | <input type="checkbox"/>            | Subject Recruitment        |
| 14  | <input type="checkbox"/>            | Others                     |

\*Please specify if there is a Lead PI in addition to the PI

The responsibilities are then added:

**3. Other investigators**

*(If the PI is not situated in the applying HA site, it is recommended to assign a qualified HA staff for site coordination)*

|  | Email           | Relevant Qualifications | Department | Responsibility                                  |
|--|-----------------|-------------------------|------------|---|
|  | test@domain.com |                         |            | Clinical Care, Documentation, Efficacy & Safety |



| No. | ✓                                   | Responsibility Description |
|-----|-------------------------------------|----------------------------|
| 1   | <input type="checkbox"/>            | Administration             |
| 2   | <input checked="" type="checkbox"/> | Clinical Care              |
| 3   | <input type="checkbox"/>            | Data/Sample Security       |
| 4   | <input checked="" type="checkbox"/> | Documentation              |
| 5   | <input checked="" type="checkbox"/> | Efficacy & Safety          |
| 6   | <input type="checkbox"/>            | Expertise Advice           |
| 7   | <input type="checkbox"/>            | Informed Consent           |
| 8   | <input type="checkbox"/>            | Lead PI                    |
| 9   | <input type="checkbox"/>            | Partners Coordinator       |
| 10  | <input type="checkbox"/>            | Protection of Subject      |
| 11  | <input type="checkbox"/>            | Site Coordinator           |
| 12  | <input type="checkbox"/>            | Staff Safety               |
| 13  | <input type="checkbox"/>            | Subject Recruitment        |
| 14  | <input type="checkbox"/>            | Others                     |

\*Please specify if there is a Lead PI in addition to the PI

To change the added responsibilities, re-select the responsibilities in the right panel then click the

<< Responsibility

button to apply the changes:

Add New Row    Delete Selected Row(s)

| Email    | Relevant Qualifications | Department | Responsibility                                  |
|----------|-------------------------|------------|---|
| main.com |                         |            | Clinical Care, Documentation, Efficacy & Safety |

<< Responsibility

| No. | ✓                                   | Responsibility Description |
|-----|-------------------------------------|----------------------------|
| 1   | <input type="checkbox"/>            | Administration             |
| 2   | <input type="checkbox"/>            | Clinical Care              |
| 3   | <input type="checkbox"/>            | Data/Sample Security       |
| 4   | <input type="checkbox"/>            | Documentation              |
| 5   | <input type="checkbox"/>            | Efficacy & Safety          |
| 6   | <input type="checkbox"/>            | Expertise Advice           |
| 7   | <input type="checkbox"/>            | Informed Consent           |
| 8   | <input checked="" type="checkbox"/> | Lead PI                    |
| 9   | <input checked="" type="checkbox"/> | Partners Coordinator       |
| 10  | <input type="checkbox"/>            | Protection of Subject      |
| 11  | <input type="checkbox"/>            | Site Coordinator           |
| 12  | <input type="checkbox"/>            | Staff Safety               |
| 13  | <input type="checkbox"/>            | Subject Recruitment        |
| 14  | <input type="checkbox"/>            | Others                     |

<< Responsibility

| Email    | Relevant Qualifications | Department | Responsibility                |
|----------|-------------------------|------------|-------------------------------|
| main.com |                         |            | Lead PI, Partners Coordinator |

<< Responsibility

| No. | ✓                                   | Responsibility Description |
|-----|-------------------------------------|----------------------------|
| 1   | <input type="checkbox"/>            | Administration             |
| 2   | <input type="checkbox"/>            | Clinical Care              |
| 3   | <input type="checkbox"/>            | Data/Sample Security       |
| 4   | <input type="checkbox"/>            | Documentation              |
| 5   | <input type="checkbox"/>            | Efficacy & Safety          |
| 6   | <input type="checkbox"/>            | Expertise Advice           |
| 7   | <input type="checkbox"/>            | Informed Consent           |
| 8   | <input checked="" type="checkbox"/> | Lead PI                    |
| 9   | <input checked="" type="checkbox"/> | Partners Coordinator       |
| 10  | <input type="checkbox"/>            | Protection of Subject      |
| 11  | <input type="checkbox"/>            | Site Coordinator           |
| 12  | <input type="checkbox"/>            | Staff Safety               |
| 13  | <input type="checkbox"/>            | Subject Recruitment        |
| 14  | <input type="checkbox"/>            | Others                     |

If you need to change the responsibility of other investigators, click the row to highlight it and then repeat the above steps.

| Email            | Relevant Qualifications | Department | Responsibility                   |
|------------------|-------------------------|------------|----------------------------------|
| test1@domain.com |                         |            | Lead PI,<br>Partners Coordinator |
| test2@domain.com |                         |            |                                  |
| test3@domain.com |                         |            |                                  |

Click on the row to highlight it

<< Responsibility

| N o. | √                        | Responsibility Description |
|------|--------------------------|----------------------------|
| 1    | <input type="checkbox"/> | Administration             |
| 2    | <input type="checkbox"/> | Clinical Care              |
| 3    | <input type="checkbox"/> | Data/Sample Security       |
| 4    | <input type="checkbox"/> | Documentation              |
| 5    | <input type="checkbox"/> | Efficacy & Safety          |
| 6    | <input type="checkbox"/> | Expertise Advice           |
| 7    | <input type="checkbox"/> | Informed Consent           |
| 8    | <input type="checkbox"/> | Lead PI                    |
| 9    | <input type="checkbox"/> | Partners Coordinator       |
| 10   | <input type="checkbox"/> | Protection of Subject      |
| 11   | <input type="checkbox"/> | Site Coordinator           |
| 12   | <input type="checkbox"/> | Staff Safety               |
| 13   | <input type="checkbox"/> | Subject Recruitment        |
| 14   | <input type="checkbox"/> | Others                     |

### 5.1.2.3. Part II

- "Part II" is about study details.

The screenshot shows a web application interface for a user named Peter Chan, who is logged in as an Applicant. The main content area is titled "PART II: STUDY DETAILS (No referral to protocols/other documents is allowed)". It contains three sections for text entry:

- 9. Scientific basis**: Includes a field for "IRB/ REC Reference No. (For Office Use)".
- 9.1 Background, current evidence and key references\* (< 30,000 characters)**: A large text area for background information.
- 9.2 Aim of study\* (< 30,000 characters)**: A text area for the study's aim.
- 9.3 Hypothesis (e.g. Compared to x control, y intervention leads to a greater rate of z outcome)\* (< 30,000 characters)**: A text area for the hypothesis.

The interface includes a top navigation bar with buttons for Save, Print, Submit, Delete, Application Summary, and Close. A left sidebar contains navigation icons for Home, Profile, Documents, Grid, and Help. At the bottom, there is a tabbed interface with tabs for Instructions, PartI, PartII (highlighted with a red box), PartIII, PartIV, PartV, and PartVI. Below the tabs are buttons for Clinical Study Categorization Form, Application Log, Document Log, Application Management Team Member Form, and Comment Sheet. A "Logout" button is located in the bottom left corner. The copyright notice "© FlexWorkflow Limited" is visible in the bottom left corner of the application area.

## 5.1.2.4. Part III

- "Part III" is about study details.

**Welcome, Peter Chan** Role: Applicant

Save Print Submit Delete Application Summary Close

**PART III: STUDY DETAILS (Sections 16 to 19 are applicable for Prospective Study only)**

**16. Study Article and Arrangements** IRB/ REC Reference No. (For Office Use)

16.1 Study design

16.1.1 How does the procedure/treatment differ from current treatment practice?\*

if others, specify

16.1.2 Methods of assignment\*

16.1.3 Degree of masking\*

16.1.4 Phase of study\*

16.2 Study article

16.2.1 Is there any study article?\*

16.2.2 Study article details

Add New Row Delete Selected Row(s)

| Article | Type | Name | Duration of exposure | Dosage | Route of administration | Was it produced under GMP? | Others, specify |
|---------|------|------|----------------------|--------|-------------------------|----------------------------|-----------------|
|---------|------|------|----------------------|--------|-------------------------|----------------------------|-----------------|

Logout

© FlexWorkflow Limited

Instructions PartI PartII **PartIII** PartIV PartV PartVI

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

Comment Box

## 5.1.2.5. Part IV

- "Part IV" is about budget and use of resources.

**22. Source of Funding**

IRB/ REC Reference No. (For Office Use)

22.1 Commercial\*  Yes  No

22.1.1 Sponsored trial  Yes  No

Specify the source of funding:

| No. | Name of Sponsor / donating body |
|-----|---------------------------------|
|-----|---------------------------------|

22.2 Non-commercial\*  Yes  No

© FlexWorkflow Limited

Logout

Instructions | PartI | PartII | PartIII | **PartIV** | PartV | PartVI

Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet

Comment Box

## 5.1.2.6. Part V

- The "Part V" is about declaration by investigator(s).

 Welcome, Peter Chan Role: Applicant

Save Print Submit Delete Application Summary Close

**PART V: DECLARATION BY INVESTIGATOR(S)**

IRB/ REC Reference No.   
(For Office Use)

26. Note: Certain trial information will be passed to a Central Database for risk management purpose and to assist HA's finance controller in sourcing insurance coverage for clinical trial activities

**26.1: Scientific Title of Study**

- I / We declare that the information supplied is to the best of our knowledge and accurate.
- I / We declare that the protocol comply with Declaration of Helsinki.
- I / We agree to uphold the protection of research subjects' right and safety through adherence to local laws, Declaration of Helsinki, institutional policies<sup>5</sup> and whenever applicable, the ICH-GCP.
- I / We understand that approval by the Cluster REC is subject to regular renewal according to local policy.
- I / We agree to report to the 
  - any planned change(s) to the study, and further agree not to implement any change(s) without receiving prior approval, except to eliminate immediate hazard to research subjects or when the change(s) involve only logistical or administrative issues.
  - any fatal events in applying site within the specific time according to the Standard Operating Procedures of the Cluster REC while pending investigation, and any serious adverse events in applying site (with an extended report) preferably within seven days but not later than 15 days (from the day it was made known to me / us).
  - any new information on the project that adversely influences the risk/benefit ratio.
  - progress report(s) (as requested by the Cluster REC) and a final report (after completion of study).

Logout

© FlexWorkflow Limited

Instructions PartI PartII PartIII PartIV **PartV** PartVI  
Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet  
Comment Box

- The **"Scientific Title of Study"** should be the same as that in Part I. Please check if they are the same.

### 26.1: Scientific Title of Study

## 5.1.2.7. Part VI

- "Part VI" is about table of attachments.

**PART VI: TABLE OF ATTACHMENTS**

IRB/ REC Reference No. (For Office Use)

Suggested Print Name: Please rename the document for your own reference (optional)

27. Research Protocol (Mandatory) No. of attachments: 0

| + | Upload Date | Created By | Document Type | File Name | Suggested Print Name | Upload Times |
|---|-------------|------------|---------------|-----------|----------------------|--------------|
|---|-------------|------------|---------------|-----------|----------------------|--------------|

28. Subject Informed Consent Form^ (Supplementary) ^ Unless waived by Cluster REC

No. of attachments: 0

| + | Upload Date | Created By | Document Type | File Name | Suggested Print Name | Upload Times |
|---|-------------|------------|---------------|-----------|----------------------|--------------|
|---|-------------|------------|---------------|-----------|----------------------|--------------|

Logout

© FlexWorkflow Limited

Instructions | PartI | PartII | PartIII | PartIV | PartV | **PartVI** | Comment Sheet

Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet

Comment Box

- The supporting documents can be attached here.

Click the  button:

**PART VI: TABLE OF ATTACHMENTS**

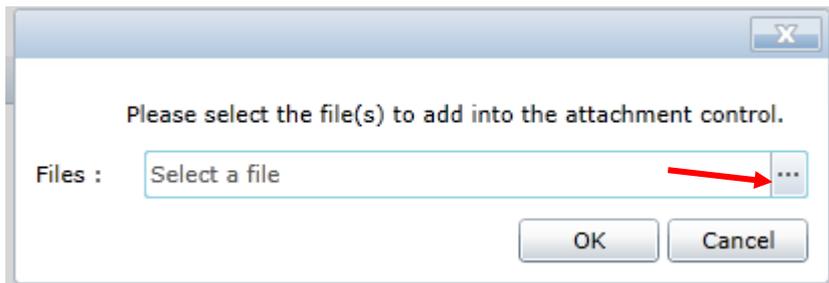
IRB/ REC Reference No. (For Office Use)

Suggested Print Name: Please rename the document for your own reference (optional)

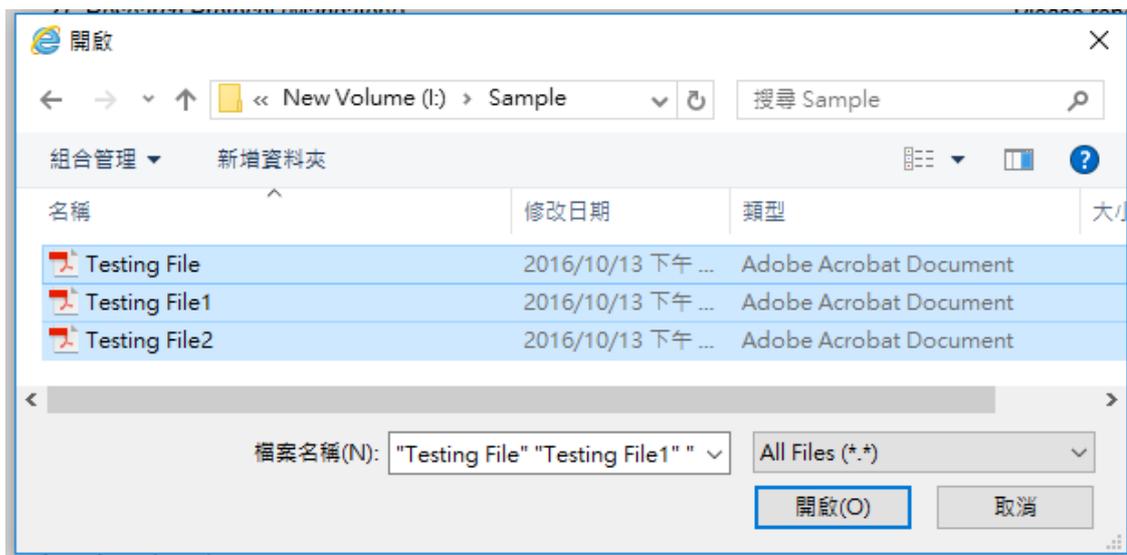
27. Research Protocol (Mandatory) No. of attachments: 0

| + | Upload Date | Created By | Document Type | File Name | Suggested Print Name | Upload Times |
|---|-------------|------------|---------------|-----------|----------------------|--------------|
|---|-------------|------------|---------------|-----------|----------------------|--------------|

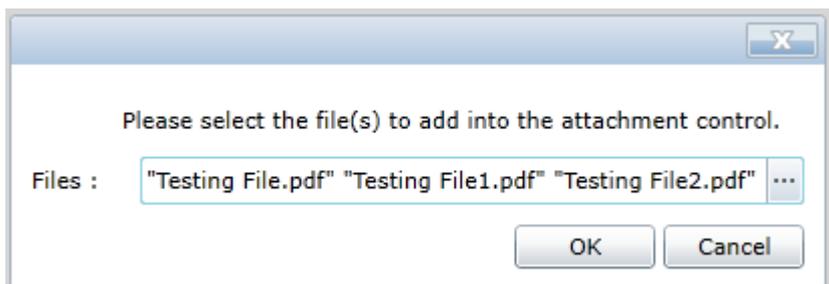
In the prompted dialog, click the  button.



Select all the document(s) that you need to upload and then click “Open”.



Click “OK”.



The files will be added.

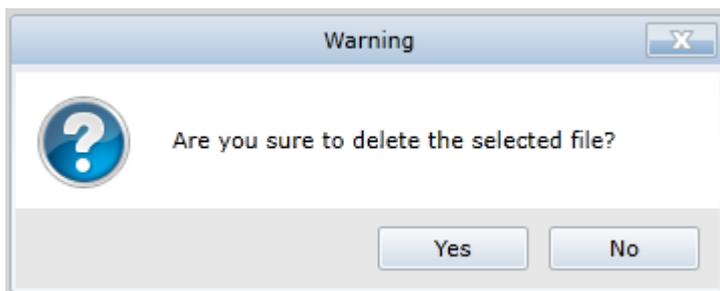
27. Research Protocol (Mandatory) Suggested Print Name:  
Please rename the document for your own reference (optional)

|  |  |  |                       |                     |                   |                   |                      | No. of attachments: 3 |
|--|--|--|-----------------------|---------------------|-------------------|-------------------|----------------------|-----------------------|
|  |  |  | Upload Date           | Created By          | Document Type     | File Name         | Suggested Print Name | Upload Times          |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File.pdf  |                      | 1                     |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File1.pdf |                      | 1                     |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File2.pdf |                      | 1                     |

If you need to delete an added file, click the  button.

|   |   |  |                       |                     |                   |                   | No. of attachments: 3 |              |
|---|---|--|-----------------------|---------------------|-------------------|-------------------|-----------------------|--------------|
|   |   |  | Upload Date           | Created By          | Document Type     | File Name         | Suggested Print Name  | Upload Times |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File.pdf  |                       | 1            |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File1.pdf |                       | 1            |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File2.pdf |                       | 1            |

Click [Yes] in the prompted dialog:



The file will be deleted:

|   |   |  |                       |                     |                   |                   | No. of attachments: 2 |              |
|---|---|--|-----------------------|---------------------|-------------------|-------------------|-----------------------|--------------|
|   |   |  | Upload Date           | Created By          | Document Type     | File Name         | Suggested Print Name  | Upload Times |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File1.pdf |                       | 1            |
|  |  |  | 11/11/2016 7:53:41 PM | ntec.app1@gmail.com | Research Protocol | Testing File2.pdf |                       | 1            |

Decide a print name of an attachment by entering it in the “**Suggested Print Name**” column. The suggested print name will be used to facilitate the system to automatically generate an approval letter where these suggested print names will be used later on in the application process.

| Suggested Print Name | Upload Times |
|----------------------|--------------|
| Reference_Doc_1      | 1            |

## 5.1.2.8. Clinical Study Categorization Form



Welcome, Peter Chan

Role: Applicant

Save Print Submit Delete Application Summary Close Clinical Study Cat

### IRB/REC Name

### Clinical Study Categorization Form

IRB/ REC Reference No.  
(For Office Use)

#### Note to Investigator

Please complete the following Clinical Study Categorization Form and submit the Form together with each application for research ethics review. Upon receipt of an application, the Secretariat will verify the information on the form and arrange for appropriate initial review through Full Review, Expedited Review or Full Review by Phase 1 Panel.

| Risk Group     | No. | Risk Factors                  | Yes                      | No                       |
|----------------|-----|-------------------------------|--------------------------|--------------------------|
| Human Subjects | 1   | Recruitment of human subjects | <input type="checkbox"/> | <input type="checkbox"/> |

Logout

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

Instructions PartI PartII PartIII PartIV PartV PartVI

Comment Box

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## 5.1.2.9. Application Log

Application Log shows a summary of information extracted from your Research Ethics Review Application Form and your subsequent submissions for REC/IRB's review and approval.

### Application Log

#### Note to Investigator

This Application Log shows all the updated information, which are extracted from your Research Ethics Review Application Form and your subsequent submissions for REC/IRB's review and approval.

#### General Information

|   |                   |
|---|-------------------|
| Work Order Number:                      | WON-20161113-0245 |
| Submission Reference Number:            | NTEC-2016-1315    |
| IRB/ REC Reference Number:              |                   |
| Initial Application Submission Date :   | 13/11/2016        |
| Initial Application Review Type :       |                   |
| Initial Application Approval Date :     | <dd/MM/yyyy>      |
| Approval Expiry Date:                   | <dd/MM/yyyy>      |
| Proposed Study Start Date:              | 30/12/2016        |
| Proposed Study End Date:                | 31/07/2018        |
| Actual Study Start Date:                | <dd/MM/yyyy>      |
| Actual Study End Date:                  | <dd/MM/yyyy>      |
| Initial Study Subject Recruitment Date: | <dd/MM/yyyy>      |
| CTC Expiry Date:                        | <dd/MM/yyyy>      |
| CTI Expiry Date:                        | <dd/MM/yyyy>      |
| Latest Progress Report Submission Date: | <dd/MM/yyyy>      |
| Final Report Submission Date:           | <dd/MM/yyyy>      |
| Termination Date:                       | <dd/MM/yyyy>      |
| Termination Reason:                     |                   |

#### Status History

| Date       | Task                         | User                | From  | To        | Open Form                  |
|------------|------------------------------|---------------------|-------|-----------|----------------------------|
| 13/11/2016 | Initial Application Approval | ntec.app1@gmail.com | New   | Draft     | <a href="#">Click Here</a> |
| 13/11/2016 | Initial Application Approval | ntec.app1@gmail.com | Draft | Submitted | <a href="#">Click Here</a> |

[Initial Study Categorization Form](#)
[Application Log](#)
[Document Log](#)
[Application Management Team Member Form](#)
[Comment Sheet](#)

## 5.1.2.10. Document Log

Document Log shows a list of documents attached to the application.

### Document Log

#### General Information

Work Order Number:

Submission Reference Number:

IRB/ REC Reference Number:

#### Uploaded Documents

| Uploaded Documents |                   |   |                         |                      |              |  |
|--------------------|-------------------|---|-------------------------|----------------------|--------------|--|
| Date               | User              | Document Type                                     | Document Name           | Suggested Print Name | Upload Times |  |
| 13/11/2016 14:     | ntec.app1@gmail.c | Research Protocol                                 | _WON-20161109-0214_2016 |                      | 1            |  |
| 13/11/2016 14:     | ntec.app1@gmail.c | Curriculum Vitae (CV) from Principal Investigator | _WON-20161109-0214_2016 |                      | 1            |  |

## 5.1.2.11. Application Management Team Member Form

Application Management Team Member Form shows the Scientific Title, Principal Investigator, Delegates and the Application Follow Up Users defined at the beginning of the application.

### Application Management Team Member Form

#### Note to Investigator

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

Scientific Title (<500 characters)\*

[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

Principal Investigator :

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app1@gmail.com | ntec.app1@gma | <input checked="" type="checkbox"/> |                |

Assign Principal Investigator who will be responsible for the Application.

Add New Row

Delete Selected Row(s)

Delegates :

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app2@gmail.com | ntec.app2@gma | <input checked="" type="checkbox"/> |                |

Please assign Delegates who will help manage and edit the application forms before research ethics approval.

