

Hospital Authority CRER Portal User Manual for Reviewer

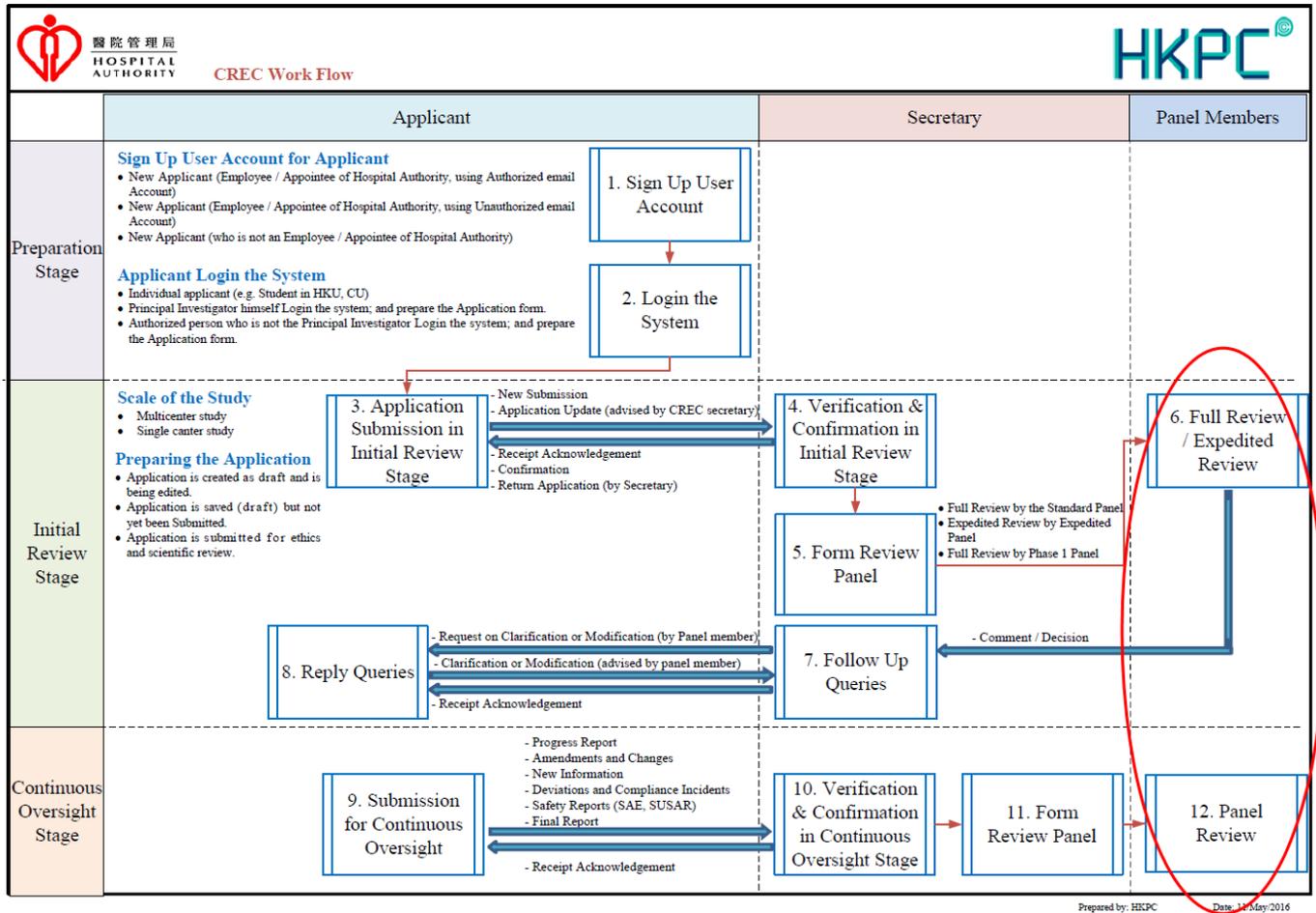
Date: December 14, 2016

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1. Introduction

This user guide is to provide guidance for Reviewer 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.