Add New Row

Delete Selected Row(s)

Application Follow Up Users :

| Email | Name | Existing Account | Please sign up |
|-------|------|------------------|----------------|
|-------|------|------------------|----------------|

al Study Categorization Form

Application Log

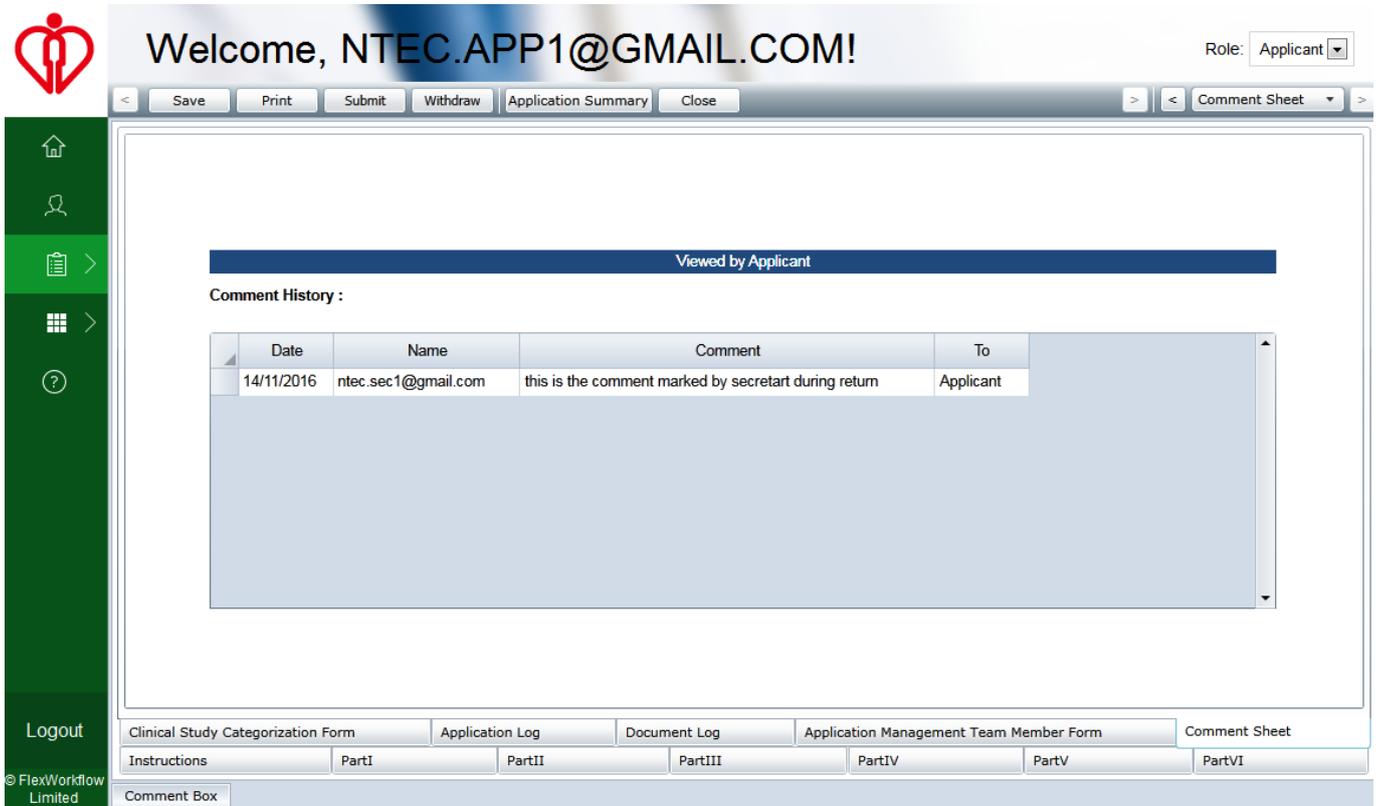
Document Log

Application Management Team Member Form

Comment Sheet

## 5.1.2.12. Comment Sheet

Comment Sheet shows the comment history throughout the application.



The screenshot displays a web application interface for a Comment Sheet. At the top, a welcome message reads "Welcome, NTEC.APP1@GMAIL.COM!". To the right, the user's role is set to "Applicant". A navigation bar includes buttons for "Save", "Print", "Submit", "Withdraw", "Application Summary", and "Close". The main content area is titled "Viewed by Applicant" and contains a "Comment History" section. This section features a table with the following data:

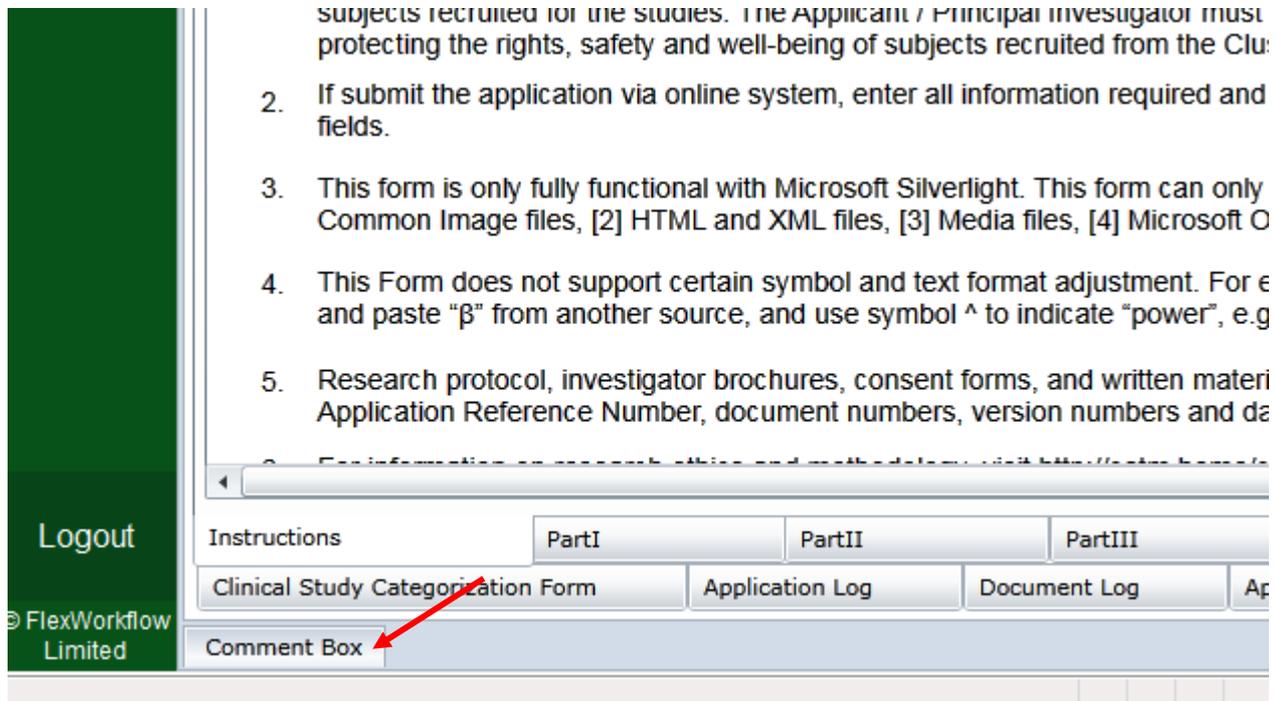
| Date       | Name                | Comment   | To        |
|------------|---------------------|---|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment marked by secretart during return | Applicant |

Below the table, there are several tabs for navigation: "Clinical Study Categorization Form", "Application Log", "Document Log", "Application Management Team Member Form", and "Comment Sheet". The "Comment Sheet" tab is currently active. At the bottom left, there is a "Logout" button and a copyright notice: "© FlexWorkflow Limited".

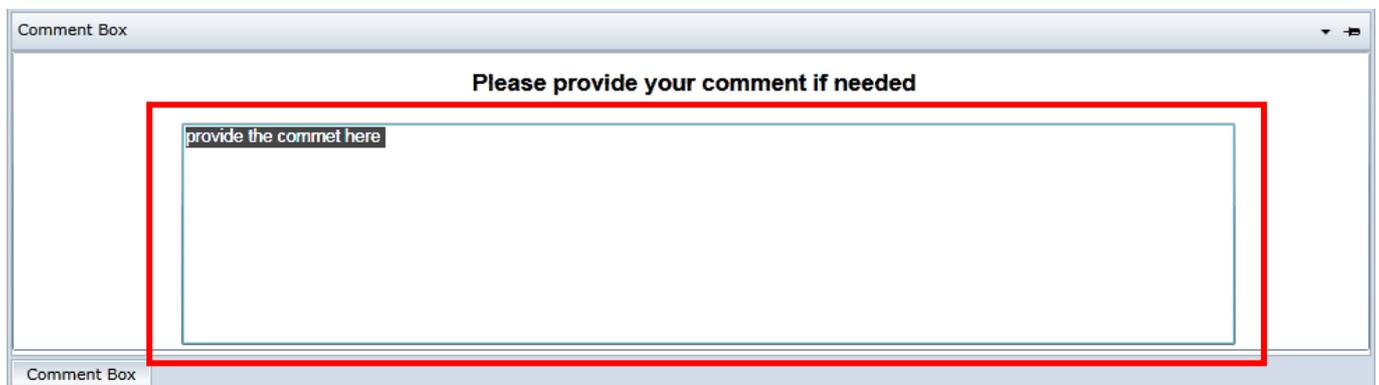
### 5.1.2.13. Comment Box

You can leave a comment to the secretary along with your application.

1. Move the cursor to the "**Comment Box**":



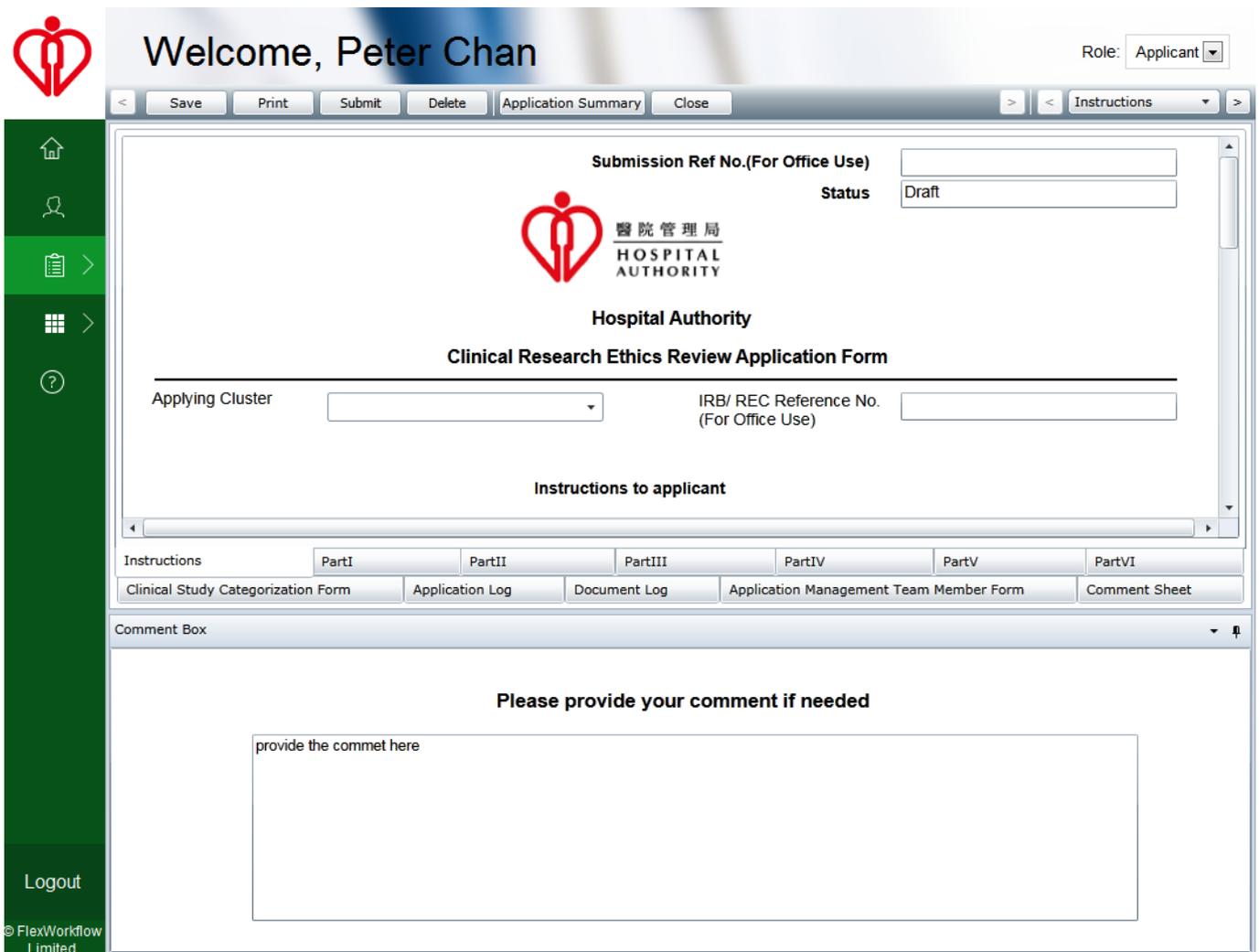
2. Provide your comments in the following area:



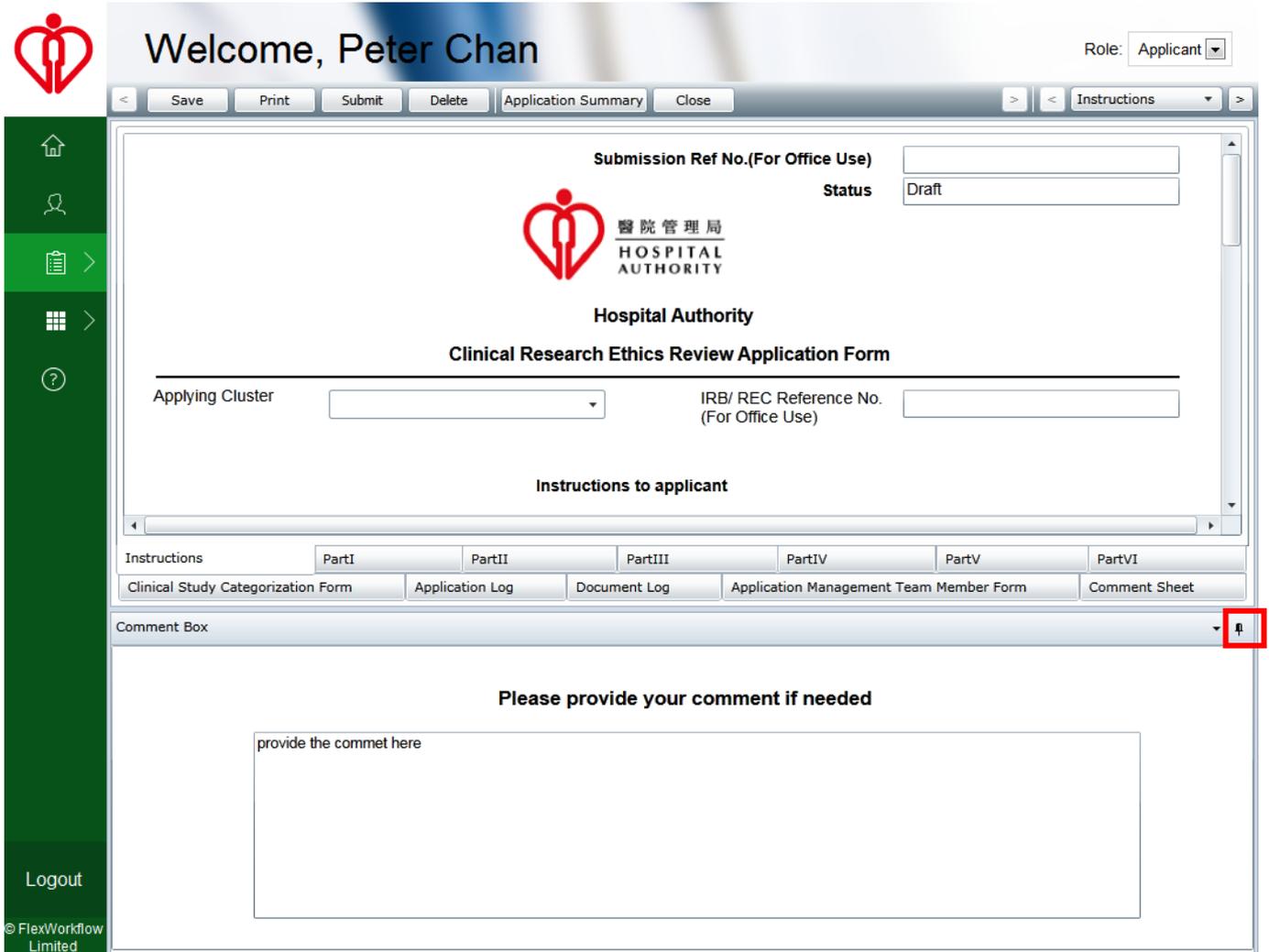
3. If you need to pin the comment box to the bottom, click the  button.



The position of the comment box will then be fixed to the bottom of the screen.



4. If you need to collapse the comment box, click the  button again.



Welcome, Peter Chan Role: Applicant

Save Print Submit Delete Application Summary Close Instructions

**Submission Ref No.(For Office Use)**

**Status**

 **醫院管理局**  
**HOSPITAL AUTHORITY**

**Hospital Authority**

**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

Instructions PartI PartII PartIII PartIV PartV PartVI

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

Comment Box 

**Please provide your comment if needed**

provide the comment here

Logout

© FlexWorkflow Limited

### 5.1.3. Submit Initial Application Form

After you have filled in the application form, submit the application form to the secretary for confirmation:

1. Click the **[Submit]** button
2. Click the **[Yes]** button in the prompted dialog.

The screenshot displays the FlexWorkflow application interface. At the top left is a red heart icon. The main header reads "Welcome, Peter Chan" and "Role: Applicant". A toolbar contains buttons for "Save", "Print", "Submit" (highlighted with a red box), "Delete", "Application Summary", and "Close". Below the toolbar is a table with the following data:

| Risk Group     | No. | Risk Factors                  | Yes                      | No                                  |
|----------------|-----|-------------------------------|--------------------------|-------------------------------------|
| Human Subjects | 1   | Recruitment of human subjects | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
|                | 13  | -----END-----                 | <input type="checkbox"/> | <input type="checkbox"/>            |

A "Message" dialog box is centered on the screen, containing the text: "Please confirm to create a new Application for Clinical Research Ethics Review." Below the text are two buttons: "Yes" (highlighted with a red box) and "No".

At the bottom of the interface, there is a "Logout" button and a series of tabs: "Clinical Study Categorization Form", "Application Log", "Document Log", "Application Management Team Member Form", and "Comment Sheet". Below these tabs are sections for "Instructions" (Part I to Part VI) and a "Comment Box". The copyright notice "© FlexWorkflow Limited" is visible in the bottom left corner.

3. Click the [OK] button in the prompted dialog.

The screenshot displays a web application interface. At the top left is a red heart logo. The main header area says "Welcome, Peter Chan" and includes a "Role: Applicant" dropdown menu. Below the header is a toolbar with buttons for "Save", "Print", "Submit", "Delete", "Application Summary", and "Close". A "Clinical Study Cat" dropdown menu is also visible. The main content area contains a text box with instructions: "Please complete the following Clinical Study Categorization Form and submit the Form together with each application for research ethics review. Upon receipt of an application, the Secretariat will verify the information on the form and arrange for appropriate initial review through Full Review, Expedited Review or Full Review by Phase 1 Panel." Below this is a table with columns: "Risk Group", "No.", "Risk Factors", "Yes", and "No".

| Risk Group     | No. | Risk Factors                  | Yes                      | No                                  |
|----------------|-----|-------------------------------|--------------------------|-------------------------------------|
| Human Subjects | 1   | Recruitment of human subjects | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
|                | 13  | -----END-----                 | <input type="checkbox"/> | <input type="checkbox"/>            |

An "Information" dialog box is overlaid on the table, containing an information icon and the text "The task is being processed." with an "OK" button.

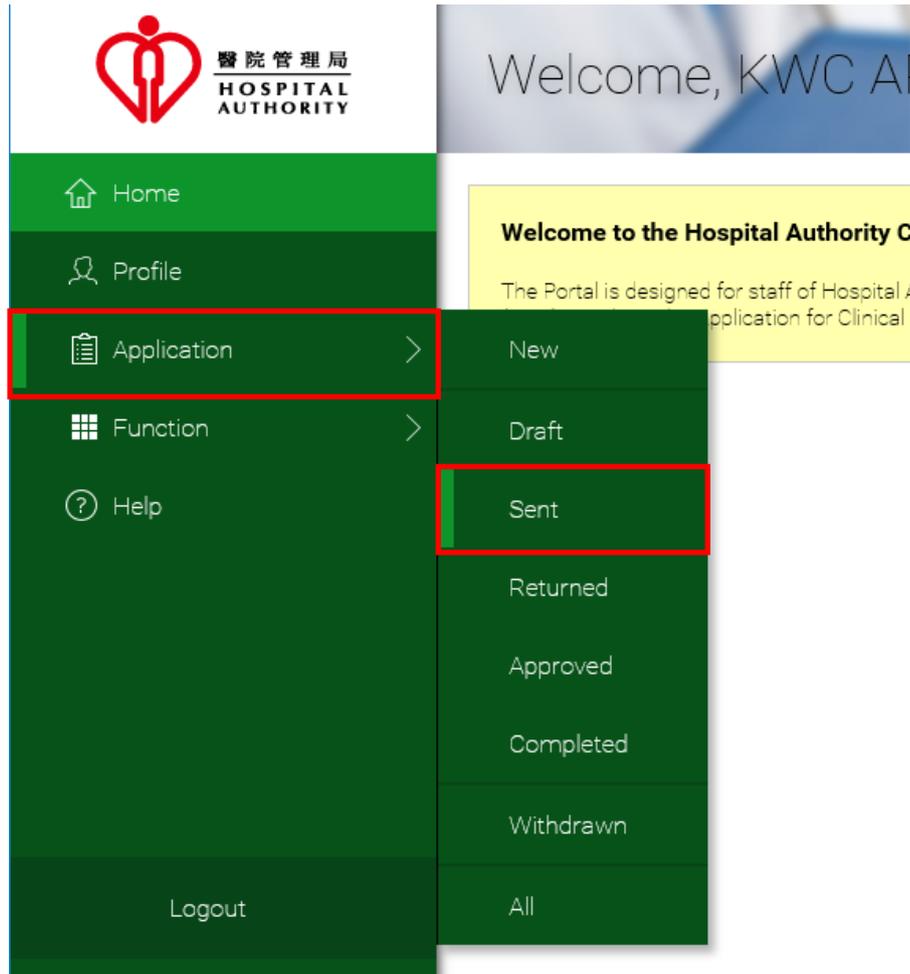
At the bottom of the interface, there is a "Logout" button and a series of tabs: "Clinical Study Categorization Form", "Application Log", "Document Log", "Application Management Team Member Form", and "Comment Sheet". Below these are sub-tabs for "Instructions", "PartI", "PartII", "PartIII", "PartIV", "PartV", and "PartVI". A "Comment Box" is located at the bottom left. The copyright notice "© FlexWorkflow Limited" is visible in the bottom left corner.

### 5.1.3.1. Submitted Initial Application

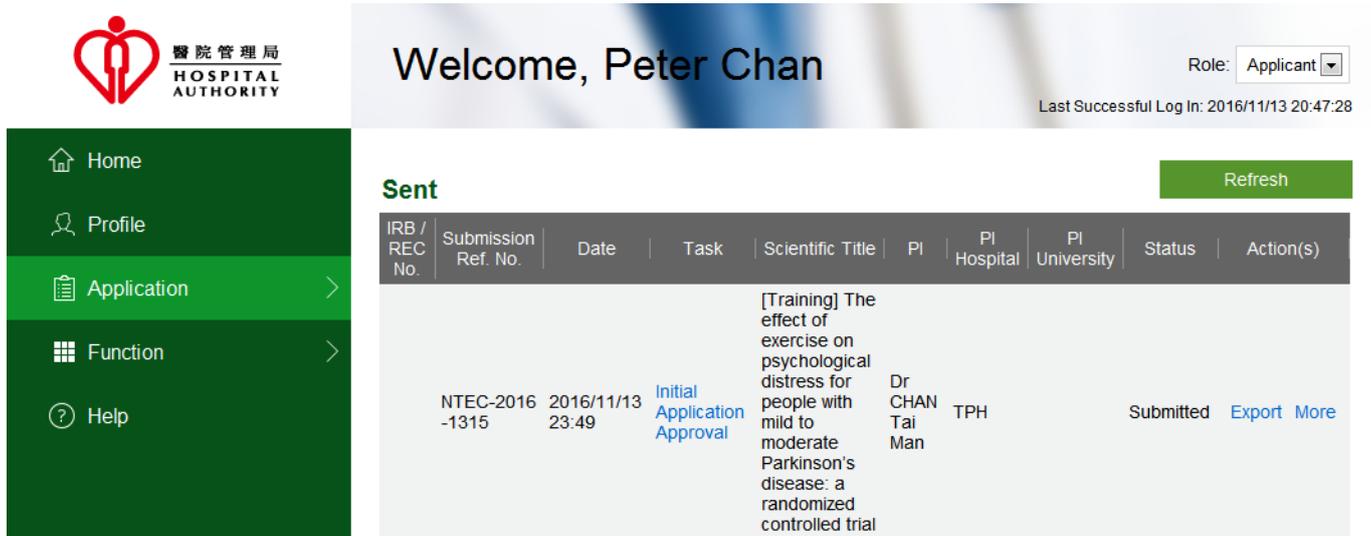
In regard to your submission, you should receive an auto-generated e-mail that confirms your submission to Secretary. Secretary will then check the application form and supporting documents. If everything is fine, Secretary will **“Confirm”** your application. Otherwise, Secretary will **“Return”** it to you for amendment.

You can keep track of the status of the application in the portal. Please follow the below steps:

1. Find your submitted application in **[Application]** ->**[Sent]**;



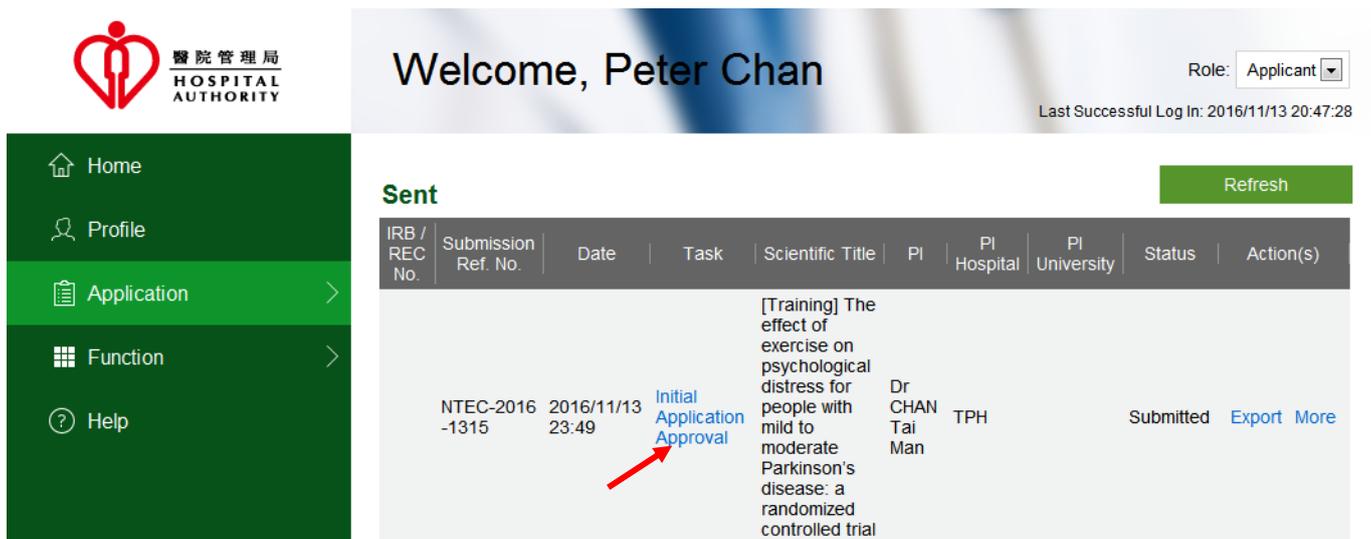
2. The application record is indexed by "**Submission Ref. No.**", "**Date**", "**Scientific Title**", "**PI**", "**PI Hospital**" and "**PI University**" for easy reference. The status is "Submitted".



The screenshot shows the Hospital Authority system interface. On the left is a green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The main content area displays a 'Welcome, Peter Chan' header with a 'Role: Applicant' dropdown and a 'Last Successful Log In: 2016/11/13 20:47:28' timestamp. Below the header is a 'Sent' section with a 'Refresh' button. A table lists application records with columns: IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). One record is shown with the status 'Submitted' and a blue link for 'Initial Application Approval'.

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|---------------|---------------------|------------------|--|---|-----------------|-------------|---------------|-----------|---|
|               | NTEC-2016-1315      | 2016/11/13 23:49 | <a href="#">Initial Application Approval</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |

3. Click on the "**Initial Application Approval**" to get back into your application form. Note that application with status "Submitted" is read-only. No modification to the application is allowed.



This screenshot is identical to the previous one, but with a red arrow pointing to the blue link 'Initial Application Approval' in the 'Task' column of the application record table.

4. If you would like to make any changes to the form after submission, you may use “**Request for Return**”  
 If you would like to change any particulars in the member form (for example, change the delegates and the application follow up users), you may use “**Change of Delegation**”.
- These options can be found by clicking [**More**].

The screenshot shows the Hospital Authority system interface. At the top left is the Hospital Authority logo. The main header says "Welcome, Peter Chan" and "Role: Applicant". Below the header is a navigation sidebar with options: Home, Profile, Application (highlighted), Function, and Help. The main content area is titled "Sent" and contains a table of applications. A red arrow points to the "More" dropdown menu for the first application, which has opened to show "Request for Return" and "Change of Delegation" options.

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)   |
|---------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|-----------|-------------|
|               | NTEC-2016-1315      | 2016/11/13 23:49 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Submitted | Export More |

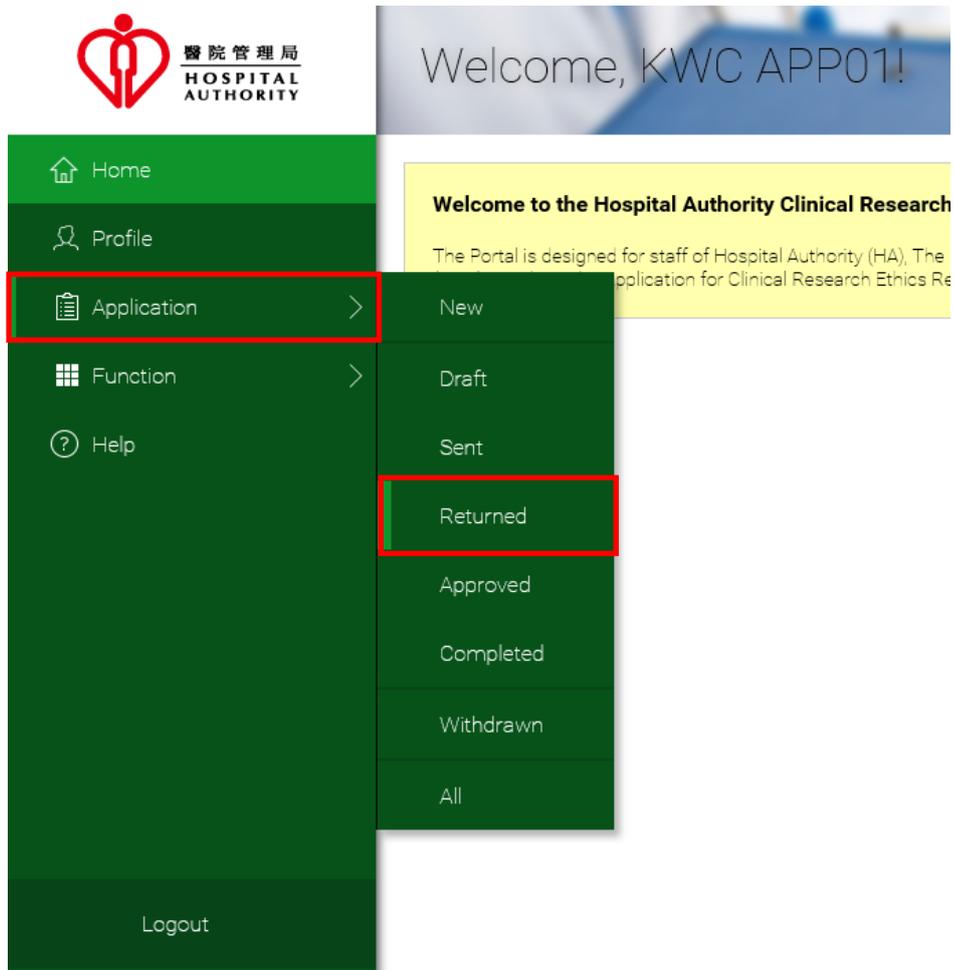
Refer to Section 5.2.1 Request of Return for Initial Application and 5.2.2 Change of Delegates for more information.

### 5.1.4. Returned Initial Application and Resubmit Initial Application

You may receive an email notification sent by Secretary if an application is returned to you. Furthermore, the application form will be returned to you in the portal. This may occur when some information is missing. You will need to get back to the portal to check, amend and re-submit the application.

Please do the following:

1. Go to **[Application]** ->**[Returned]**;



2. Status of application should be "Returned"

The screenshot shows the Hospital Authority system interface. The user is logged in as 'Applicant'. The main content area displays a table of applications with the status 'Returned' highlighted by a red arrow. The table has the following data:

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title | PI          | PI Hospital | PI University | Status   | Action(s) |
|---------------|---------------------|------------------|--|------------------|-------------|-------------|---------------|----------|-----------|
|               | KWC-2016-0001       | 2016/11/01 23:01 | <a href="#">Email (Initial Application Approval)</a> | Testing for case | MR CHAN MAN |             | POLYU         | Returned |           |

Note: if you find that status is "Approved with Comment" / "Pending for Comment", please refer to the section 5.1.8 "Returned Initial Application after Review".

3. The secretary may leave a comment. You can view the comment in "Comment Sheet":

The screenshot shows the 'Comment Sheet' view for application NTEC.APP1@GMAIL.COM. The 'Comment History' table contains the following data:

| Date       | Name                | Comment   | To        |
|------------|---------------------|---|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment marked by secretart during return | Applicant |

The 'Comment Sheet' tab is highlighted with a red box in the bottom navigation bar.

4. Re-submit the application to Secretary after modification.

Welcome, NTEC.APP1@GMAIL.COM! Role: Applicant

Save Print **Submit** Withdraw Application Summary Close

Comment Sheet

Viewed by Applicant

Comment History :

| Date       | Name                | Comment  | To        |
|------------|---------------------|--|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment marked by secretat during return | Applicant |

Message

Are you sure to submit the application to CREC?

Yes No

Logout

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

Instructions PartI PartII PartIII PartIV PartV PartVI

Comment Box

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The “Return and Resubmit” process may happen more than once until Secretary confirms the application. Please refer to Section 5.1.5 Confirmed Initial Application.

### 5.1.4.1. Resubmitted Application

To view re-submitted application:

1. Go to [Application] > [Sent]

The screenshot displays the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the logo of the Hospital Authority, featuring a red heart shape with a white figure inside, and the text '醫院管理局 HOSPITAL AUTHORITY'. To the right of the logo is a large banner with the text 'Welcome, Peter Chan!'. Below the banner is a yellow box containing the text: 'Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese Universities to submit the Application for Clinical Research Ethics Review.' On the left side, there is a dark green navigation menu with the following items: 'Home', 'Profile', 'Application', 'Function', 'Help', and 'Logout'. The 'Application' item is selected, and a sub-menu is open to its right, listing the following application statuses: 'New', 'Draft', 'Sent', 'Returned', 'Approved', 'Completed', 'Withdrawn', and 'All'.

2. The status is "Re-submitted".

The screenshot displays the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, Help, and Logout. The top header shows the Hospital Authority logo and the text 'Welcome, Peter Chan!'. On the right, it indicates the user's role as 'Applicant' and the last successful login time as '2016/11/13 21:02:19'. Below the header is a table titled 'Sent' with a 'Refresh' button. The table contains one entry with the following details:

| IRB / REC No.  | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status       | Action(s)   |
|----------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|--------------|-------------|
| NTEC-2016-1315 |                     | 2016/11/14 00:40 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Re-submitted | Export More |

A red arrow points to the 'Re-submitted' status in the table.

### 5.1.5. Confirmed Initial Application

You will receive a confirmation E-mail once Secretary has confirmed every necessary piece of information and when the documents of the application are ready. Once the application is confirmed by Secretary, the review process will be arranged by Secretary.

To view a confirmed application:

1. Go to [Application] > [Sent]

 醫院管理局  
HOSPITAL  
AUTHORITY

# Welcome, Peter Chan!

**Welcome to the Hospital Authority Clinical Research Ethics Review**

The Portal is designed for staff of Hospital Authority (HA), The Chinese Univers  
submit the Application for Clinical Research Ethics Review.

- Home
- Profile
- Application >
  - New
  - Draft
  - Sent
  - Returned
  - Approved
  - Completed
  - Withdrawn
  - All
- Function >
- Help
- Logout

2. The status is "Confirmed".



Welcome, Peter Chan!

Role: Applicant

Last Successful Log In: 2016/11/14 00:46:53

Home

Profile

Application

Function

Help

Logout

Sent

Refresh

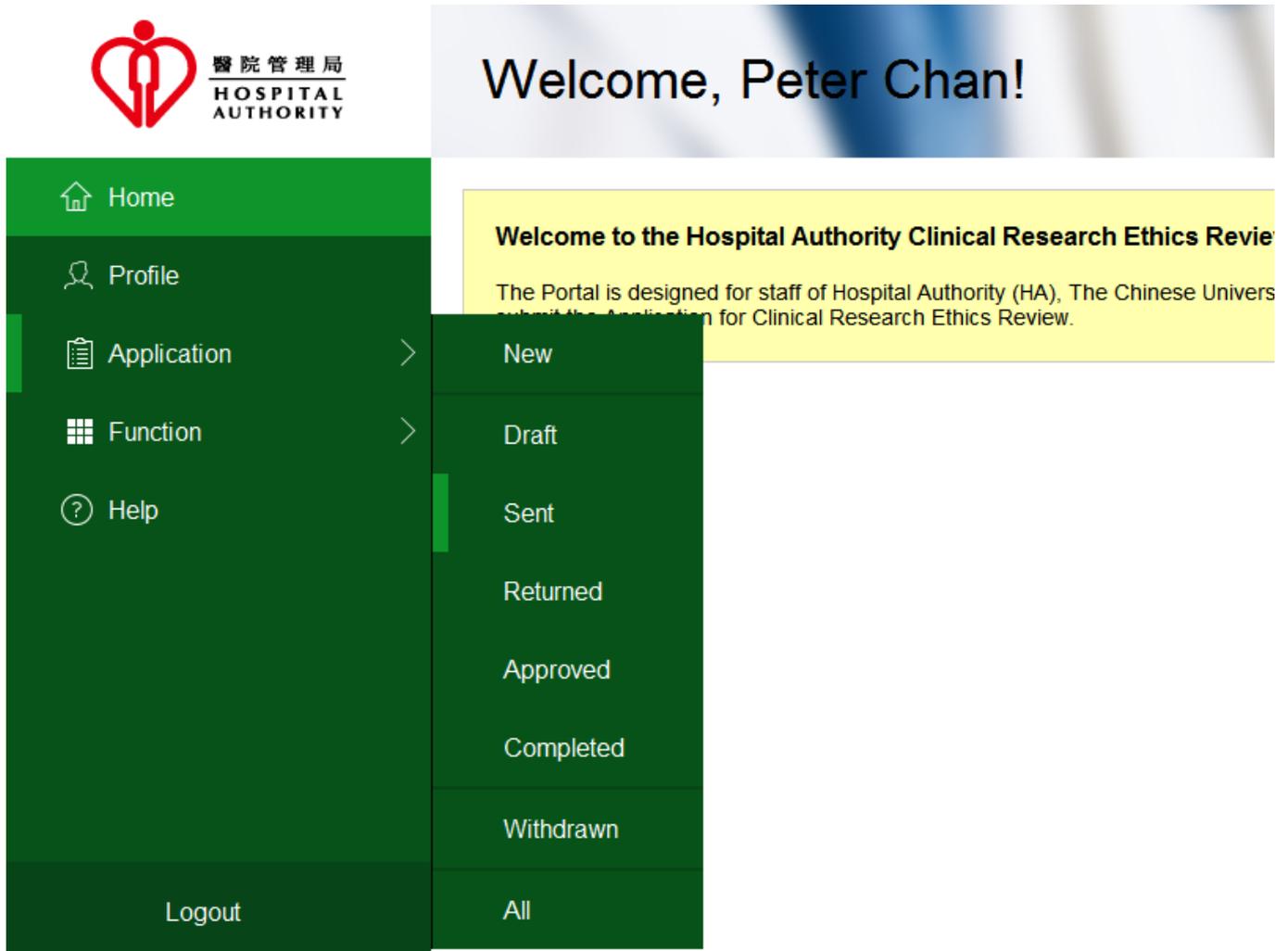
| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|---------------|---------------------|------------------|--|---|-----------------|-------------|---------------|-----------|---|
|               | NTEC-2016-1315      | 2016/11/14 00:48 | <a href="#">Initial Application Approval</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Confirmed | <a href="#">Export</a> <a href="#">More</a> |



### 5.1.6. For Review Initial Application

After the application has been confirmed by the secretary, if the application has been passed to the reviewers for review, the application will be in “For Review” status:

1. Go to [Application] > [Sent]



2. The status is "For Review":

 醫院管理局  
HOSPITAL  
AUTHORITY

Welcome, NTEC.APP1@GMAIL.COM! Role: Applicant

Last Successful Log In: 2016/11/14 00:51:48

**Sent** Refresh

| IRB / REC No.  | Submission Ref. No. | Date             | Task   | Scientific Title  | PI              | PI Hospital | PI University | Status     | Action(s)                                   |
|----------------|---------------------|------------------|--|---|-----------------|-------------|---------------|------------|---|
| NTEC-2016-1315 |                     | 2016/11/14 00:58 | <a href="#">Initial Application Approval</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | For Review | <a href="#">Export</a> <a href="#">More</a> |

Logout

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### 5.1.7. Reviewed Initial Application

After a reviewer has reviewed the application, the status will be changed to "Reviewed":

1. Go to [Application] > [Sent]

The screenshot displays the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the Hospital Authority logo, featuring a red heart shape with a white figure inside, and the text "醫院管理局 HOSPITAL AUTHORITY". To the right of the logo is a large banner with the text "Welcome, Peter Chan!". Below the banner is a yellow box containing the text: "Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong, and other institutions to submit the Application for Clinical Research Ethics Review." On the left side, there is a dark green navigation menu with the following items: Home, Profile, Application, Function, Help, and Logout. The "Application" item is expanded, showing a sub-menu with the following options: New, Draft, Sent, Returned, Approved, Completed, Withdrawn, and All. The "Sent" option is highlighted with a green bar.

2. The status is "Reviewed":



Welcome, NTEC.APP1@GMAIL.COM!

Role: Applicant

Last Successful Log In: 2016/11/14 00:57:08

- Home
- Profile
- Application
- Function
- Help
- Logout

© FlexWorkflow Limited

Sent

Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)                                   |
|---------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|----------|---|
|               | NTEC-2016-1315      | 2016/11/14 00:58 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Reviewed | <a href="#">Export</a> <a href="#">More</a> |

### 5.1.8. Returned Initial Application after Review

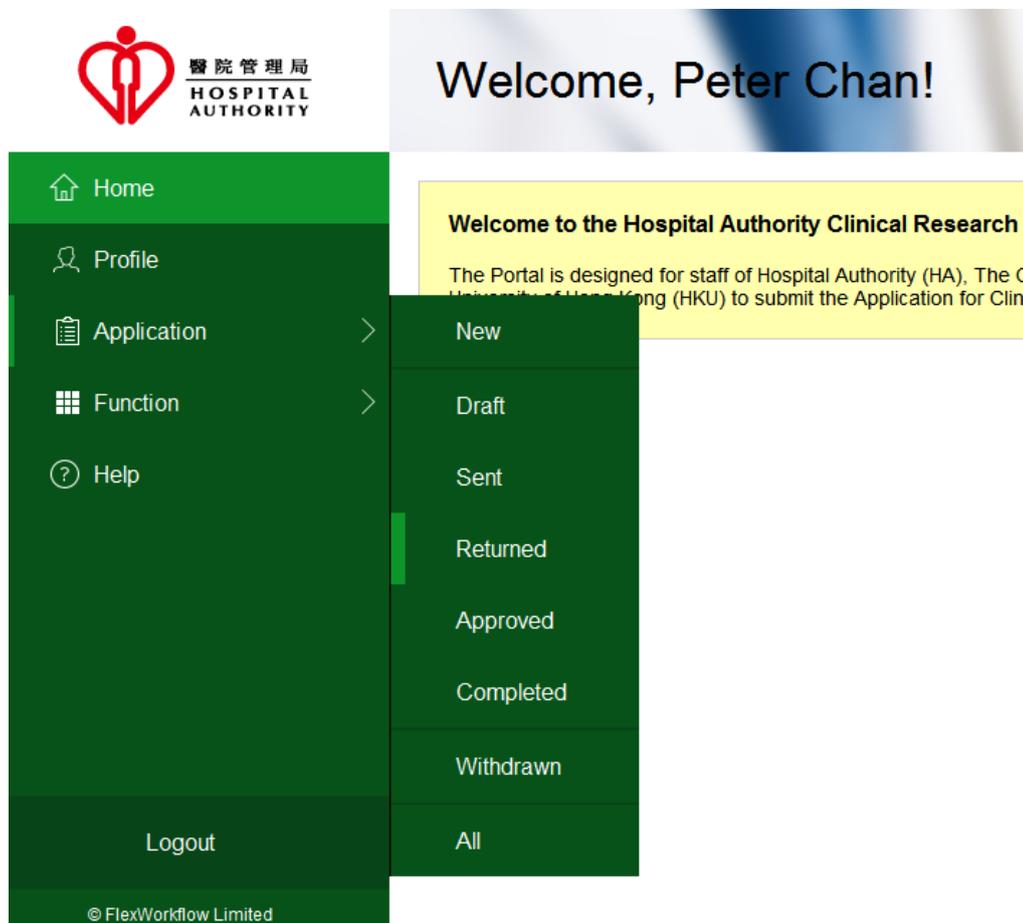
After the review of an application by reviewers, Secretary will consolidate the reviews and mark whether the application is approved.