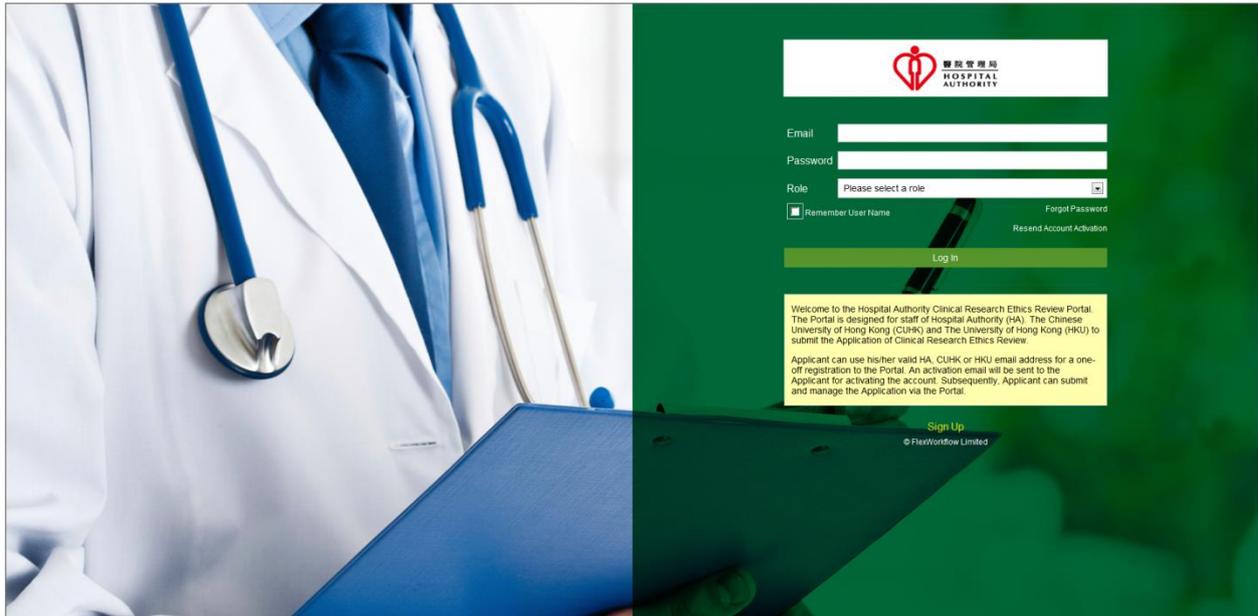


Prepared by: HKPC Date: 11 May 2016

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. Login the Portal

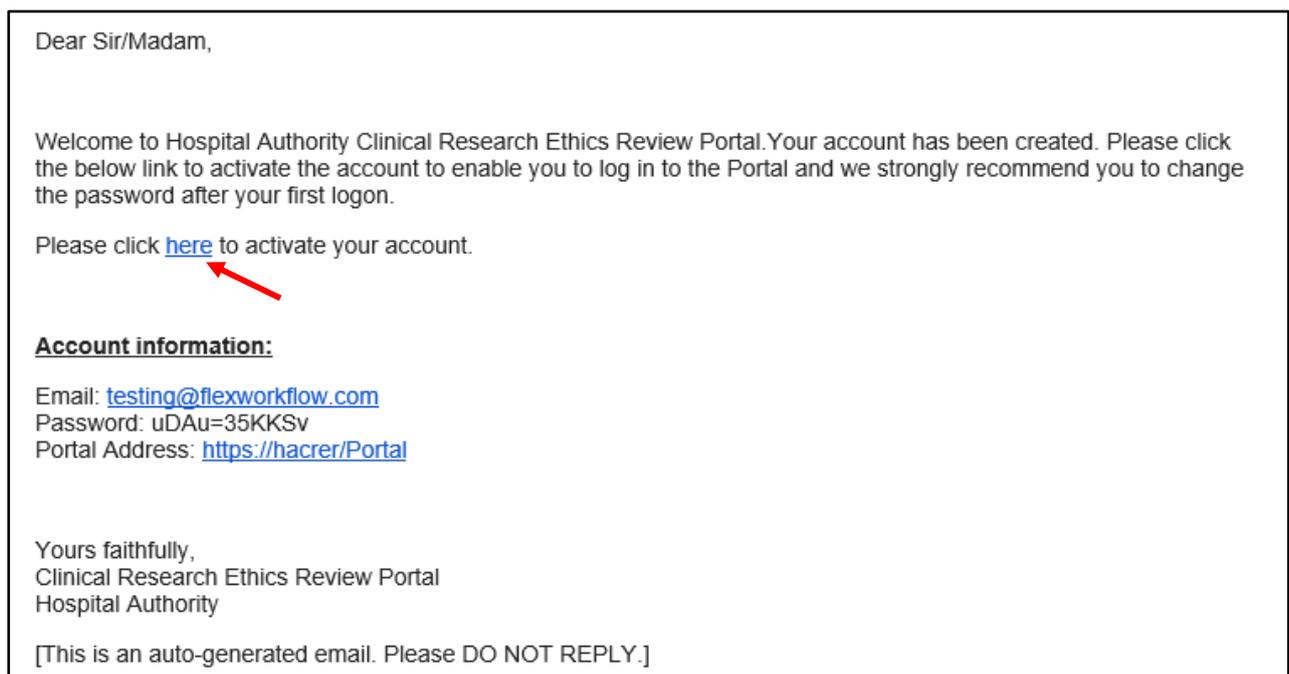
Hospital Authority Clinical Research Ethics Review Portal (HACRER Portal) requires you to input **your email address and password** to login as shown above.

If you **do not have** any account on the portal, please contact your cluster secretary for a new account.

If you **have** an account, please make sure you have activated your user account. Please refer to Section 3.1 Activate User Account and Section 3.2 Login for procedures on account activation and login.