If the application is not approved, secretary will return the application to the applicant. Depending on the decision marked by the secretary, the application may have one of the following statuses:

- Approved with Comment
- Pending for Comment

To view the status:

1. Go to **[Application] > [Returned]**



2. The status could be “Approved with Comment” or “Pending for Comment”:

**醫院管理局 HOSPITAL AUTHORITY**

Welcome, Peter Chan! Role: Applicant

Last Successful Log In: 2016/11/14 01:07:30

Returned Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status                | Action(s)   |
|---------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|-----------------------|-------------|
|               | NTEC-2016-1315      | 2016/11/14 01:10 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Approved with Comment | Export More |

Logout

© FlexWorkflow Limited

**醫院管理局 HOSPITAL AUTHORITY**

Welcome, Peter Chan! Role: Applicant

Last Successful Log In: 2016/11/14 09:25:51

Returned Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status              | Action(s)   |
|---------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|---------------------|-------------|
|               | NTEC-2016-1315      | 2016/11/14 09:39 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Pending for Comment | Export More |

Logout

© FlexWorkflow Limited

3. You can open the application and go to the "Comment Sheet" to view the comment:

The screenshot shows a web application interface. At the top left is a red heart logo. The top bar displays "Welcome, Peter Chan!" and a role dropdown menu set to "Applicant". Below the top bar is a navigation menu with buttons: Save, Print, Submit, Withdraw, Application Summary, Close, and Comment Sheet. The main content area is titled "Viewed by Applicant" and contains a "Comment History" section. This section features a table with the following data:

| Date       | Name                | Comment             | To        |
|------------|---------------------|---------------------|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment | Applicant |

Below the table is a large empty light blue area. At the bottom of the interface, there is a navigation bar with tabs: Clinical Study Categorization Form, Application Log, Document Log, Application Management Team Member Form, and Comment Sheet (highlighted with a red box). Below these tabs are sub-tabs: Instructions, PartI, PartII, PartIII, PartIV, PartV, and PartVI. A "Comment Box" is visible at the bottom left of the main content area. The bottom left corner of the page contains the text "FlexWorkflow Limited".

4. You may modify the application content and re-submit it to Secretary again by clicking the **[Submit]** button; you may withdraw the application by clicking the **[Withdraw]** button.

Welcome, Peter Chan! Role: Applicant

Save Print Submit Withdraw Application Summary Close Instructions

**Submission Ref No.(For Office Use)** NTEC-2016-1315  
**Status** Pending for Comment

 醫院管理局  
HOSPITAL  
AUTHORITY

**Hospital Authority**  
**Clinical Research Ethics Review Application Form**

Applying Cluster: NTEC IRB/ REC Reference No. (For Office Use):

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the relevant fields.

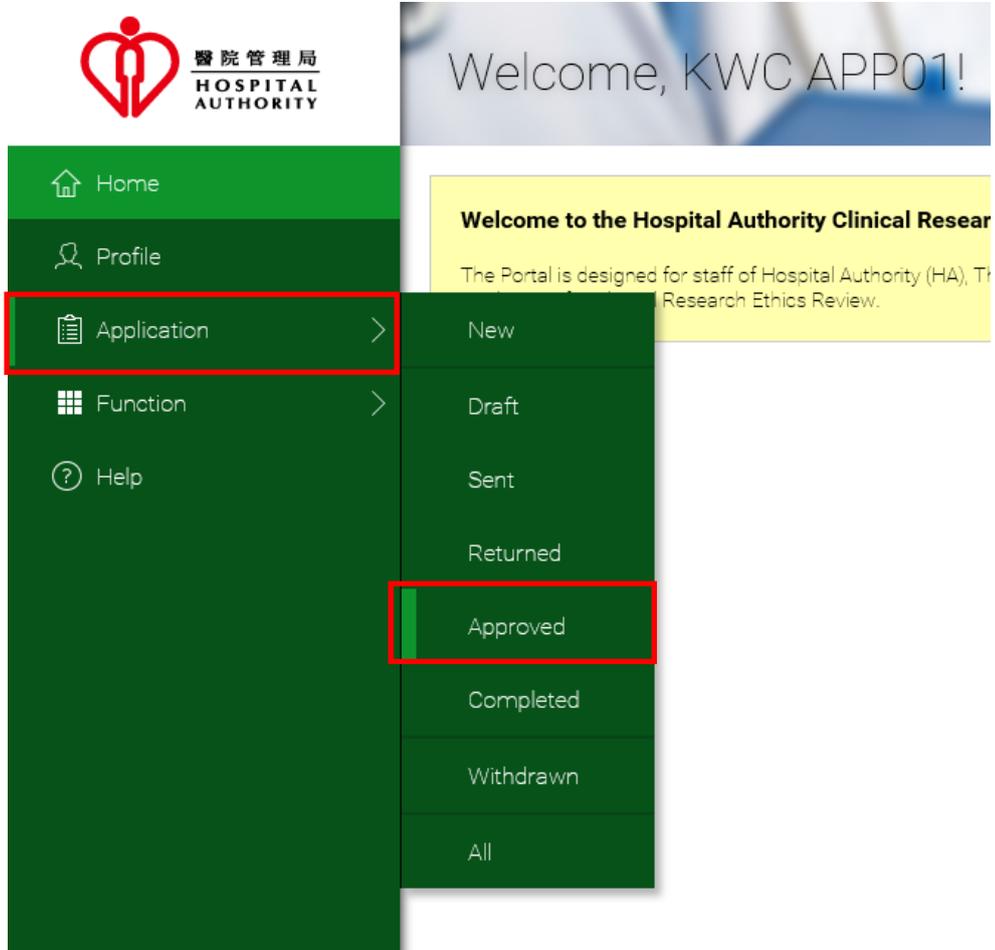
Logout FlexWorkflow Limited

Instructions | Part I | Part II | Part III | Part IV | Part V | Part VI  
Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet  
Comment Box

### 5.1.9. Approved Initial Application after Review

Upon the approval of your application, you will receive a notification email. You can find the application and read the comments (if any) by following the below steps:

1. Go to **[Application] > [Approved]**



- You can now find that the application is attached with an “**IRB / REC No**” which is input by Secretary during the process of confirmation.

You can search your application based on the “**IRB / REC No**” in [Function] -> [Application Search]. For further information, please refer to Section .8.2 Search of Application by Filter.

The screenshot shows the Hospital Authority web application interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The main content area has a header with a welcome message 'Welcome, Peter Chan!' and a role dropdown set to 'Applicant'. Below the header is a table titled 'Approved' with a 'Refresh' button. The table contains one row of application data.

| IRB / REC No.      | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)   |
|--------------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|----------|-------------|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 11:02 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Approved | Export More |

You can find that there are some options under the column “**Action(s)**” > [More]. You can carry out some post-approval actions **after your submission is approved**. Please refer to Section 6 Manage an Application (Post-Approval).

---

## 5.2. Change of Initial application

### 5.2.1. Request of Return for Initial Application

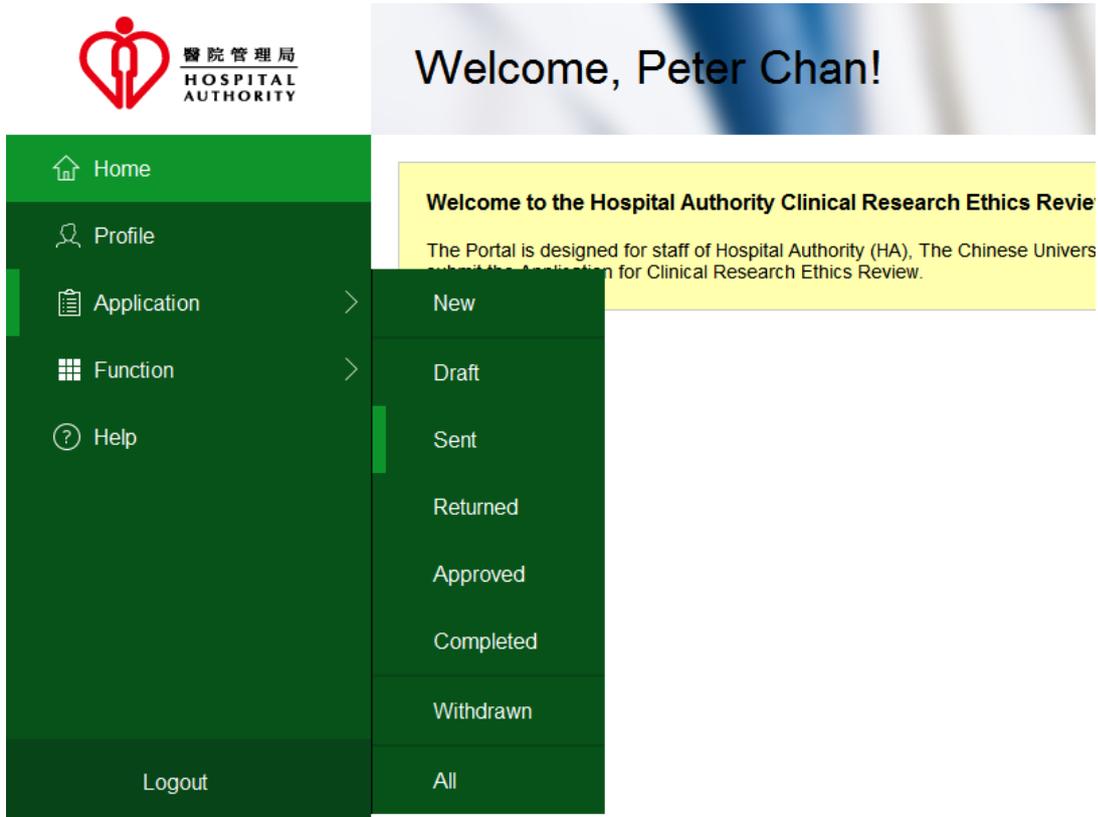
HACRER Portal allows you to make a request to the secretary for returning an application. You can then modify the returned application and then re-submit it back to Secretary again.

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

- Submitted
- Re-submitted
- Confirmed
- For Review
- Reviewed

Please follow the below steps to request for a return:

1. Go to **[Application]** > **[Sent]**;



2. Click **[More]** of the application you are going to modify.
3. Select **“Request for Return”**; a “Request for Return Form” should appear:

The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application, Function, Help, and Logout. The main content area has a header with a welcome message for Peter Chan, his role as Applicant, and the last successful login time. Below the header is a table titled "Sent" with a "Refresh" button. The table has columns for IRB/REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). A red arrow points to the "More" link in the Action(s) column of the first row. A dropdown menu is open, showing "Request for Return" and "Change of Delegation" options, with another red arrow pointing to "Request for Return".

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)   |
|---------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|-----------|-------------|
|               | NTEC-2016-1313      | 2016/11/13 21:04 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Submitted | Export More |

Dropdown menu options:

- Request for Return
- Change of Delegation

4. Input the reason for requesting the return of application;
5. Click [**Submit**] to finish the request.

The screenshot shows a web application interface. At the top left is a red heart logo with a person inside. The header area says "Welcome, Peter Chan!" and "Role: Applicant" with a dropdown arrow. Below the header is a navigation bar with buttons: "< Print Submit Application Summary Close >". On the right side of the navigation bar is a dropdown menu labeled "Request For Return".

The main content area is titled "Request for Return Form" and contains the following fields:

- Submission Reference Number: NTEC-2016-1313
- IRB/REC Reference Number: (empty)
- Work Order Number: WON-20161113-0240
- Request for Return Reason: (empty text area)

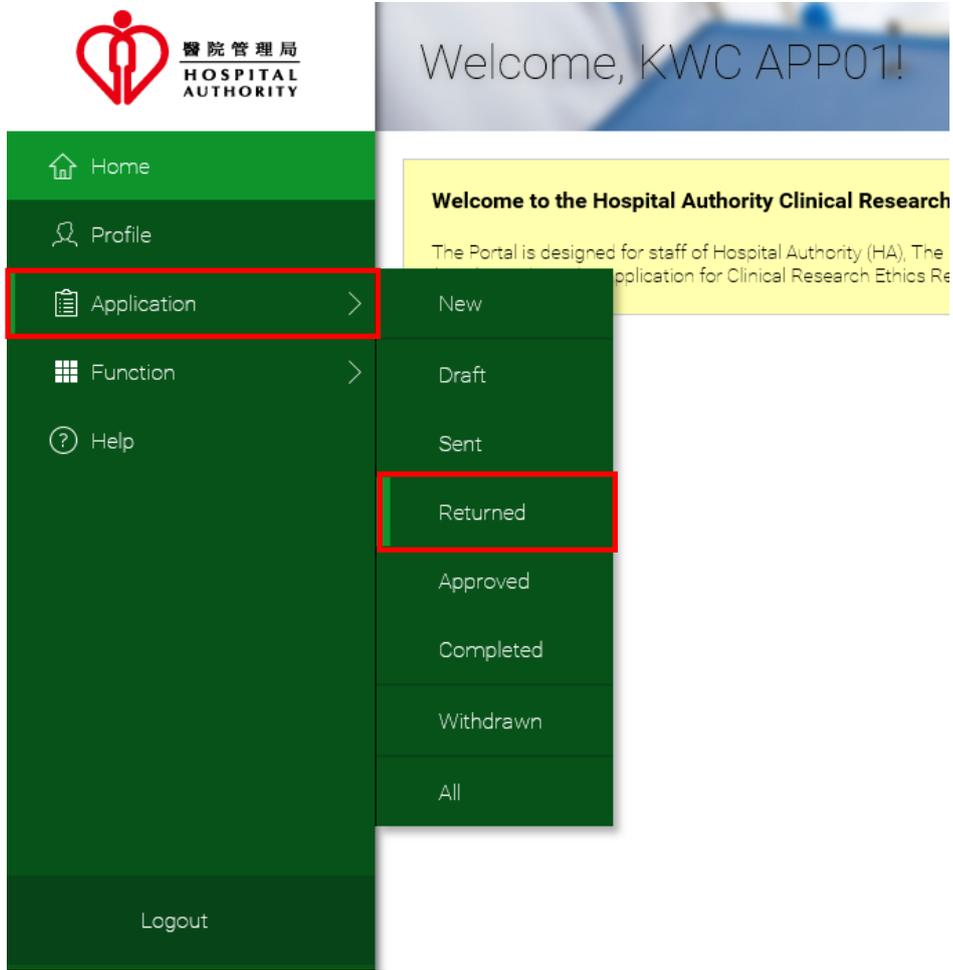
On the left side, there is a green sidebar with icons for Home, Profile, Applications, and Help. At the bottom of the sidebar is a "Logout" button. The footer of the page includes "© FlexWorkflow Limited" and a "Comment Box" button.

**Important!** Please note that the status of the application will remain unchanged even when you have requested for a return, and will change to "Returned" only when Secretary has returned the application to you.

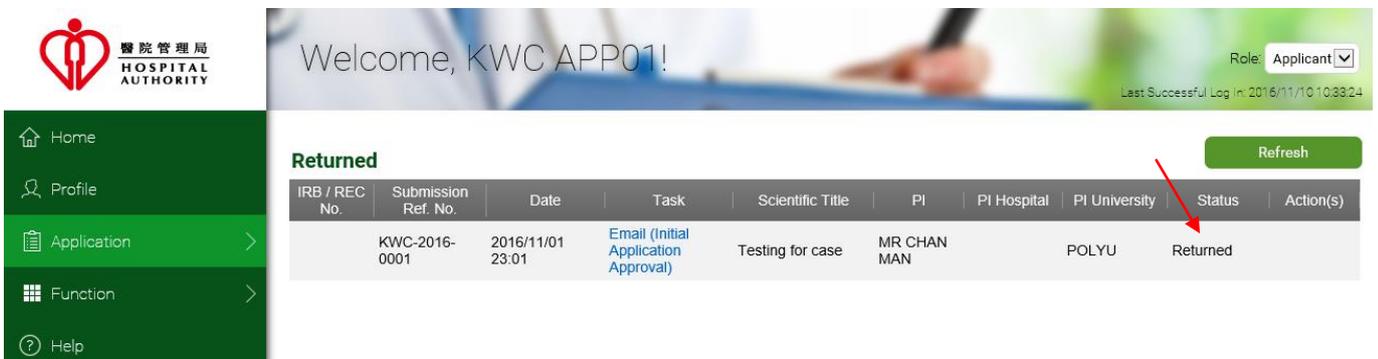
If your return request is accepted, you may receive an email notification about it.

Follow the below steps to view and edit your application if Secretary has returned it to you:

1. Go to **[Application] > [Returned]**;



2. The status of returned applications should be "Returned". Open the application and modify it.



3. Click **[Submit]** after you have finished the modification. Your application is then re-submitted to the secretary for confirmation.

## 5.2.2. Change of Delegates

If there is any change of “Delegates” in “Management Member Team Form”, you need to make a request to the secretary for a change of delegates.

Note: In Pre-Approval, only Principal Investigator can use this function.

1. Go to **[Application]** > **[Sent]**;
2. Click **[More]** of the application you are going to modify;
3. Select **“Change of Delegation”**.

The screenshot shows the Hospital Authority system interface. On the left is a navigation menu with options: Home, Profile, Application, Function, and Help. The 'Application' menu item is selected. The main content area displays a 'Welcome, Peter Chan!' banner with a role dropdown set to 'Applicant' and a 'Refresh' button. Below the banner is a table titled 'Sent' with columns: IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). A table row is visible with the following data: IRB / REC No. NTEC-2016-1313, Submission Ref. No. 2016/11/13 21:04, Date 2016/11/13 21:04, Task Initial Application Approval, Scientific Title [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial, PI Dr CHAN Tai Man, PI Hospital TPH, PI University Submitted, Status Submitted, and Action(s) Export More. A dropdown menu is open from the 'More' link, showing options: Request for Return and Change of Delegation. Red arrows point to the 'More' link and the 'Change of Delegation' option.

| IRB / REC No.  | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)   |
|----------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|-----------|-------------|
| NTEC-2016-1313 | 2016/11/13 21:04    | 2016/11/13 21:04 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         | Submitted     | Submitted | Export More |

4. The Application Management Team Member Form will be shown.  
     Insert new members to the list of delegation / application follow up users.
5. Click **[Submit]** to finish modification.

The screenshot shows a web application interface for Peter Chan, with a role of 'Applicant'. The interface includes a navigation sidebar on the left and a main content area. The main content area contains two tables: 'Delegates' and 'Application Follow Up Users'. Both tables have columns for 'Email', 'Name', 'Existing Account', and 'Please sign up'. The 'Delegates' table has one row with 'ntec.app2@gmail.com' and 'ntec.app2@gma', with a checked 'Existing Account' and an unchecked 'Please sign up'. The 'Application Follow Up Users' table has one row with 'ntec.app3@gmail.com' and 'ntec.app3@gma', with a checked 'Existing Account' and an unchecked 'Please sign up'. Below the 'Delegates' table is a note: 'Please assign Delegates who will help manage and edit the application forms before research ethics approval.' There are buttons for 'Add New Row' and 'Delete Selected Row(s)' between the two tables.

Delegates :

| Email               | Name          | Existing Account                    | Please sign up           |
|---------------------|---------------|-------------------------------------|--------------------------|
| ntec.app2@gmail.com | ntec.app2@gma | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Please assign Delegates who will help manage and edit the application forms before research ethics approval.

Add New Row      Delete Selected Row(s)

Application Follow Up Users :

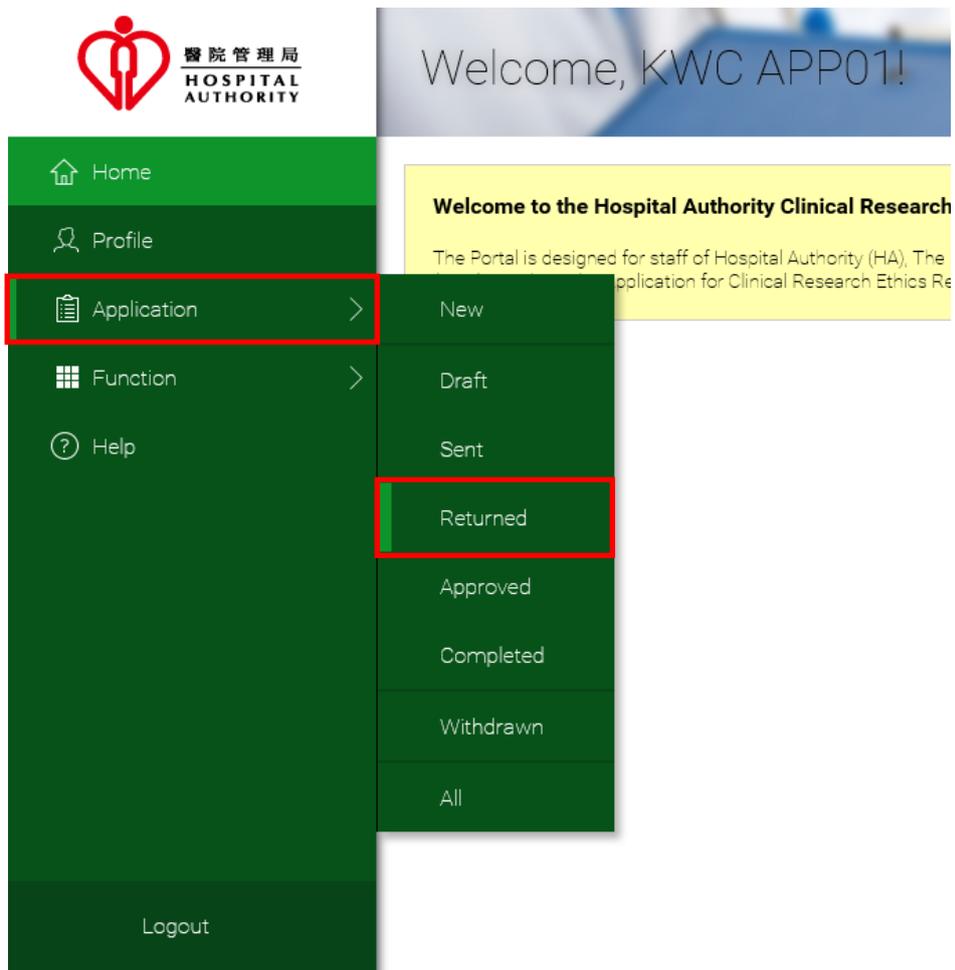
| Email               | Name          | Existing Account                    | Please sign up           |
|---------------------|---------------|-------------------------------------|--------------------------|
| ntec.app3@gmail.com | ntec.app3@gma | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

### 5.2.3. Withdraw Initial Application

You can withdraw the application if it is in the following statuses:

- Returned
- Approved with Comment
- Pending for Comment

1. Go to **[Application] > [Returned]**



2. Open the application.

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)   |
|---------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|----------|-------------|
|               | NTEC-2016-1313      | 2016/11/14 10:46 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Returned | Export More |

3. Click the [Withdraw] button and click [Yes] in the prompted dialog.

Are you sure to discard the inputted information?

Yes No

1. Cluster Research Ethics Committee/Institutional Review Board (IRB)/Hospital Authority ("HA")/University personnel are responsible for the safety and well-being of subjects recruited for the studies. The HA is responsible for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the system.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments: [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol  $\beta$  and paste "B" from another source, and use symbol  $\wedge$  to indicate "power", e.g.  $4 \times 10^3$  instead of  $4 \times 10^3$ .

4. Go to [Application] > [Withdrawn]

The screenshot shows the user interface of the Hospital Authority Clinical Research Ethics Review Portal. The user is logged in as Peter Chan, with the role of Applicant. The navigation menu on the left includes Home, Profile, Application, Function, and Help. The 'Application' menu item is highlighted with a red box, and its sub-menu is open, showing options: New, Draft, Sent, Returned, Approved, Completed, Withdrawn, and All. The 'Withdrawn' option is also highlighted with a red box. A yellow banner at the top right contains the text: 'Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong (CUHK) and The University of Hong Kong (HKU) to submit the Application for Clinical Research Ethics Review.'

5. The withdrawn application will be shown in the "Withdrawn" pool with the status "Withdrawn".

The screenshot shows the 'Withdrawn' pool of applications. The user is logged in as Peter Chan, with the role of Applicant. The navigation menu on the left includes Home, Profile, Application, Function, and Help. The 'Application' menu item is highlighted with a green bar. The 'Withdrawn' pool is displayed as a table with the following data:

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|---------------|---------------------|------------------|--|---|-----------------|-------------|---------------|-----------|---|
|               | NTEC-2016-1313      | 2016/11/14 10:50 | <a href="#">Initial Application Approval</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Withdrawn | <a href="#">Export</a> <a href="#">More</a> |

## 5.2.4. Delete Initial Application

If the application is in the "Draft" status, it means it is not yet submitted to Secretary and you can still delete it.

1. Click **[Application]** > **[Draft]**.

The screenshot displays the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the Hospital Authority logo and name in Chinese and English. The user is identified as Peter Chan, with a role of 'Applicant' and a last successful login time of 2016/11/13 20:47:28. A yellow banner welcomes the user to the portal, explaining its purpose for staff of HA, CUHK, and HKU. A dark green sidebar menu is open, showing options: Home, Profile, Application, Function, Help, and Logout. The 'Application' menu item is highlighted with a red box, and its sub-menu is also highlighted with a red box, showing options: New, Draft, Sent, Returned, Approved, Completed, Withdrawn, and All. The 'Draft' option is the target of the instruction.

2. Open the drafted application that you want to delete.

 醫院管理局  
HOSPITAL  
AUTHORITY

Welcome, Peter Chan

Role: Applicant

Last Successful Log In: 2016/11/13 20:47:28

**Draft** [Refresh](#)

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title  | PI | PI Hospital | PI University | Status | Action(s)                                   |
|---------------|---------------------|------------------|--|---|----|-------------|---------------|--------|---|
|               |                     | 2016/11/13 21:36 | <a href="#">Initial Application Approval</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial |    |             |               | Draft  | <a href="#">Export</a> <a href="#">More</a> |

Home

Profile

Application >

Function >

Help

Logout

© FlexWorkflow Limited

3. Click the [Delete] button:

Welcome, Peter Chan Role: Applicant

Save Print Submit **Delete** Application Summary Close

Submission Ref No.(For Office Use)

Status

 醫院管理局  
HOSPITAL  
AUTHORITY

**Hospital Authority**

**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10<sup>3</sup>.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified,for example, by Application Reference Number, document numbers, version numbers and dates.

Logout

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Instructions PartI PartII PartIII PartIV PartV PartVI

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

Comment Box

4. The following dialog will ask for your confirmation. Click **[Yes]** to proceed.

The screenshot shows a web application window titled "Welcome, Peter Chan" with a role dropdown set to "Applicant". The main content area is the "Hospital Authority Clinical Research Ethics Review Application Form". A "Message" dialog box is open, displaying the text: "Please confirm to discard the current information." with "Yes" and "No" buttons. The "Yes" button is highlighted with a red box. The background form includes fields for "Submission Ref No.", "Status" (Draft), "Applying Cluster" (NTEC), and "IRB/ REC Reference No.". A list of instructions is visible below the dialog box.

**Message**

Please confirm to discard the current information.

**Yes** **No**

**Hospital Authority**  
**Clinical Research Ethics Review Application Form**

Applying Cluster: NTEC IRB/ REC Reference No. (For Office Use)

- Cluster Research Ethics Committee/Institutional Review Board (IRB) of the Hospital Authority ("HA")/University per... subjects recruited for the studies. The A... protecting the rights, safety and well-being of subjects recruited from the Cluster.
- If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
- This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
- This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10³.
- Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.

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5. Click [OK] in the following prompted dialog:

The screenshot displays a web application interface for a Clinical Research Ethics Review Application Form. The interface includes a navigation menu on the left with icons for home, user profile, list, grid, and help. The main content area features a header with the Hospital Authority logo and the text 'Hospital Authority Clinical Research Ethics Review Application Form'. Below the header, there are input fields for 'Applying Cluster' (set to NTEC) and 'IRB/ REC Reference No. (For Office Use)'. A status field shows 'Deleted'. An 'Information' dialog box is overlaid on the form, displaying the message 'The task is being processed.' and an 'OK' button highlighted with a red box. The dialog box also contains a close button (X). The main content area contains a list of instructions for users. The bottom of the interface shows a 'Logout' button and a footer with the text '© FlexWorkflow Limited'. The bottom right corner of the page shows 'Page 99 of 160'.

Role: Applicant

Submission Ref No.(For Office Use) [ ]

Status Deleted

醫院管理局  
HOSPITAL  
AUTHORITY

Hospital Authority

Clinical Research Ethics Review Application Form

Applying Cluster NTEC IRB/ REC Reference No. (For Office Use) [ ]

Information

The task is being processed.

OK

1. Cluster Research Ethics Committee/Ins Hospital Authority ("HA")/University per subjects recruited for the studies. The A protecting the rights, safety and well-be

2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.

3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.

4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10^3 instead of 4x10³.

5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified,for example, by Application Reference Number, document numbers, version numbers and dates.

Logout

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Instructions PartI PartII PartIII PartIV PartV PartVI

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet

Comment Box

Page 99 of 160

6. The drafted application that you have deleted will be removed from the "Draft" pool.

 醫院管理局  
HOSPITAL  
AUTHORITY

Welcome, Peter Chan

Role: Applicant

Last Successful Log In: 2016/11/13 20:47:28

Home

Profile

Application >

Function >

Help

Logout

© FlexWorkflow Limited

**Draft** Refresh

| IRB / REC No. | Submission Ref. No. | Date | Task | Scientific Title | PI | PI Hospital | PI University | Status | Action(s) |
|---------------|---------------------|------|------|------------------|----|-------------|---------------|--------|-----------|
| No Task       |                     |      |      |                  |    |             |               |        |           |

7. Click [Application] > [Withdrawn]

The screenshot displays the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the logo of the Hospital Authority, featuring a stylized heart and the text '醫院管理局 HOSPITAL AUTHORITY'. The top right shows a welcome message 'Welcome, Peter Chan', a role dropdown menu set to 'Applicant', and the text 'Last Successful Log In: 2016/11/13 20:47:28'. A yellow banner below the header reads 'Welcome to the Hospital Authority Clinical Research Ethics Review Portal.' followed by a description of the portal's purpose. On the left, a dark green sidebar menu contains options: Home, Profile, Application (highlighted with a red box), Function, Help, and Logout. A sub-menu is open for 'Application', listing: New, Draft, Sent, Returned, Approved, Completed, Withdrawn (highlighted with a red box), and All. At the bottom of the sidebar, it says '© FlexWorkflow Limited'.

8. The deleted application will be shown in the "Withdrawn" pool with the status "Deleted".

The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. At the bottom of the sidebar are 'Logout' and '© FlexWorkflow Limited'. The main header area displays 'Welcome, Peter Chan' and 'Role: Applicant'. Below the header is a 'Withdrawn' section with a 'Refresh' button. A table lists applications, with one entry highlighted in grey. A red arrow points to the 'Deleted' status in the table.

| IRB / REC No.  | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI              | PI Hospital | PI University | Status  | Action(s)   |
|----------------|---------------------|------------------|------------------------------|---|-----------------|-------------|---------------|---------|-------------|
| NTEC-2016-1314 |                     | 2016/11/13 21:50 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Deleted | Export More |

### 5.3. Clone to Draft

Applicant can use the “Clone to Draft” function to copy an old application form data to a new one in order to speed up the data filling time.

1. Search the application and open the application form
2. Click [**Clone to Draft**]

The screenshot shows a web application interface for the Hospital Authority. At the top, a banner reads "Welcome, Peter Chan". Below this is a navigation bar with buttons for "Print", "Clone to Draft" (highlighted with a red box), "Application Summary", and "Close". On the left is a dark green sidebar with icons for home, user profile, application forms, and help. The main content area displays the "Hospital Authority Clinical Research Ethics Review Application Form". It includes fields for "Submission Ref No.(For Office Use)", "Status", "Applying Cluster" (with "NTEC" entered), and "IRB/ REC Reference No. (For Office Use)". Below the form is a section titled "Instructions to applicant" with a list of instructions.

- The following dialog will be prompted. Click [OK] to proceed.

**Welcome, Peter Chan** Role

Print Create Application Summary Close

### Application Management Team Member Form

**Note to Investigator**

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

**Message**

Data has been copied from old application to this application.  
 You can review the details on other forms.  
 Please input Application Management Team Member for this application before creation.

**OK**

**Scientific Title (<500**  
 [Training] The effect o  
 controlled trial

Principal Investigator :

| Email | Name | Existing Account         | Please sign up             |
|-------|------|--------------------------|----------------------------|
|       |      | <input type="checkbox"/> | <a href="#">Click here</a> |

- Enter the "Principial Investigator", "Delegates" and "Application Follow Up Users".

**Welcome, Peter Chan** Role: Applicant

Print Create Application Summary Close

Application Manag

**Principal Investigator :**

| Email | Name | Existing Account         | Please sign up             |
|-------|------|--------------------------|----------------------------|
|       |      | <input type="checkbox"/> | <a href="#">Click here</a> |

*Assign Principal Investigator who will be responsible for the Application.*

Add New Row Delete Selected Row(s)

**Delegates :**

| Email | Name | Existing Account | Please sign up |
|-------|------|------------------|----------------|
|       |      |                  |                |

*Please assign Delegates who will help manage and edit the application forms before research ethics approval.*

Add New Row Delete Selected Row(s)

**Application Follow Up Users :**

| Email | Name | Existing Account | Please sign up |
|-------|------|------------------|----------------|
|       |      |                  |                |

Logout

© FlexWorkflow Limited

Application Management Team Member Form Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log

5. Click the [Create] button.

**Welcome, Peter Chan** Role: Applicant

Print **Create** Application Summary Close

### Application Management Team Member Form

**Note to Investigator**

Please complete the following Application Management Team Member Form before opening a new Application Form. Upon submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

**Scientific Title (<500 characters)\***

[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

**Principal Investigator :**

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app1@gmail.com | ntec.app1@gma | <input checked="" type="checkbox"/> |                |

Assign Principal Investigator who will be responsible for the Application.

Add New Row Delete Selected Row(s)

**Delegates :**

| Email               | Name          | Existing Account                    | Please sign up |
|---------------------|---------------|-------------------------------------|----------------|
| ntec.app2@gmail.com | ntec.app2@gma | <input checked="" type="checkbox"/> |                |

Logout

© FlexWorkflow Limited

Application Management Team Member Form Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log

6. You will be directed to the "Instructions" page. The following dialog reminds you to read the instruction form. Click the [OK] button to proceed.

The screenshot shows a web application interface for the Hospital Authority. At the top, it says "Welcome, Peter Chan" and "Role: Applicant". The main content area is titled "Hospital Authority Clinical Research Ethics Review Application Form". It includes fields for "Applying Cluster" (NTEC) and "IRB/ REC Reference No. (For Office Use)". A message dialog box is overlaid on the form, with the text: "Please read the Instruction Form first before create a draft." and an "OK" button highlighted in red. The form contains several numbered instructions for users. At the bottom, there is a navigation bar with tabs for "Application Management Team Member Form", "Instructions", "PartI", "PartII", "PartIII", "PartIV", "PartV", "PartVI", "Clinical Study Categorization Form", "Application Log", and "Document Log".

Submission Ref No.(For Office Use)

Status

醫院管理局  
HOSPITAL  
AUTHORITY

Hospital Authority

Clinical Research Ethics Review Application Form

Applying Cluster  IRB/ REC Reference No. (For Office Use)

Message

Please read the Instruction Form first before create a draft.

OK

1. Cluster Research Ethics Committee/Ins Hospital Authority ("HA")/University per subjects recruited for the studies. The A protecting the rights, safety and well-being of subjects recruited from the Cluster. ee clinical studies conducted by safety and well-being of the human ie the final responsibility for
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10^3 instead of 4x10<sup>3</sup>.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.
6. For information on research ethics and methodology, visit <http://cetm.home/ces/re/Home.aspx> or [http://www.ha.org.hk/ho/research\\_ethics/rec\\_home.htm](http://www.ha.org.hk/ho/research_ethics/rec_home.htm)

Logout

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Application Management Team Member Form Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log

7. After reading the instruction, click the [Create] button again.

**Welcome, Peter Chan** Role: Applicant

Print **Create** Application Summary Close

Submission Ref No.(For Office Use)   
Status

 醫院管理局  
HOSPITAL  
AUTHORITY

**Hospital Authority**  
**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10³.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.
6. For information on research ethics and methodology, visit <http://cetm.home/ces/re/Home.aspx> or [http://www.ha.org.hk/ho/research\\_ethics/rec\\_home.htm](http://www.ha.org.hk/ho/research_ethics/rec_home.htm)

Logout

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Application Management Team Member Form    Instructions    PartI    PartII    PartIII    PartIV  
PartV    PartVI    Clinical Study Categorization Form    Application Log    Document Log

8. You will be directed to the "Application Log" page. The following dialog informs you that the application log is cleared. Click the [OK] button to proceed.

**Welcome, Peter Chan** Role: Applicant

Print Create Application Summary Close Application Log

### Application Log

**Note to Investigator**

This Application Log shows all the updated information, which are extracted from your Research Ethics Review Application Form and your subsequent submissions for REC/IRB's review and approval.

**General Information**

Work Order Number: [WorkOrderNumber]

Submission Reference Number:

IRB/ REC Reference Number:

Initial Application Submission Date :

Initial Application Review Type :

Initial Application Approval Date :

Approval Expiry Date: <dd/MM/yyyy>

Proposed Study Start Date: <dd/MM/yyyy>

Proposed Study End Date: <dd/MM/yyyy>

Actual Study Start Date: <dd/MM/yyyy>

Actual Study End Date: <dd/MM/yyyy>

Initial Study Subject Recruitment Date: <dd/MM/yyyy>

CTC Expiry Date: <dd/MM/yyyy>

CTI Expiry Date: <dd/MM/yyyy>

Latest Progress Report Submission Date: <dd/MM/yyyy>

**Message**

Please note the Application Log is cleared in order not to affect the new application draft.

OK

Logout

© FlexWorkflow Limited

PartV PartVI Clinical Study Categorization Form Application Log Document Log

Application Management Team Member Form Instructions PartI PartII PartIII PartIV

9. Click the [Create] button again.

**Welcome, Peter Chan** Role: Applicant

Print **Create** Application Summary Close

### Application Log

**Note to Investigator**

This Application Log shows all the updated information, which are extracted from your Research Ethics Review Application Form and your subsequent submissions for REC/IRB's review and approval.

**General Information**

|   |   |
|---|---|
| Work Order Number:                      | <input type="text" value="[WorkOrderNumber]"/>  |
| Submission Reference Number:            | <input type="text"/>                            |
| IRB/ REC Reference Number:              | <input type="text"/>                            |
| Initial Application Submission Date :   | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Initial Application Review Type :       | <input type="text"/>                            |
| Initial Application Approval Date :     | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Approval Expiry Date:                   | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Proposed Study Start Date:              | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Proposed Study End Date:                | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Actual Study Start Date:                | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Actual Study End Date:                  | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Initial Study Subject Recruitment Date: | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| CTC Expiry Date:                        | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| CTI Expiry Date:                        | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |
| Latest Progress Report Submission Date: | <input type="text" value="&lt;dd/MM/yyyy&gt;"/> |

Logout

© FlexWorkflow Limited

PartV PartVI Clinical Study Categorization Form Application Log Document Log

Application Management Team Member Form Instructions PartI PartII PartIII PartIV

10. The following dialog is prompted to ask for your confirmation. Click [Yes] to proceed.

The screenshot displays a web application interface. At the top left is a red heart logo. The main header area says "Welcome, Peter Chan" and "Role: Applicant". Below this is a navigation bar with buttons for "Print", "Create", "Application Summary", and "Close". The main content area is titled "Application Log" and contains a "Note to Investigator" section with the text: "This Application Log shows all the updated information, which are extracted from your Research Ethics Review Application Form and your subsequent submissions for REC/IRB's review and approval." Below the note is a "General Information" section with various fields for dates and numbers, each with a placeholder "<dd/MM/yyyy>". A modal dialog box titled "Message" is overlaid on the form, containing the text: "Please confirm to create a new application for clinical research ethics review." The dialog has two buttons: "Yes" (highlighted with a red box) and "No". At the bottom of the application, there is a footer with "© FlexWorkflow Limited" and a navigation bar with buttons for "PartV", "PartVI", "Clinical Study Categorization Form", "Application Log", "Document Log", "Application Management Team Member Form", "Instructions", "PartI", "PartII", "PartIII", and "PartIV".

11. Click [OK] in the following prompted dialog.

The screenshot shows a web application interface for a user named Peter Chan, with the role of 'Applicant'. The main page is titled 'Application Log' and contains a 'Note to Investigator' and a 'General Information' section. A modal dialog box is open in the center, displaying the message 'The task is being processed.' and an 'OK' button, which is highlighted with a red box. The dialog box also has a title bar that says 'Information' and a close button. The background page shows various fields for application details, such as 'Work Order Number', 'Submission Reference Number', and 'Approval Expiry Date', each with a corresponding input field. The interface includes a navigation menu on the left and a footer with copyright information for FlexWorkflow Limited.

12. Click [Application] > [Draft].

The screenshot shows the user interface of the Hospital Authority Clinical Research Ethics Review Portal. At the top left is the Hospital Authority logo with the text '醫院管理局 HOSPITAL AUTHORITY'. The main header area displays 'Welcome, Peter Chan' and 'Role: Applicant' with a dropdown arrow. Below the header is a yellow banner with the text: 'Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong (CUHK) and The University of Hong Kong (HKU) to submit the Application for Clinical Research Ethics Review.' On the left side, there is a dark green navigation sidebar with the following items: Home, Profile, Application, Function, Help, and Logout. The 'Application' item is highlighted with a red box, and a sub-menu is open to its right, listing: New, Draft, Sent, Returned, Approved, Completed, Withdrawn, and All. The 'Draft' item in this sub-menu is also highlighted with a red box. At the bottom of the sidebar, it says '© FlexWorkflow Limited'.

13. You will find your cloned application. It is in the "Draft" status. You can open it, edit its content and then submit it.

The screenshot shows the Hospital Authority system interface. At the top left is the logo of the Hospital Authority (醫院管理局). The main header area displays 'Welcome, Peter Chan' and the user's role as 'Applicant'. A 'Refresh' button is visible in the top right. On the left is a dark green sidebar menu with options: Home, Profile, Application (highlighted), Function, Help, and Logout. The main content area is titled 'Draft' and contains a table with one application entry.

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title  | PI Hospital | PI University | Status | Action(s)   |
|---------------|---------------------|------------------|------------------------------|---|-------------|---------------|--------|-------------|
|               |                     | 2016/11/13 21:36 | Initial Application Approval | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial |             |               | Draft  | Export More |

14. Submit a draft application:

**Welcome, Peter Chan** Role: Applicant

Save Print **Submit** Delete Application Summary Close

Submission Ref No.(For Office Use)

Status

 醫院管理局  
HOSPITAL  
AUTHORITY

**Hospital Authority**  
**Clinical Research Ethics Review Application Form**

Applying Cluster  IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10<sup>3</sup> instead of 4x10³.
5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified, for example, by Application Reference Number, document numbers, version numbers and dates.

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Logout

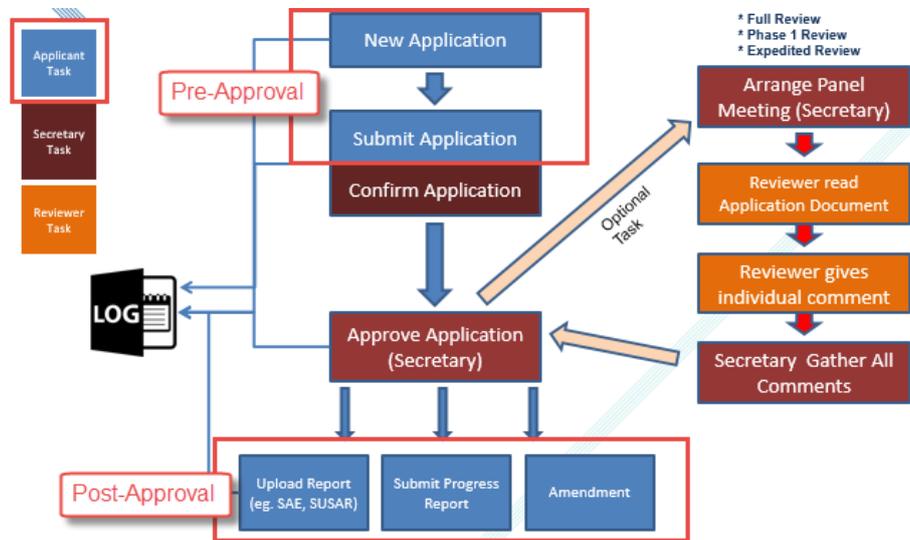
Instructions | PartI | PartII | PartIII | PartIV | PartV | PartVI

Clinical Study Categorization Form | Application Log | Document Log | Application Management Team Member Form | Comment Sheet

Comment Box

## 6. Manage an Application (Post-Approval)

### Overview of Post-Approval Activities



You can perform some post-approval operations after your application has been approved.

## 6.1. Upload Report / Submit Post-Approval Activities

After the “Initial Application Approval” is approved, Principal Investigator or Application Follow Up Users can upload and submit several kinds of documents in the Post-Approval stage, including:

- **Progress Report**
- **Final Report**
- **SAE Report**
- **SUSAR Report**
- **Protocol Deviation**
- **Renewed CTC**
- **Renewed CTI**

The procedures of submitting these reports are similar. Let’s take “Progress Report” as an example.

Please follow the below steps:

1. Go to **[Application]** ->**[Approved]**;



- Click **[More]** of the application and select “Upload Progress Report”;

## Approved

Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title | PI         | PI Hospital | PI University | Status   | Action(s)          |
|---------------|---------------------|------------------|------------------------------|------------------|------------|-------------|---------------|----------|--------------------|
| IRB-1234      | KWC-2016-0003       | 2016/11/04 01:16 | Initial Application Approval | sample title     | Peter Chan |             | CUHK          | Approved | Export <b>More</b> |

- Upload Progress Report
- Upload Final Report
- Upload SAE Report
- Upload SUSAR Report
- Submit Amendment Application Form
- Submit Protocol Deviation Form
- Submit New/Renewed CTC
- Submit New/Renewed CTI
- Change of Delegation

- Fill in the Research Progress Report Form (*Some columns should be filled in already based on the approved application*);
- Click the “**Download Progress Report**” button to download the template; or “**Download New Information Report**”;
- Fill in the downloaded report and **upload** the report by clicking  button under “Upload Attachment”;

Upload Attachment

Suggested Print Name:  
Please rename the document for your own reference (optional)





No. of attachments: 0

|  | Upload Date | Created By | Document Type | File Name | Suggested Print Name | Upload Times |
|--|-------------|------------|---------------|-----------|----------------------|--------------|
|  |             |            |               |           |                      |              |

- Click **[Submit]** button to submit the progress report. Secretary will receive.

7. For each Post-Approval application (e.g. Upload SUSAR Report, Upload Progress Report) that you have submitted to Secretary, you can find the record in **[Application] > [Sent]**:

The screenshot displays the Hospital Authority system interface. At the top left is the Hospital Authority logo. The main header area shows a welcome message for Peter Chan and user information: Role: Applicant, Last Successful Log in: 2016/11/14 13:00. A navigation sidebar on the left includes Home, Profile, Application, Function, and Help. The main content area is titled 'Sent' and features a 'Refresh' button. Below this is a table listing application records.