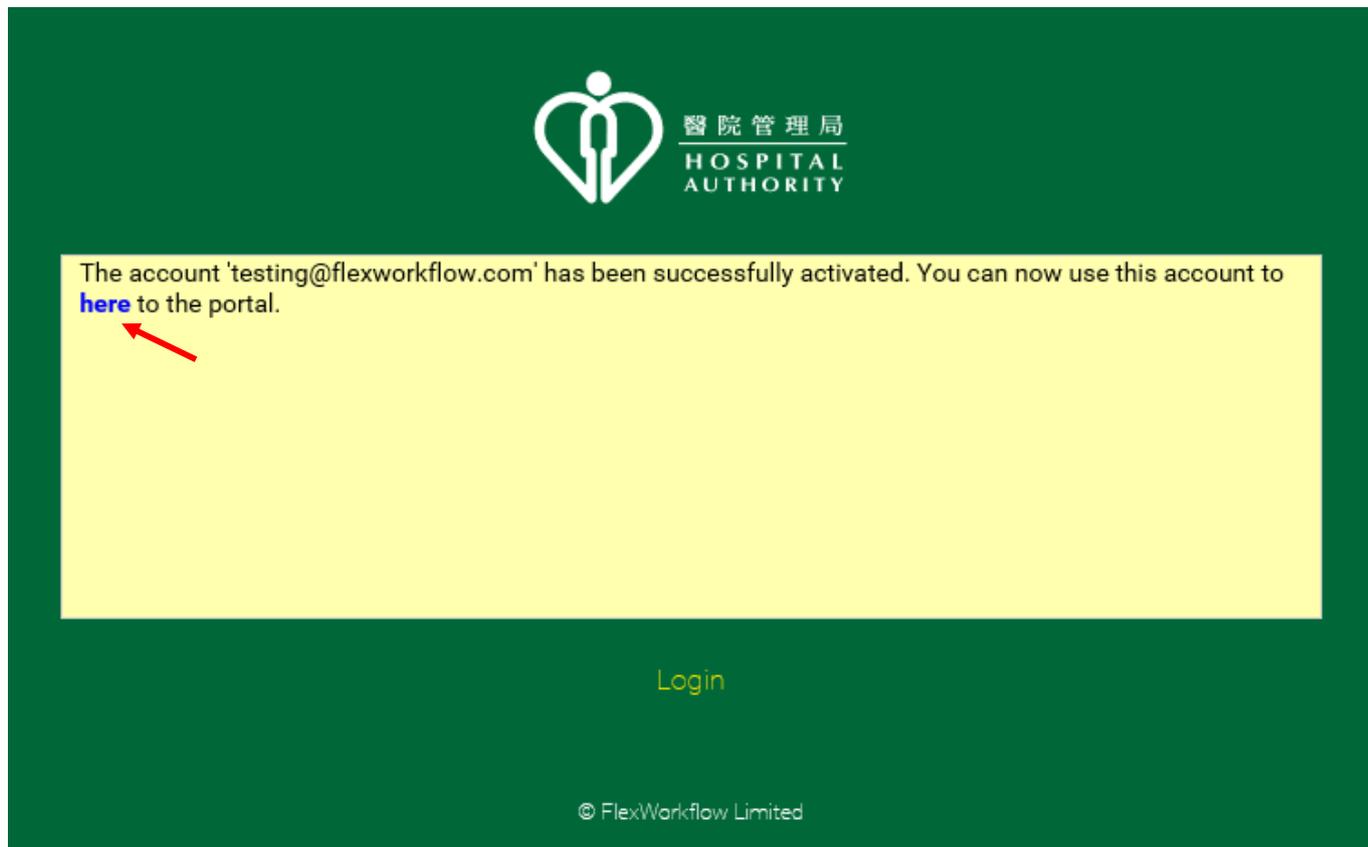
3.1. Activate User Account

1. You will receive an auto-generated email **after the creation of your account by the cluster secretary**. Please do as below:
 - 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 login without activation*)



Confirmation email after registration

2. After clicking the activation link, you will be directed to the following page if account activation is successful.
3. Click the "[here](#)" link to go to the login page.



Page showing successful activation

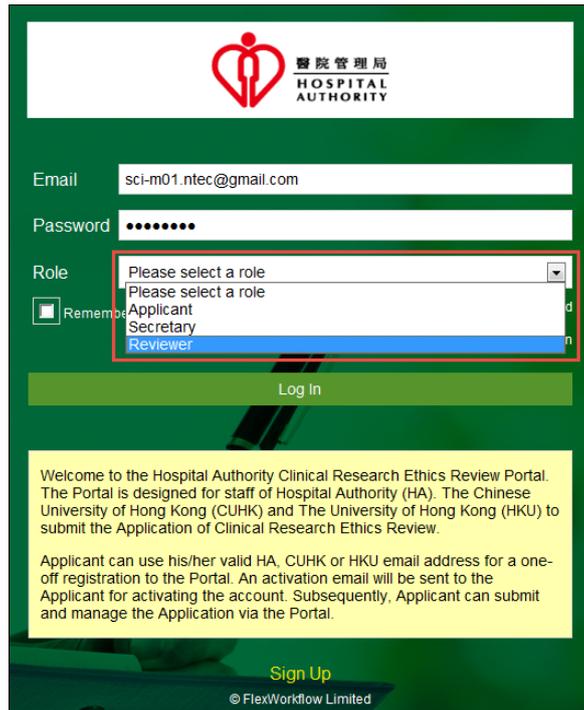
You have now completed the account registration. Please refer to Section 3.2 Login to log into the portal.

3.2. Login

Now you can log into the system if account registration and activation are completed successfully. If you have forgotten your password, please refer to Section 9.2 Forgot Password Handling.

Please follow below steps:

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



醫務管理局
HOSPITAL
AUTHORITY

Email sci-m01.ntec@gmail.com

Password

Role Please select a role
Please select a role
Applicant
Secretary
Reviewer

Remember Me

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.