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|---------------|---------------------|------------------|--|---|-----------------|-------------|---------------|-----------|---|
| Test123456    | NTEC-2016-1312      | 2016/11/13 18:21 | <a href="#">Submit Renewed CTI</a>             | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |
| Test123456    | NTEC-2016-1312      | 2016/11/13 18:46 | <a href="#">Submit Renewed CTC</a>             | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |
| Test123456    | NTEC-2016-1312      | 2016/11/13 19:02 | <a href="#">Submit Protocol Deviation Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |
| Test123456    | NTEC-2016-1312      | 2016/11/13 18:48 | <a href="#">Upload SUSAR Report</a>            | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |
| Test123456    | NTEC-2016-1312      | 2016/11/13 18:47 | <a href="#">Upload SAE Report</a>              | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |
| Test123456    | NTEC-2016-1312      | 2016/11/13 18:54 | <a href="#">Upload Final Report</a>            | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |
| Test123456    | NTEC-2016-1312      | 2016/11/13 18:02 | <a href="#">Upload Progress Report</a>         | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial This is revised | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |

### 6.1.1. Request for Return of Post-Approval Application

For each Post-Approval application (e.g. Upload SUSAR Report, Upload Progress Report) that you have submitted to Secretary, you can request for return if necessary.

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

- Submitted
- Re-submitted
- Confirmed
- For Review
- Reviewed

1. Go to **[Application]** > **[Sent]**.
2. Choose **[More]** > **[Request for Return]**.

The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The main content area has a header with the user's name 'Welcome, Peter Chan!' and role 'Applicant'. Below the header is a table titled 'Sent' with a 'Refresh' button. The table has columns for IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). A single application is listed with the status 'Submitted'. A dropdown menu is open over the 'Action(s)' column, showing 'Request for Return' and 'Change of Delegation' options.

| IRB / REC No.      | Submission Ref. No. | Date             | Task              | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)   |
|--------------------|---------------------|------------------|-------------------|---|-----------------|-------------|---------------|-----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 13:32 | Upload SAE Report | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Submitted | Export More<br>Request for Return<br>Change of Delegation |

3. Fill in the request reason and then submit it.

**Important!** Please note that the status of the application will remain unchanged even when you have requested for a return. It will change to "Returned" only when Secretary has returned the application to you.

## 6.1.2. Re-submit / Withdraw Returned Post-Approval Application

Secretary will then review each of your Post-Approval applications (e.g. Upload SUSAR Report, Upload Progress Report) and may return them to you. You can resubmit or withdraw the returned Post-Approval applications.

1. Go to **[Application] > [Returned]**. Open the returned post-approval application.

The screenshot shows the Hospital Authority system interface. On the left is a green navigation sidebar with icons for Home, Profile, Application, Function, and Help. The main content area displays a 'Welcome, Peter Chan!' message and a 'Returned' table. The table has columns for IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). A single application is listed with the status 'Returned' and actions 'Export' and 'More'. A 'Refresh' button is located to the right of the table.

| IRB / REC No.      | Submission Ref. No. | Date             | Task              | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)   |
|--------------------|---------------------|------------------|-------------------|---|-----------------|-------------|---------------|----------|-------------|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 13:54 | Upload SAE Report | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Returned | Export More |

2. Click **[Submit]** to resubmit or **[Withdraw]** to withdraw the returned post-approval application.

The screenshot shows the 'Serious Adverse Event (SAE) Report Form' interface. At the top, there is a navigation bar with buttons for Save, Print, Submit, Withdraw, Application Summary, and Close. The form is divided into sections: 'Note to Investigator' with a text box containing instructions, and 'Background Information' with a 'Study title' field containing the same text as in the previous screenshot. Below this are fields for 'IRB/REC Reference Number' (Testing IRB - 0001), 'Protocol Number', and 'Proposed Study End Date' (31/07/2018). At the bottom, there are tabs for SAE Report, Application Log, Document Log, Application Management Team Member Form, and Comment Sheet. A 'Logout' button is visible in the sidebar.

3. Re-submitted applications with the status "Re-submitted" will be displayed in **[Application] > [Sent]**, while withdrawn applications with the status "Withdrawn" will be displayed in **[Application] > [Withdrawn]**.

### 6.1.3. Confirmed Post-Approval Application

Each submitted Post-Approval application (e.g. Upload SUSAR Report, Upload Progress Report) will be reviewed by the Secretary. Once the Secretary has confirmed every necessary piece of information and when the documents of the application are ready, Secretary will confirm the application. Review processes will then be arranged by Secretary.

To view confirmed applications:

1. Go to **[Application] > [Sent]**
2. The status is "Confirmed".



The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The main content area has a header with the user's name 'Welcome, NTEC.APP1@GMAIL.COM!' and a role dropdown set to 'Applicant'. Below the header is a 'Sent' section with a 'Refresh' button. A table displays application details:

| IRB / REC No.      | Submission Ref. No. | Date             | Task                              | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|--------------------|---------------------|------------------|-----------------------------------|---|-----------------|-------------|---------------|-----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 14:40 | <a href="#">Upload SAE Report</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Confirmed | <a href="#">Export</a> <a href="#">More</a> |

### 6.1.4. For Review Post-Approval Application

For each Post-Approval application (e.g. Upload SUSAR Report, Upload Progress Report) that has been confirmed by the secretary, if the application has been passed to the reviewers for review, the application will be in “For Review” status:

1. Go to **[Application] > [Sent]**
2. The status is “For Review”.

The screenshot shows the Hospital Authority system interface. On the left is a green sidebar menu with options: Home, Profile, Application (highlighted), Email, Review Arrangement, and Reviewer Maintenance. The main content area has a header with the Hospital Authority logo and name, a welcome message 'Welcome, Peter Chan!', a role dropdown set to 'CREC Secretary', and a 'Last Successful Log In' timestamp of '2016/11/14 14:01:34'. Below the header is a 'For Review' section with a 'Refresh' button. A table lists applications with columns: IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). One application is visible with the status 'For Review' and actions 'Export' and 'More'.

| IRB / REC No.      | Submission Ref. No. | Date             | Task                              | Scientific Title  | PI              | PI Hospital | PI University | Status     | Action(s)                                   |
|--------------------|---------------------|------------------|-----------------------------------|---|-----------------|-------------|---------------|------------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 14:43 | <a href="#">Upload SAE Report</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | For Review | <a href="#">Export</a> <a href="#">More</a> |

## 6.1.5. Reviewed Post-Approval Application

After reviewers have reviewed a post-approval application (e.g. Upload SUSAR Report, Upload Progress Report), its status will be changed to "Reviewed".

1. Go to **[Application]** > **[Sent]**
2. The status is in "Reviewed".

The screenshot displays the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The top header features the Hospital Authority logo and a welcome message for Peter Chan, with a role dropdown set to 'Applicant' and a 'Refresh' button. The main content area shows a table of 'Sent' applications. One application is listed with the status 'Reviewed' and 'Export More' options.

| IRB / REC No.      | Submission Ref. No. | Date             | Task                              | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)                                   |
|--------------------|---------------------|------------------|-----------------------------------|---|-----------------|-------------|---------------|----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 14:43 | <a href="#">Upload SAE Report</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Reviewed | <a href="#">Export</a> <a href="#">More</a> |

### 6.1.6. Returned Post-Approval Application after Review

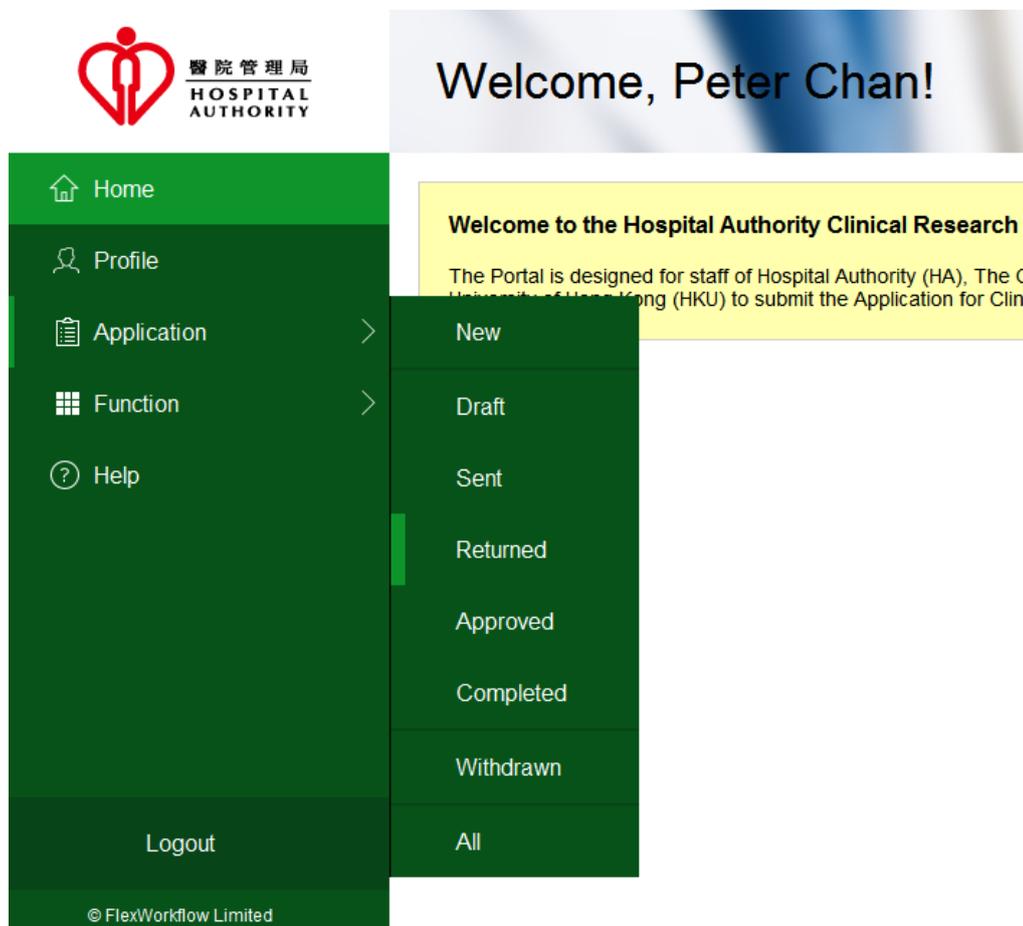
For each post-approval application (e.g. Upload SUSAR Report, Upload Progress Report), once reviewers have finished the review, Secretary will consolidate the result and mark whether the post-approval application is approved.

If the application is not approved, secretary will return the application to the applicant. Depending on the decision marked by the secretary, the application may have one of the following statuses:

- Approved with Comment
- Pending for Comment

To view the status:

1. Go to **[Application] > [Returned]**



2. The status could be “Approved with Comment” or “Pending for Comment”:

Welcome, Peter Chan! Role: Applicant  
Last Successful Log In: 2016/11/14 14:57:11

**Returned** Refresh

| IRB / REC No.      | Submission Ref. No. | Date             | Task                              | Scientific Title  | PI              | PI Hospital | PI University | Status                | Action(s)                                   |
|--------------------|---------------------|------------------|-----------------------------------|---|-----------------|-------------|---------------|-----------------------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 15:05 | <a href="#">Upload SAE Report</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Approved with Comment | <a href="#">Export</a> <a href="#">More</a> |

Welcome, Peter Chan! Role: Applicant  
Last Successful Log In: 2016/11/14 14:57:11

**Returned** Refresh

| IRB / REC No.      | Submission Ref. No. | Date             | Task                              | Scientific Title  | PI              | PI Hospital | PI University | Status              | Action(s)                                   |
|--------------------|---------------------|------------------|-----------------------------------|---|-----------------|-------------|---------------|---------------------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 15:05 | <a href="#">Upload SAE Report</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Pending for Comment | <a href="#">Export</a> <a href="#">More</a> |

3. You can open the application and go to the “Comment Sheet” to view the comment:

Welcome, Peter Chan! Role: Applicant

Save Print Submit Withdraw Application Summary Close

Comment Sheet

Viewed by Applicant

Comment History :

| Date       | Name                | Comment             | To        |
|------------|---------------------|---------------------|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment | Applicant |

Logout

SAE Report Application Log Document Log Application Management Team Member Form **Comment Sheet**

Comment Box

4. You may modify the post-approval application content, and then re-submit it to Secretary again by clicking the **[Submit]** button; you may also withdraw the post-approval application if necessary by clicking the **[Withdraw]** button.

Welcome, Peter Chan! Role: Applicant

Save Print **Submit** **Withdraw** Application Summary Close

Comment Sheet

Viewed by Applicant

Comment History :

| Date       | Name                | Comment             | To        |
|------------|---------------------|---------------------|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment | Applicant |

Logout

SAE Report Application Log Document Log Application Management Team Member Form Comment Sheet

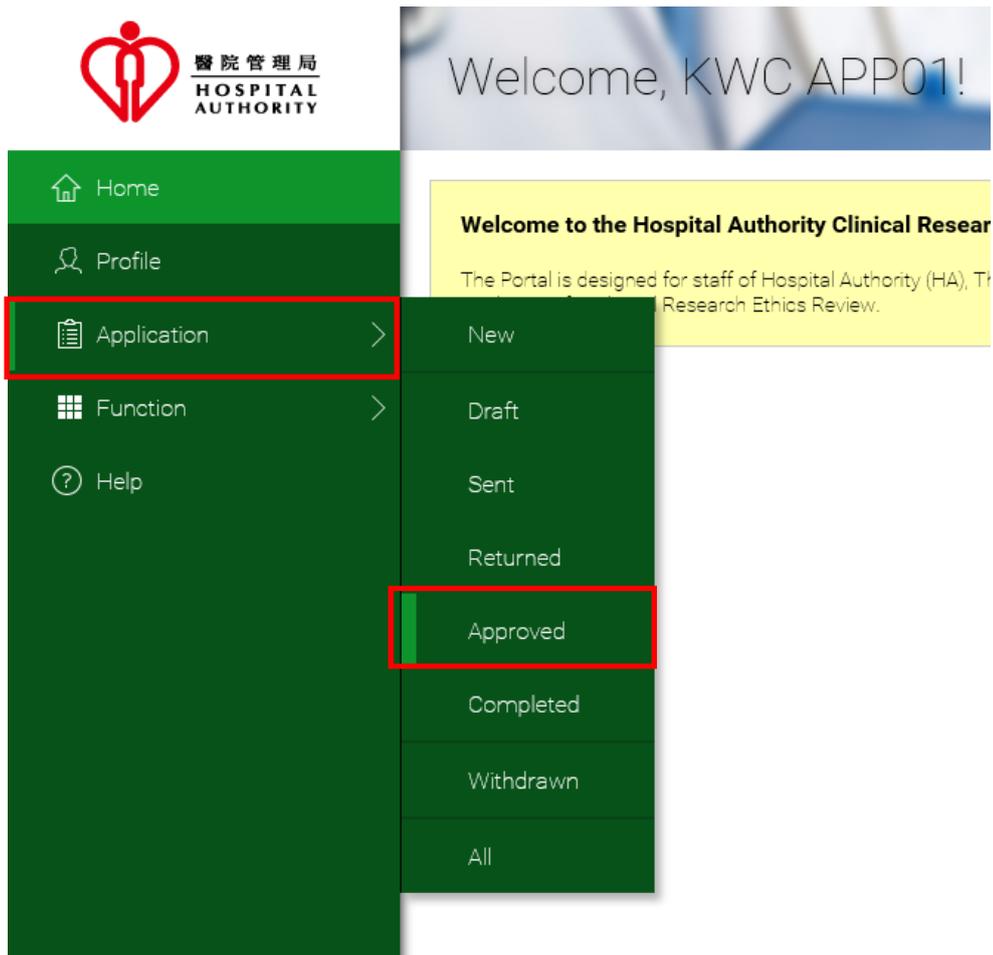
© FlexWorkflow Limited Comment Box

### 6.1.7. Approved Post-Approval Application after Review

For each post-approval application (e.g. Upload SUSAR Report, Upload Progress Report), once reviewers have finished the review, Secretary will consolidate the result and mark whether the post-approval application is approved.

You are able to find the post-approval application and read the comments (if any) by following the below steps:

1. Go to **[Application] > [Approved]**



2. The application status becomes "Approved".



---

## 6.2. Completed Initial Approval Application

Once the "Upload Final Report" application is approved, the "Initial Approval Application" will be changed to "Completed" status.

### 6.3. Amendment of Approved Application

Once the “Initial Application Approval” application (also known as pre-approval) is approved, if any amendment is required, Principal Investigator or Application Follow Up Users can submit an amendment application. The amendment application will be passed to Secretary for review.

Please follow below steps:

1. Go to **[Application]** ->**[Approved]**:



2. Click **[More]** of the application and select **[Submit Amendment Application Form]**;

## Approved

Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task                         | Scientific Title | PI         | PI Hospital | PI University | Status   | Action(s)          |
|---------------|---------------------|------------------|------------------------------|------------------|------------|-------------|---------------|----------|--------------------|
| IRB-1234      | KWC-2016-0003       | 2016/11/04 01:16 | Initial Application Approval | sample title     | Peter Chan |             | CUHK          | Approved | Export <b>More</b> |

- Upload Progress Report
- Upload Final Report
- Upload SAE Report
- Upload SUSAR Report
- Submit Amendment Application Form**
- Submit Protocol Deviation Form
- Submit New/Renewed CTC
- Submit New/Renewed CTI
- Change of Delegation

3. Go to the page and revise the content that you need.



Welcome, Peter Chan!

Role: Applicant

Print Submit Application Summary Close

PartII

9. Scientific basis IRB/ REC Reference No. Testing IRB - 0001  
(For Office Use)

9.1 Background, current evidence and key references\* (< 30,000 characters)

Tremendous health burden of Parkinson's disease (PD)  
PD is a chronic, neurodegenerative disease affecting 1-2% of the population over the age of 65 years[1]. It is characterized by four cardinal motor symptoms including resting tremor, stiffness, bradykinesia and postural instability, which greatly impair patients' physical wellbeing and functional capacity. The treatment of PD used to focus solely on management of motor symptoms. However, non-motor symptoms of PD, such as cognitive, neuropsychiatric, sleep, autonomic, sensory and disturbances, have been reported to have a greater impact on health-related quality of life (HRQoL) and gaining increasing attention in the recent decade [2]. With the prolonged life expectancy and increasing number of people with Parkinson's disease, demand for long term health care is growing rapidly and one of the most serious challenges facing the healthcare system is how to empower and engage people with PD in adopting a more active role in daily living and chronic disease management. PD population is at high risks of psychological distress  
Psychological distress like anxiety and depressive symptoms are prevalent among PD population, which results from frustration over the loss of body control and diminished feelings of mastery and expression[3]. It has been reported that the incidence of anxiety and depression was up to 30% and 40% among PD population, which is much higher than individuals with other chronic

9.2 Aim of study\* (< 30,000 characters)

The objective of this study is to determine the preliminary effect and feasibility of a programme on enhancing psychosocial distress, physiological and spiritual wellbeing and HRQoL among people with PD.  
(Revised)

Logout

FlexWorkflow

Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log  
Document Log Application Management Team Member Form Comment Sheet Amendment Application Form Previous Attachment List

4. Before submitting your amendment, go to the “Amendment Application Form” page.

Then click the [Amendment] button to compare the changes.

Welcome, Peter Chan! Role: Applicant

Print Submit Application Summary Close Amendment Appli

### Amendment Application Form

**Note to Investigator**

To report any amendment needs to be made to any study document/material, please complete and submit the following application form to REC/IRB in accordance with the requirements set out in the SOP of the REC/IRB.

**Background Information**

Study title: [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial

IRB/REC Reference Number: Testing IRB - 0001 Anticipated Start Date: 30/12/2016

Principal Investigator (PI): CHAN Tai Man Anticipated End Date: 31/07/2018

**Input Information**

List of Amended Fields :

| No. | Field Name | Current Condition | Amendment | Proposed By | Reason for Change | Will change increase risk to participants? |
|-----|------------|-------------------|-----------|-------------|-------------------|--|
|-----|------------|-------------------|-----------|-------------|-------------------|--|

Logout

Document Log Application Management Team Member Form Comment Sheet Amendment Application Form Previous Attachment List

Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log

Comment Box

FlexWorkflow Limited

- The message "Comparison in progress. Please wait for a minute!" informs you that system is comparing the amendment with the original application.

The screenshot displays the 'Amendment Application Form' interface. At the top, a welcome message 'Welcome, Peter Chan!' is visible, along with a 'Role: Applicant' dropdown menu. The main content area is titled 'Amendment Application Form' and contains several sections:

- Note to Investigator:** A text box containing the instruction: "To report any amendment needs to be made to any study document/material, please complete and submit the following application form to REC/IRB in accordance with the requirements set out in the SOP of the REC/IRB."
- Background Information:** This section includes:
  - Study title:** "[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial"
  - IRB/REC Reference Number:** "Testing IRB - 0001"
  - Anticipated Start Date:** "30/12/2016"
  - Principal Investigator (PI):** "CHAN Tai Man"
  - Anticipated End Date:** "31/07/2018"
- Input Information:** This section features a 'List of Amended Fields' table and an 'Amendment' button. A red message 'Comparison in progress: Please wait for a minute!' is displayed next to the button.

The 'List of Amended Fields' table has the following columns: No., Field Name, Current Condition, Amendment, Proposed By, Reason for Change, and Will change increase risk to participants?. The table body is currently empty.

At the bottom of the interface, there is a navigation bar with buttons for 'Document Log', 'Application Management Team Member Form', 'Comment Sheet', 'Amendment Application Form', and 'Previous Attachment List'. Below this, there are buttons for 'Instructions', 'PartI', 'PartII', 'PartIII', 'PartIV', 'PartV', 'PartVI', 'Clinical Study Categorization Form', and 'Application Log'.

6. After a while, you will find the comparison of amended fields and updated documents.

Please fill in the column **“Proposed By”**, **“Reason for Change”** and **“Will change increase risk to participants”**.

**Amended Fields:**

List of Amended Fields :

Amendment

| No. | Field Name       | Current Condition  | Amendment   | Proposed By | Reason for Change | Will change increase risk to participants? |
|-----|------------------|--|---|-------------|-------------------|--|
| 1   | 9.2 Aim of study | The objective of this study is to determine the preliminary effect and feasibility of a programme on enhancing psychosocial distress, physiological and spiritual wellbeing and HRQoL among people with PD | The objective of this study is to determine the preliminary effect and feasibility of a programme on enhancing psychosocial distress, physiological and spiritual wellbeing and HRQoL among |             |                   |  |

List of Updated Documents :

| No. | Document Section Name | Current Condition | Amendment | Proposed By | Reason for Change | Will change increase risk to participants? |
|-----|-----------------------|-------------------|-----------|-------------|-------------------|--|
| 1   | 27. Research Protocol |                   |           |             |                   |  |

7. If you go back to the application form, fields that are revised will be surrounded by a yellow line:

Role: Applicant

Print Submit Application Summary Close

**PART II: STUDY DETAILS (No referral to protocols/other documents is allowed)** Go to Amendment Application Form

9. Scientific basis IRB/ REC Reference No. Testing IRB - 0001  
(For Office Use)

9.1 Background, current evidence and key references\* (< 30,000 characters)

Tremendous health burden of Parkinson's disease (PD)  
 PD is a chronic, neurodegenerative disease affecting 1-2% of the population over the age of 65 years[1]. It is characterized by four cardinal motor symptoms including resting tremor, stiffness, bradykinesia and postural instability, which greatly impair patients' physical wellbeing and functional capacity. The treatment of PD used to focus solely on management of motor symptoms. However, non-motor symptoms of PD, such as cognitive, neuropsychiatric, sleep, autonomic, sensory and disturbances, have been reported to have a greater impact on health-related quality of life (HRQoL) and gaining increasing attention in the recent decade [2]. With the prolonged life expectancy and increasing number of people with Parkinson's disease, demand for long term health care is growing rapidly and one of the most serious challenges facing the healthcare system is how to empower and engage people with PD in adopting a more active role in daily living and chronic disease management.  
 PD population is at high risks of psychological distress  
 Psychological distress like anxiety and depressive symptoms are prevalent among PD population, which results from frustration over the loss of body control and diminished feelings of mastery and expression[3]. It has been reported that the incidence of anxiety and depression was up to 30% and 40% among PD population, which is much higher than individuals with other chronic

9.2 Aim of study\* (< 30,000 characters)

The objective of this study is to determine the preliminary effect and feasibility of a programme on enhancing psychosocial distress, physiological and spiritual wellbeing and HRQoL among people with PD. (Revised)

9.3 Hypothesis (e.g. Compared to x control, y intervention leads to a greater rate of z outcome)\* (< 30,000 characters)

8. Click the **[Submit]** button to submit your amendment.

9. Go to **[Application] > [Sent]**

You will find the submitted **“Submit Amendment Application Form”** task.

醫院管理局 HOSPITAL AUTHORITY

Welcome, Peter Chan! Role: Applicant

Last Successful Log in: 2016/11/14 11:02:13

Refresh

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|-----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 11:57 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |

### 6.3.1. Request for Return of Amendment Application

After you have submitted “Submit Amendment Application Form” to Secretary, you can request for a return if necessary.

Amendment Applications with the following statuses could be requested for a return:

- Submitted
- Re-submitted
- Confirmed
- For Review
- Reviewed

4. Go to **[Application]** > **[Sent]**.
5. Choose **[More]** > **[Request for Return]**.

The screenshot shows the user interface of the NTEC APP1@GMAIL.COM system. On the left is a green sidebar with navigation options: Home, Profile, Application (selected), Function, and Help. The top header includes the Hospital Authority logo and a welcome message. The main content area displays a table of 'Sent' applications. A dropdown menu is open under the 'Submitted' status of the first application, showing 'Request for Return' and 'Change of Delegation' options.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|-----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 11:57 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Submitted | <a href="#">Export</a> <a href="#">More</a> |

6. Fill in the request reason and then submit it.

**Important!** Please note that the status of the application will remain unchanged even when you have requested for a return. It will change to “Returned” only when Secretary has returned the application to you.

### 6.3.2. Re-submit / Withdraw Returned Amendment Application

Secretary will then review your “Submit Amendment Application Form” and may return it to you. You can resubmit or withdraw the returned amendment application.

1. Go to [Application] > [Returned].

The screenshot shows the Hospital Authority system interface. On the left is a green navigation sidebar with icons for Home, Profile, Application, Function, and Help. The main content area displays a 'Welcome, Peter Chan!' message with a 'Role: Applicant' dropdown and a 'Last Successful Log In: 2016/11/14 11:59:12' timestamp. Below this is a 'Returned' section with a 'Refresh' button. A table lists returned applications:

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 12:06 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Returned | <a href="#">Export</a> <a href="#">More</a> |

2. Click [Submit] to resubmit or [Withdraw] to withdraw the returned amendment application.

The screenshot shows the 'Clinical Research Ethics Review Application Form' for a returned application. The form includes the following fields and sections:

- Submission Reference No.(For Office Use):** NTEC-2016-1315
- Status:** Returned
- Buttons:** Save, Print, Submit, Withdraw, Application Summary, Close, Instructions, Go to Amendment Application Form
- Applying Cluster:** NTEC
- IRB/ REC Reference No. (For Office Use):** Testing IRB - 0001
- Instructions to applicant:**
  1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted by Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the human subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
  2. If submit the application via online system, enter all information required and upload relevant application dossier files to the required fields.
  3. This form is only fully functional with Microsoft Silverlight. This form can only support retrieval of the following attachments - [1] Common Image files, [2] HTML and XML files, [3] Media files, [4] Microsoft Office files (except \*.mdb files), [5] PDF files, [6] Text files.
  4. This Form does not support certain symbol and text format adjustment. For example, enter text "beta" instead of symbol "β" or copy and paste "β" from another source, and use symbol ^ to indicate "power", e.g. 4x10^3 instead of 4x10³.
  5. Research protocol, investigator brochures, consent forms, and written materials to subjects must be uniquely identified for example
- Navigation:** Instructions, PartI, PartII, PartIII, PartIV, PartV, PartVI, Clinical Study Categorization Form, Application Log, Document Log, Application Management Team Member Form, Comment Sheet, Amendment Application Form, Previous Attachment List, Comment Box

3. Re-submitted applications with the status “Re-submitted” will be displayed in [Application] > [Sent], while withdrawn applications with the status “Withdrawn” will be displayed at [Application] > [Withdrawn].

### 6.3.3. Confirmed Amendment Application

The submitted “Submit Amendment Application Form” will be reviewed by Secretary. Once the secretary has confirmed every necessary piece of information and when the documents of the application are ready, Secretary will confirm the application. Review processes will then be arranged by Secretary.

To view confirmed application:

1. Go to **[Application] > [Sent]**
2. The status is in “Confirmed”.

The screenshot displays the Hospital Authority system interface. On the left is a green sidebar with navigation options: Home, Profile, Application (selected), Function, and Help. The top header shows the Hospital Authority logo and a welcome message for Peter Chan, with a role dropdown set to 'Applicant' and a last login timestamp. The main content area is titled 'Sent' and features a table of applications. A 'Refresh' button is located in the top right of the table area.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status    | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|-----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 12:47 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Confirmed | <a href="#">Export</a> <a href="#">More</a> |

### 6.3.4. For Review Amendment Application

After the Amendment Application (“Submit Amendment Application Form”) has been confirmed by the secretary, if the application has been passed to the reviewers for review, the application will be in “For Review” status.

1. Go to **[Application]** > **[Sent]**
2. The status is “For Review”.

The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The top header includes the Hospital Authority logo, a welcome message for Peter Chan, and a role dropdown set to 'Applicant'. Below the header, a 'Sent' section contains a table with one application entry. The application is for 'Testing IRB - 0001' with submission reference 'NTEC-2016-1315' and date '2016/11/14 12:53'. The task is 'Submit Amendment Application Form'. The scientific title is '[Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial'. The PI is 'Dr CHAN Tai Man' at 'TPH' hospital. The status is 'For Review' with 'Export' and 'More' action links. A 'Refresh' button is located above the table.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status     | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|------------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 12:53 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | For Review | <a href="#">Export</a> <a href="#">More</a> |

### 6.3.5. Reviewed Amendment Application

After a reviewer has reviewed the amendment application, its status will be changed to "Reviewed".

1. Go to [Application] > [Sent]
2. The status is "For Review".

The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application (highlighted), Function, and Help. The top header includes the Hospital Authority logo and the text 'Welcome, Peter Chan!' with a role dropdown set to 'Applicant' and a last login timestamp. The main content area is titled 'Sent' and features a table of applications. A 'Refresh' button is located in the top right of the table area.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 12:53 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Reviewed | <a href="#">Export</a> <a href="#">More</a> |

### 6.3.6. Returned Amendment Application after Review

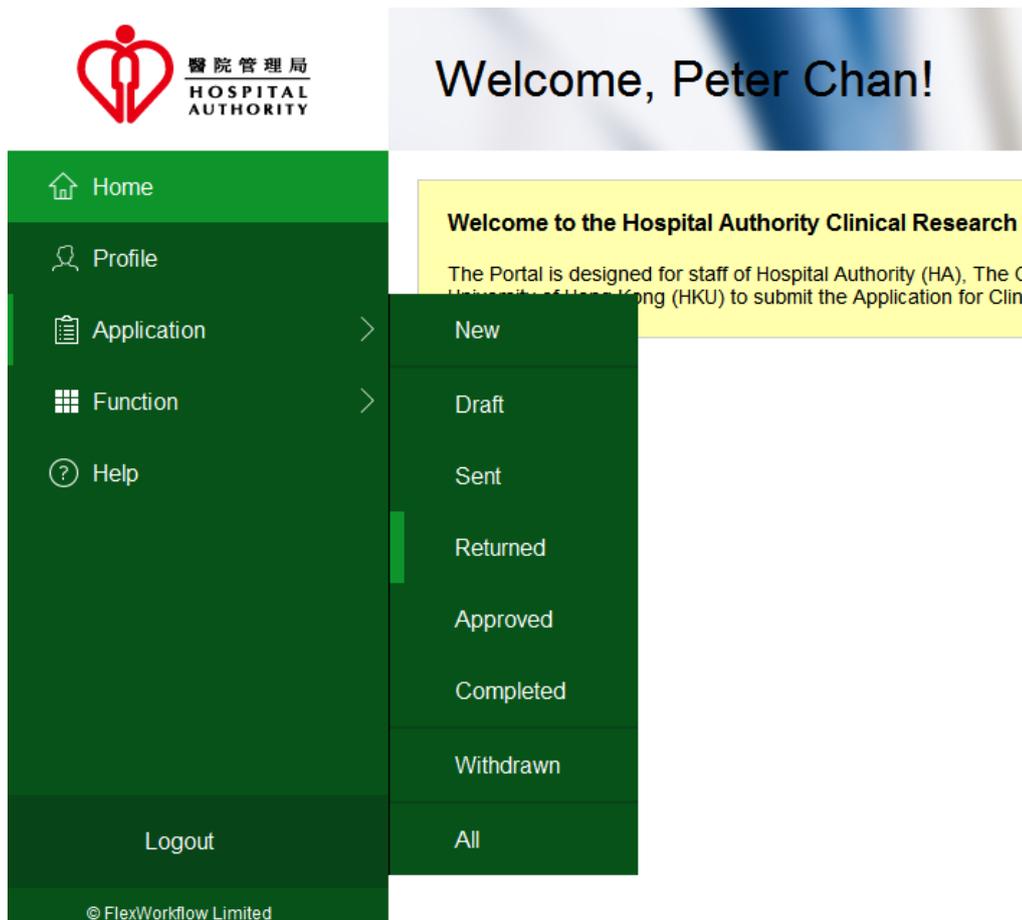
After the reviews of amendment application form by reviewers, Secretary will consolidate the reviews and mark whether the amendment application is approved.

If the amendment application is not approved, secretary will return the amendment application to the applicant. Depending on the decision marked by the secretary, the amendment application may have one of the following statuses:

- Approved with Comment
- Pending for Comment

To view the status:

1. Go to **[Application] > [Returned]**



2. The status could be “Approved with Comment” or “Pending for Comment”:

The screenshot shows the Hospital Authority system interface. The user is Peter Chan, logged in as an Applicant. The application status is 'Approved with Comment'. A red arrow points to the 'Approved with Comment' status in the table.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status                | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|-----------------------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 12:53 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Approved with Comment | <a href="#">Export</a> <a href="#">More</a> |

The screenshot shows the Hospital Authority system interface. The user is Peter Chan, logged in as an Applicant. The application status is 'Pending for Comment'. A red arrow points to the 'Pending for Comment' status in the table.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status              | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|---------------------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 12:53 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Pending for Comment | <a href="#">Export</a> <a href="#">More</a> |

3. You can open the application and go to the "Comment Sheet" to view the comment:

Welcome, Peter Chan! Role: Applicant

Save Print Submit Withdraw Application Summary Close

Comment Sheet

Viewed by Applicant

Comment History :

| Date       | Name                | Comment             | To        |
|------------|---------------------|---------------------|-----------|
| 14/11/2016 | ntec.sec1@gmail.com | this is the comment | Applicant |

Logout

Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form **Comment Sheet**

Instructions PartI PartII PartIII PartIV PartV PartVI

Comment Box

FlexWorkflow Limited

4. You may modify the application content, and then re-submit it to Secretary again by clicking the **[Submit]** button; you may withdraw the application if necessary by clicking the **[Withdraw]** button.

Welcome, Peter Chan! Role: Applicant

Save Print **Submit** Withdraw Application Summary Close

Submission Ref No.(For Office Use) NTEC-2016-1315  
Status Pending for Comment

醫院管理局  
HOSPITAL AUTHORITY

**Hospital Authority**  
**Clinical Research Ethics Review Application Form**

Applying Cluster NTEC IRB/ REC Reference No. (For Office Use)

**Instructions to applicant**

1. Cluster Research Ethics Committee/Institutional Review Board ("REC/IRB") is dedicated to oversee clinical studies conducted Hospital Authority ("HA")/University personnel in the Cluster with the aim of protecting the rights, safety and well-being of the subjects recruited for the studies. The Applicant / Principal Investigator must be designated to take the final responsibility for protecting the rights, safety and well-being of subjects recruited from the Cluster.
2. If submit the application via online system, enter all information required and upload relevant application dossier files to the relevant fields.

Logout  
FlexWorkflow Limited

Instructions PartI PartII PartIII PartIV PartV PartVI  
Clinical Study Categorization Form Application Log Document Log Application Management Team Member Form Comment Sheet  
Comment Box

### 6.3.7. Approved Amendment Application

Upon the approval of your amendment application, you can find the approved amendment application. If you need to upload a report, please go back to the **Initial Application Approval** to upload.

1. Go to **[Application] > [Approved]**.
2. In the **“Initial Application Approval”** (which should have with the same Submission Ref. No. as the “Submit Amendment Application Form”), click **[More]** and choose a report to upload.

The screenshot shows the Hospital Authority system interface. On the left is a dark green sidebar with navigation options: Home, Profile, Application, Function, and Help. The main content area has a header with a welcome message 'Welcome, Peter Chan!' and a 'Refresh' button. Below the header is a table titled 'Approved' with columns: IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). Two rows of data are visible. The first row has a 'Submit Amendment Application Form' link. The second row has an 'Initial Application Approval' link highlighted with a red box. To the right of the second row, a dropdown menu is open, listing various report upload and form submission options. A red arrow points to the 'More' link in the 'Action(s)' column of the second row.

| IRB / REC No.      | Submission Ref. No. | Date             | Task  | Scientific Title  | PI              | PI Hospital | PI University | Status   | Action(s)                                   |
|--------------------|---------------------|------------------|---|---|-----------------|-------------|---------------|----------|---|
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 13:11 | <a href="#">Submit Amendment Application Form</a> | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Approved | <a href="#">Export</a> <a href="#">More</a> |
| Testing IRB - 0001 | NTEC-2016-1315      | 2016/11/14 11:03 | <a href="#">Initial Application Approval</a>      | [Training] The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | TPH         |               | Approved | <a href="#">Export</a> <a href="#">More</a> |

- Upload Progress Report
- Upload Final Report
- Upload SAE Report
- Upload SUSAR Report
- Submit Amendment Application Form
- Submit Protocol Deviation Form
- Submit New/Renewed CTC
- Submit New/Renewed CTI
- Change of Delegation

## 6.4. Change of Delegation

You can also change the delegates and application follow up users in post-approval period:

1. Go to [Application] ->[Approved];



2. Click **[More]** of the application you are going to modify;

Select **[Change of Delegation]**. The Application Management Team Member Form should appear.

### Approved

Refresh

| IRB / REC No. | Submission Ref. No. | Date             | Task   | Scientific Title | PI         | PI Hospital | PI University | Status   | Action(s)                                   |
|---------------|---------------------|------------------|--|------------------|------------|-------------|---------------|----------|---|
| IRB-1234      | KWC-2016-0003       | 2016/11/04 01:16 | <a href="#">Initial Application Approval</a> | sample title     | Peter Chan |             | CUHK          | Approved | <a href="#">Export</a> <a href="#">More</a> |

- Upload Progress Report
- Upload Final Report
- Upload SAE Report
- Upload SUSAR Report
- Submit Amendment Application Form
- Submit Protocol Deviation Form
- Submit New/Renewed CTC
- Submit New/Renewed CTI
- Change of Delegation**

3. Change the member list.

Welcome, KWC APP01!

Print Submit Application Summary Close

submission of the Form, each of the team members (PI, Delegates, Application Follow-up Users) will receive a notifying email to start contribute to this Application.

Principal Investigator :

| Email               | Name      | Existing Account                    | Please sign up |
|---------------------|-----------|-------------------------------------|----------------|
| app01.kwc@gmail.com | KWC APP01 | <input checked="" type="checkbox"/> |                |

Assign Principal Investigator who will be responsible for the Application.

Add New Row Delete Selected Row(s)

Delegates :

| Email | Name | Existing Account         | Please sign up             |
|-------|------|--------------------------|----------------------------|
|       |      | <input type="checkbox"/> | <a href="#">Click here</a> |

Please assign Delegates who will help manage and edit the application forms before research ethics approval.

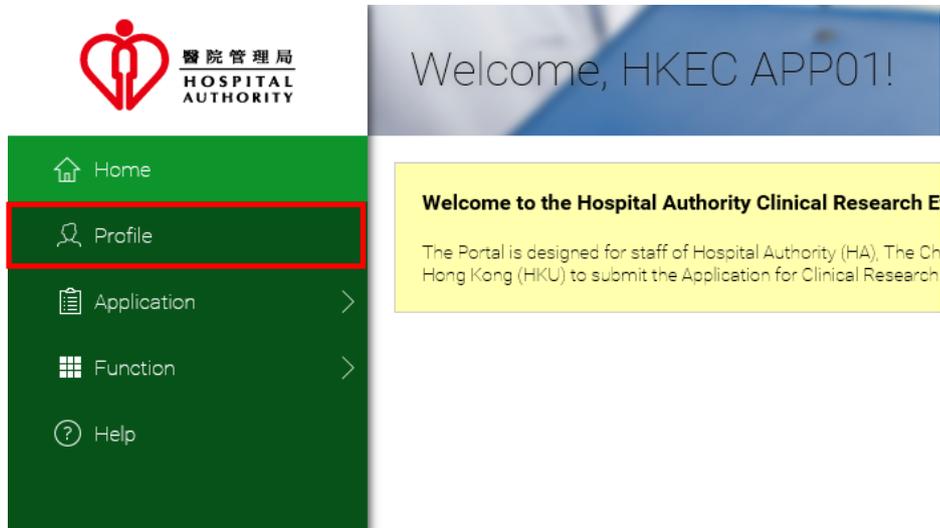
4. Click **[Submit]** to finish the modification.

## 7. Maintain User Profile

### 7.1. Amendment of User Profile / Change of Password

If you want to amend any information of your user information (**except login email address**), please do the following:

- Go to **[Application]** ->**[Profile]**;



- Amend your personal information;
- Make sure you have entered the **same password** in “New Password” and “Confirm Password” if you are going to change your password;
- Click **[Update]** button to update your user profile.

|                   |   |            |                                      |
|-------------------|---|------------|--------------------------------------|
| User Name:        | <input type="text" value="app01.hkec@gmail.com"/> |            |                                      |
| Job Title:        | <input type="text" value="Job Title"/>            |            |                                      |
| First Name:       | <input type="text" value="PreUAT"/>               | Last Name: | <input type="text" value="Account"/> |
| Institution:      | <input type="text" value="HKEC"/>                 |            |                                      |
| Contact Number:   | <input type="text" value="Contact Number"/>       |            |                                      |
| Old Password:     | <input type="text" value="Existing Password"/>    |            |                                      |
| New Password:     | <input type="text" value="New Password"/>         |            |                                      |
| Confirm Password: | <input type="text" value="Confirm New Password"/> |            |                                      |

**Password Policy:**

1. Min Length Password is 8
2. Contains at least one numeric character
3. Contains at least one upper case
4. Contains at least one lower case

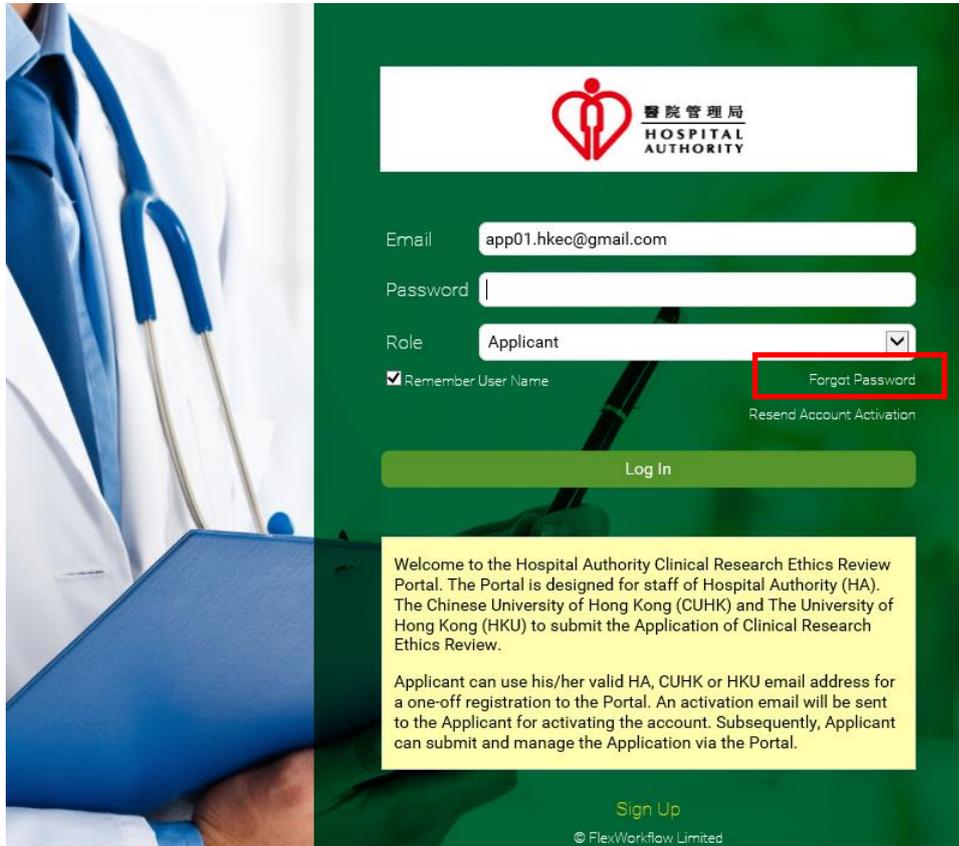
|                                       |                                      |
|---------------------------------------|--------------------------------------|
| <input type="button" value="Update"/> | <input type="button" value="Reset"/> |
|---------------------------------------|--------------------------------------|

Change your personal info in profile page

## 7.2. Forgot Password Handling

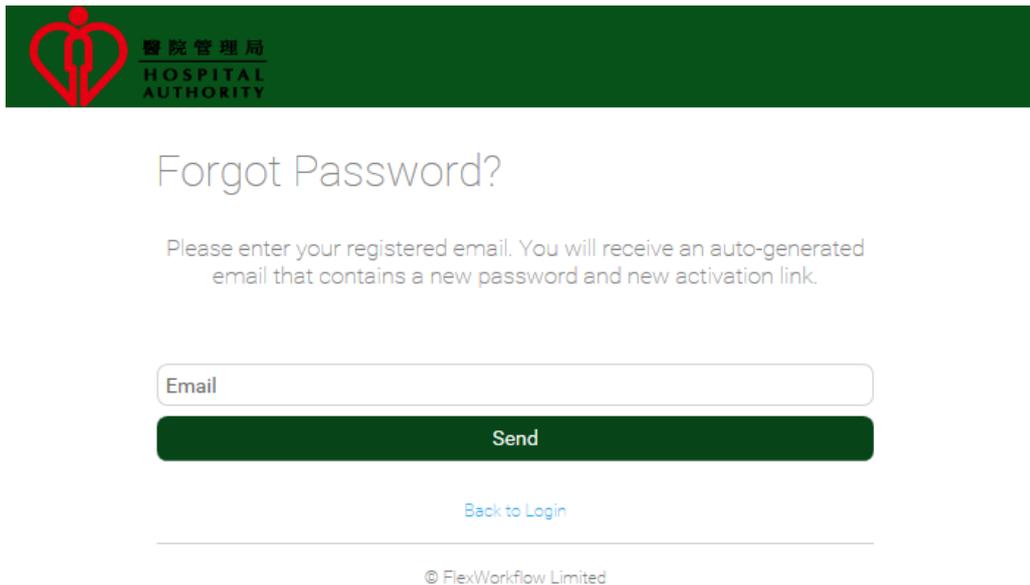
If you have forgotten your password, you can follow the steps below to regain access to the account.

1. Click **[Forgot Password]** to proceed



The screenshot shows the Hospital Authority login interface. At the top left is a partial image of a doctor in a white coat with a blue stethoscope. The main area is a green background with a white header containing the Hospital Authority logo and name in Chinese and English. Below the header are input fields for Email (containing 'app01.hkec@gmail.com'), Password, and Role (set to 'Applicant'). There is a checked checkbox for 'Remember User Name' and a 'Forgot Password' button highlighted with a red box. Below these is a 'Log In' button and a 'Resend Account Activation' link. A yellow text box contains the following text: 'Welcome to the Hospital Authority Clinical Research Ethics Review Portal. The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong (CUHK) and The University of Hong Kong (HKU) to submit the Application of Clinical Research Ethics Review. Applicant can use his/her valid HA, CUHK or HKU email address for a one-off registration to the Portal. An activation email will be sent to the Applicant for activating the account. Subsequently, Applicant can submit and manage the Application via the Portal.' At the bottom right, there is a 'Sign Up' link and a copyright notice for FlexWorkflow Limited.

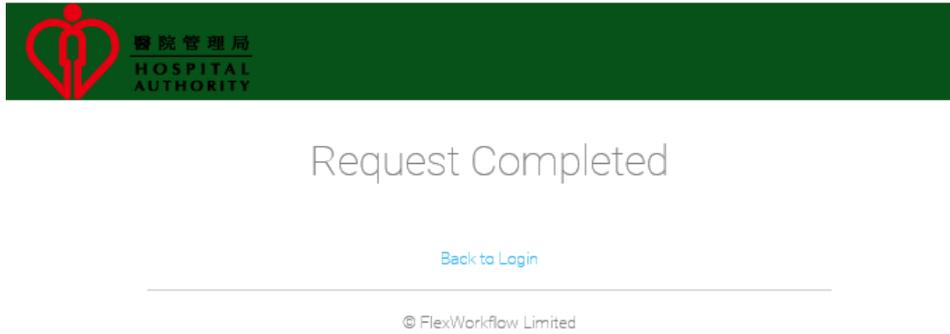
2. Enter your e-mail and then press the **[Send]** button.



The screenshot shows the 'Forgot Password?' page. It features the Hospital Authority logo and name at the top left. The main heading is 'Forgot Password?'. Below it is a text prompt: 'Please enter your registered email. You will receive an auto-generated email that contains a new password and new activation link.' There is an input field for 'Email' and a green 'Send' button. Below the button is a blue link for 'Back to Login'. At the bottom, there is a copyright notice for FlexWorkflow Limited.

Input e-mail to regain access

- 
3. After clicking the “Send” button, the following page “Request Completed” can be seen.



Page shown after submitting request

4. You should receive an e-mail that contains a new password and a new activation link. Please login the account using the new password.

## 8. Search Application

### 8.1. Search of Application by Status

By clicking at the function menu **[Application]**, you can perform any action to handle your application. You can find your application **by status** from each folder. If you want to search the application by filter, please refer to Section 8.2 Search of Application by Filter.

Application operation

| Option          | Function   |
|-----------------|--|
| <b>New</b>      | Trigger a new application. Please refer to Section 5.1 Creation of New Application   |
| <b>Draft</b>    | Fill in the necessary information on the application form. Please refer to Section 5.1.2 Fill in Application Form  |
| <b>Sent</b>     | Submitted application with the following status can be found here. <ul style="list-style-type: none"> <li>- Submitted</li> <li>- Re-submitted</li> <li>- Confirmed</li> <li>- For Review</li> <li>- Reviewed</li> </ul> Please refer to Section 5.1.2 Fill in Application Form |
| <b>Returned</b> | Any returned application from the Secretary can be found here.<br>Their statuses could be: <ul style="list-style-type: none"> <li>- Returned</li> </ul>  |

|                  |  |
|------------------|--|
|                  | <p>(Please refer to Section 5.1.4 Returned Initial Application and Resubmit Initial Application)</p> <ul style="list-style-type: none"> <li>- Approved with Comment</li> <li>- Pending for Comment</li> </ul> <p>(Please refer to Section 5.1.8 Returned Initial Application after Review)</p> |
| <b>Approved</b>  | Approved applications are listed here. Please refer to Section 5.1.9 Approved Initial Application after Review.  |
| <b>Completed</b> | Completed applications are listed here.  |
| <b>Withdrawn</b> | <p>Application with the following statuses can be found here:</p> <ul style="list-style-type: none"> <li>- Withdrawn</li> <li>- Deleted</li> <li>- Terminated.</li> </ul>  |
| <b>All</b>       | Every application carried out by the user can be found here.   |

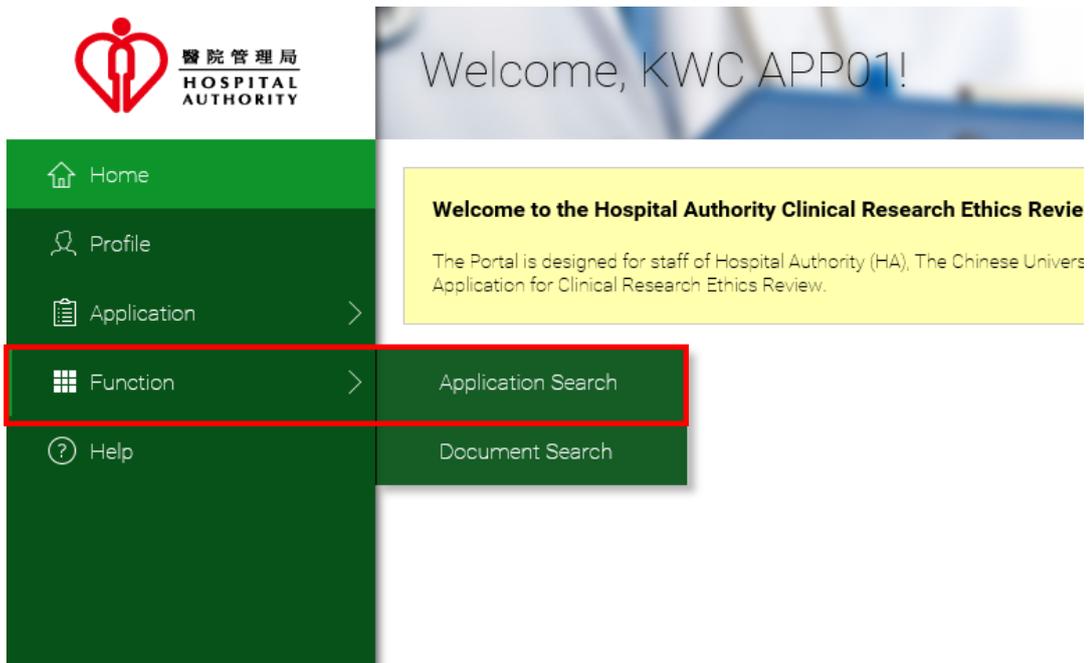
## 8.2. Search of Application by Filter

Instead of searching by status, you can also search your application **by filter**.

### 8.2.1. Application Search

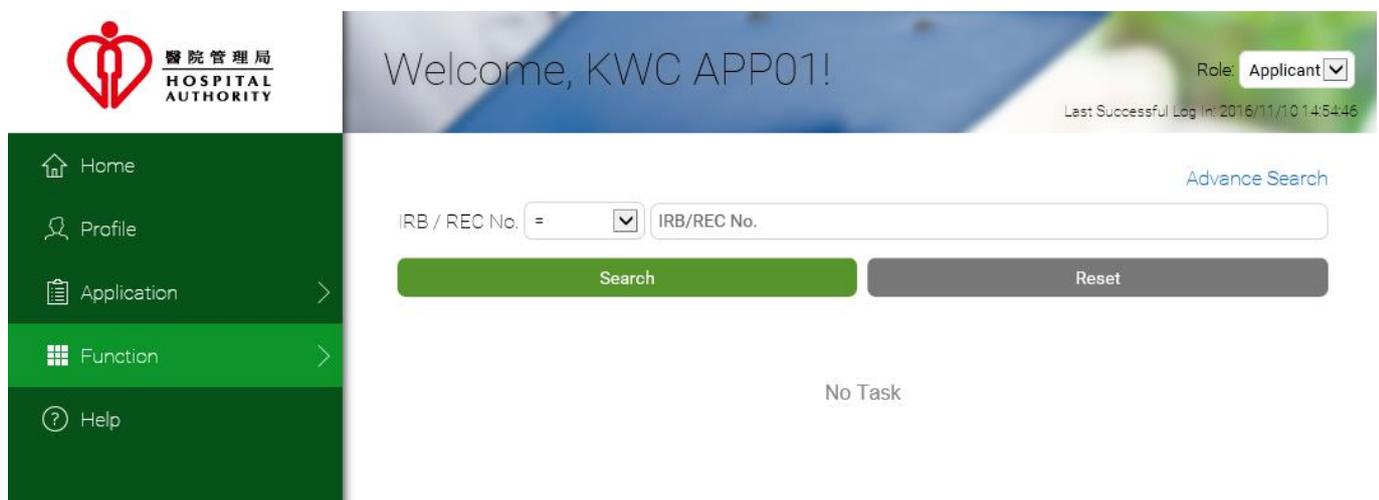
Please follow below steps:

1. Go to **[Function]** ->**[Application Search]**;



Application Search

2. A searching criterion for the “**IRB / REC No.**” should appear;
3. Input the number based on “**=**” or “**LIKE**”;
4. Click the **[Search]** button to perform searching.



5. Apart from using “IRB / REC No.”, you may also use other provided criteria for searching. Click **[Advanced Search]**

The screenshot shows the Hospital Authority system interface. On the left is a green sidebar with navigation options: Home, Profile, Application, Function (highlighted), and Help. The main content area has a header with the Hospital Authority logo and the text "Welcome, KWC APP01!". In the top right corner, there is a "Role: Applicant" dropdown and "Last Successful Log In: 2016/11/10 14:54:46". Below the header is a search form with a dropdown menu set to "=", a text input field containing "IRB/REC No.", and a green "Search" button. A red arrow points to a blue "Advance Search" link in the top right corner. Below the search form, the text "No Task" is displayed.

6. In the provided criteria, input the value that you need. The criteria are joined by the “AND” operator for searching.

If a criterion is left empty, that criterion is ignored in the search process.

Click the [Search] button.

The screenshot shows the Hospital Authority system interface with the "Basic Search" form. The sidebar is the same as in the previous screenshot. The main content area has the same header. Below the header, there is a "Basic Search" link in the top right corner. The search form contains several criteria, each with a dropdown menu set to "=", a text input field, and a dropdown menu set to "=":

- IRB / REC No. = [dropdown] IRB/REC No.
- Task Name = [dropdown] Task Scientific Title = [dropdown] Scientific Title
- Submission Ref. No. = [dropdown] Submission Ref. No. Applying Sites = [dropdown] Applying Sites
- PI = [dropdown] PI PI Hospital = [dropdown] PI Hospital
- PI University = [dropdown] PI University Review Type = [dropdown] Review Type
- Approval Expiry Date <= [dropdown] Approval Expiry Date From

At the bottom of the form are a green "Search" button and a grey "Reset" button.

7. After searching, the search results are displayed.

You can check the checkbox of the record and then click the **[Export to XLS]** button.

Note that only “Initial Application Approval” and “Submit Amendment Application Form” tasks can be exported to XLS.

The screenshot displays the Hospital Authority system interface. On the left is a green sidebar with navigation options: Home, Profile, Application, Function, Help, and Logout. The main content area shows a search form with various filters and a table of results. A red box highlights the 'Export to XLS' button above the table. The table has columns for IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Status, and Action(s). Two records are visible, both with checkboxes in the IRB / REC No. column.

Logo: 醫院管理局 HOSPITAL AUTHORITY

Welcome, KWC APP01! Role: Applicant

Last Successful Log in: 2016/11/10 14:54

Search filters:

- Task Name = Task Scientific Title = Scientific Title
- Submission Ref. No. = Submission Ref. No. Applying Sites = Applying Sites
- PI = PI PI Hospital = PI Hospital
- PI University = PI University Review Type = Review Type
- Approval Expiry Date <= Approval Expiry Date From

Buttons: Search, Reset

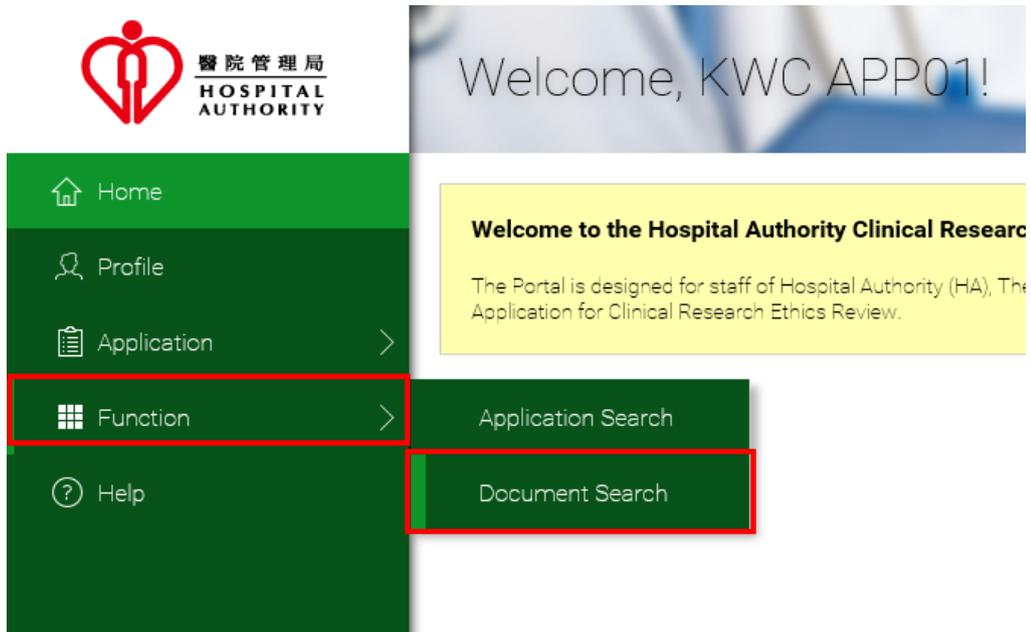
Export to XLS

| IRB / REC No.                       | Submission Ref. No. | Date             | Task                         | Scientific Title   | PI              | PI Hospital | PI University | Status   | Action(s)   |
|-------------------------------------|---------------------|------------------|------------------------------|--|-----------------|-------------|---------------|----------|-------------|
| <input checked="" type="checkbox"/> |                     | 2016/11/10 11:00 | Initial Application Approval | this is an sampe   |                 |             |               | Draft    | Export More |
| <input checked="" type="checkbox"/> | KWC-2016-0004       | 2016/11/08 20:26 | Initial Application Approval | The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial | Dr CHAN Tai Man | PYNEH       |               | Reviewed | Export More |

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## 8.2.2. Document Search

1. Go to [Function] ->[Document Search];



Search your document with different criteria

2. In the provided criteria, input the value that you need. The “Like” search is used, i.e. search item with criteria that contain the filled value.

The criteria are joined by the “AND” operator for searching.

If a criterion is left empty, that criterion is ignored in the search process.

3. Click [Submit] to search.

The screenshot shows the search interface of the Hospital Authority Clinical Research Portal. The navigation sidebar is on the left, with the 'Function' menu item highlighted. The main content area displays the search form. At the top right, the user is identified as 'KWC APP01!' with a role of 'Applicant' and a last successful log in of '2016/11/10 14:54:46'. The search form includes the following fields: 'IRB / REC No.' (with a value of 'IRB/REC No.'), 'Document Type' (with a value of 'Document Type'), 'Document Name' (with a value of 'Document Name'), 'Suggested Print Name' (with a value of 'Suggested Print Name'), and 'Tag' (with a value of 'Tag'). There is a checkbox for 'Attachment within 1 year' which is currently unchecked. Below the form are two buttons: a green 'Search' button and a grey 'Reset' button. A 'Download' button is also visible. The text 'No Document' is displayed at the bottom of the search results area.

| <b>Criteria</b>          | <b>Description</b>   |
|--------------------------|--|
| IRB / REC No.            | Search documents with this IRB / REC No.   |
| Document Type            | <p>Search documents with this Document Type. Support the following Document Type:</p> <ul style="list-style-type: none"> <li>▪ Meeting Minutes</li> <li>▪ Research Protocol</li> <li>▪ Subject Informed Consent Form</li> <li>▪ Investigator's Brochure</li> <li>▪ Written Information for Subject</li> <li>▪ Questionnaire</li> <li>▪ Certificate for Clinical Trial Test Attachment Table</li> <li>▪ Conflict of Interest Declaration by all Investigators</li> <li>▪ Indemnity Agreement</li> <li>▪ Clinical Trial Insurance Certificate</li> <li>▪ Other Documents</li> <li>▪ Supporting document from academia</li> <li>▪ Curriculum Vitae (CV) from Principal Investigator</li> <li>▪ Curriculum Vitae (CV) from other investigates</li> <li>▪ REC/IRB decision document</li> <li>▪ Other Funding Sources</li> </ul> |
| Document Name            | Search documents with this Document Name.  |
| Suggested Print Name     | Search documents with this Suggested Print Name.   |
| Tag                      | Search Meeting Minutes with this Tag value.  |
| Attachment within 1 year | Search documents within 1 year.  |

4. After searching, the search results are displayed.

You can check the checkbox of the document and then click the **[Download]** button to download the documents.

The screenshot shows the Hospital Authority system interface. On the left is a green sidebar with navigation options: Home, Profile, Application, Function, and Help. The main content area displays a search form with fields for IRB / REC No., Document Type, Document Name, Suggested Print Name, and Tag. A checkbox for 'Attachment within 1 year' is present. Below the form are 'Search' and 'Reset' buttons. A table of search results is shown below, with a 'Download' button highlighted in a red box above it. The table has columns for Name, Size, and Last Modified Date. Several rows have checkboxes checked, indicating they are selected for download.

|                                     | Name  | Size      | Last Modified Date  |
|-------------------------------------|---|-----------|---------------------|
| <input checked="" type="checkbox"/> | _WON-20161101-0122_20161101 - Copy (4).pdf        | 484.17 KB | 2016-11-02 09:23:09 |
| <input checked="" type="checkbox"/> | _WON-20161101-0122_20161101 - Copy - Copy (7).pdf | 484.17 KB | 2016-11-02 00:32:07 |
| <input type="checkbox"/>            | filling draft - Copy (7) - Copy.pdf               | 37.17 MB  | 2016-11-01 22:29:40 |
| <input checked="" type="checkbox"/> | Testing Document.pdf                              | 90.02 KB  | 2016-11-03 09:18:12 |
| <input checked="" type="checkbox"/> | _WON-20161101-0122_20161101 - Copy (10).pdf       | 484.17 KB | 2016-11-02 09:22:46 |

## 9. Summary of Status

### Initial Application Approval

| Status                | Description   | Found In                    |
|-----------------------|---|-----------------------------|
| Draft                 | The application is not yet submitted to secretary by applicant.                     | [Application] > [Draft]     |
| Submitted             | The application is submitted to secretary by applicant.                             | [Application] > [Sent]      |
| Re-submitted          | The application has been returned and re-submitted to secretary again by applicant. | [Application] > [Sent]      |
| Confirmed             | The application is confirmed by secretary.  | [Application] > [Sent]      |
| For Review            | The application is assigned to reviewer for review by secretary.                    | [Application] > [Sent]      |
| Reviewed              | The application has been reviewed by reviewer.                                      | [Application] > [Sent]      |
| Approved              | The application is approved by secretary.   | [Application] > [Approved]  |
| Returned              | The application is returned by secretary.   | [Application] > [Returned]  |
| Approved with Comment | The application is returned by secretary.   | [Application] > [Returned]  |
| Pending for Comment   | The application is returned by secretary.   | [Application] > [Returned]  |
| Deleted               | The application in "Draft" status is deleted by applicant.                          | [Application] > [Withdrawn] |
| Withdrawn             | The application has been returned and withdrawn by applicant.                       | [Application] > [Withdrawn] |
| Terminated            | The application in "Approved" status is terminated by secretary.                    | [Application] > [Withdrawn] |
| Closed                | The returned application is not re-submitted before the expiry date.                | [Application] > [Withdrawn] |

### Submit Amendment Application Form

| Status                | Description   | Found In                    |
|-----------------------|---|-----------------------------|
| Submitted             | The application is submitted to secretary by applicant.                             | [Application] > [Sent]      |
| Re-submitted          | The application has been returned and re-submitted to secretary again by applicant. | [Application] > [Sent]      |
| Confirmed             | The application is confirmed by secretary.  | [Application] > [Sent]      |
| For Review            | The application is assigned to reviewer for review by secretary.                    | [Application] > [Sent]      |
| Reviewed              | The application has been reviewed by reviewer.                                      | [Application] > [Sent]      |
| Approved              | The application is approved by secretary.   | [Application] > [Approved]  |
| Returned              | The application is returned by secretary.   | [Application] > [Returned]  |
| Approved with Comment | The application is returned by secretary.   | [Application] > [Returned]  |
| Pending for Comment   | The application is returned by secretary.   | [Application] > [Returned]  |
| Withdrawn             | The application has been returned and withdrawn by applicant.                       | [Application] > [Withdrawn] |
| Closed                | The returned application is not re-submitted before the expiry date.                | [Application] > [Withdrawn] |

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**Submit Renewed CTI**

**Submit Renewed CTC**

**Submit Protocol Deviation Form**

**Upload SUSAR Report**

**Upload SAE Report**

**Upload Final Report**

**Upload Progress Report**

| <b>Status</b>         | <b>Description</b>  | <b>Found In</b>             |
|-----------------------|---|-----------------------------|
| Submitted             | The application is submitted to secretary by applicant.                             | [Application] > [Sent]      |
| Re-submitted          | The application has been returned and re-submitted to secretary again by applicant. | [Application] > [Sent]      |
| Confirmed             | The application is confirmed by secretary.  | [Application] > [Sent]      |
| For Review            | The application is assigned to reviewer for review by secretary.                    | [Application] > [Sent]      |
| Reviewed              | The application has been reviewed by reviewer.                                      | [Application] > [Sent]      |
| Approved              | The application is approved by secretary.   | [Application] > [Approved]  |
| Returned              | The application is returned by secretary.   | [Application] > [Returned]  |
| Approved with Comment | The application is returned by secretary.   | [Application] > [Returned]  |
| Pending for Comment   | The application is returned by secretary.   | [Application] > [Returned]  |
| Withdrawn             | The application has been returned and withdrawn by applicant.                       | [Application] > [Withdrawn] |
| Closed                | The returned application is not re-submitted before the expiry date.                | [Application] > [Withdrawn] |