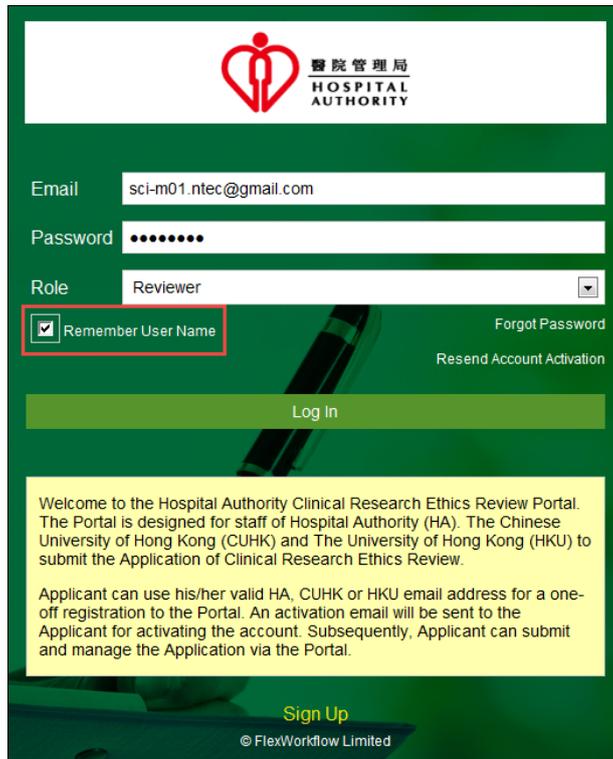
Applicant can use his/her valid HA, CUHK or HKU email address for a one-off registration to the Portal. An activation email will be sent to the Applicant for activating the account. Subsequently, Applicant can submit and manage the Application via the Portal.

Sign Up

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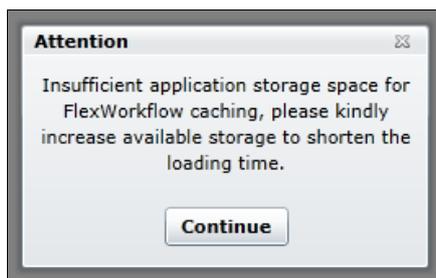
Select your role

In the login page, there is an option “**Remember User Name**” which allows you to save your user name in the login page.



Check the “Remember User Name” box

You may see the following dialog if you create or open an application for the first time. Click the [**Continue**] button followed by the [**Yes**] button to proceed.



Prompted dialog

4. Introduction of Reviewer's Home Page


Role: Reviewer Last Successful Log In: 2016/11/14 14:42:02

Welcome, NTEC SCI M01!

Home Refresh

IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Status	Action(s)
20161115	NTEC-2016-1315	2016/11/14 14:44	Upload SAE Report(Review)	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	Export
20161114	NTEC-2016-1316	2016/11/14 14:40	Initial Application Approval (Review)	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		For Review	Export

[Home](#)
[Profile](#)
[For Review](#)
[Help](#)
[Logout](#)
© FlexWorkflow Limited

User name is shown at the top of welcome page

Function Menu	Description
Home	Display every received application.
Profile	Profile page of the login user. Please refer to Section 9 Maintain User Profile for more information.
For Review	You can filter the applications to review based on cluster.
Help	Useful tips and reminders about the portal.
Logout	Allows you to log out from the current user account.
Role	Allows you to swap your roles quickly. <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** or change the role at the top right corner of the portal.



The screenshot shows the user interface of the HACRER Portal. On the left is a dark green vertical sidebar with the Hospital Authority logo (聖局 TAL CITY) and two white chevron arrows pointing right. The main content area has a blue header with the text "Welcome, SIU MING CHAN!". To the right of the header, it displays "Role: Applicant Reviewer" and "Last Successful Log In: 0001/01/01 00:00:00". Below the header is a yellow box with the following text:

Welcome to the Hospital Authority Clinical Research Ethics Review Portal.

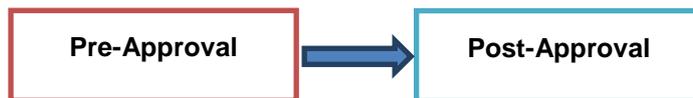
The Portal is designed for staff of Hospital Authority (HA), The Chinese University of Hong Kong (CUHK) and The University of Hong Kong (HKU) to submit the Application for Clinical Research Ethics Review.

5. Workflow Introduction

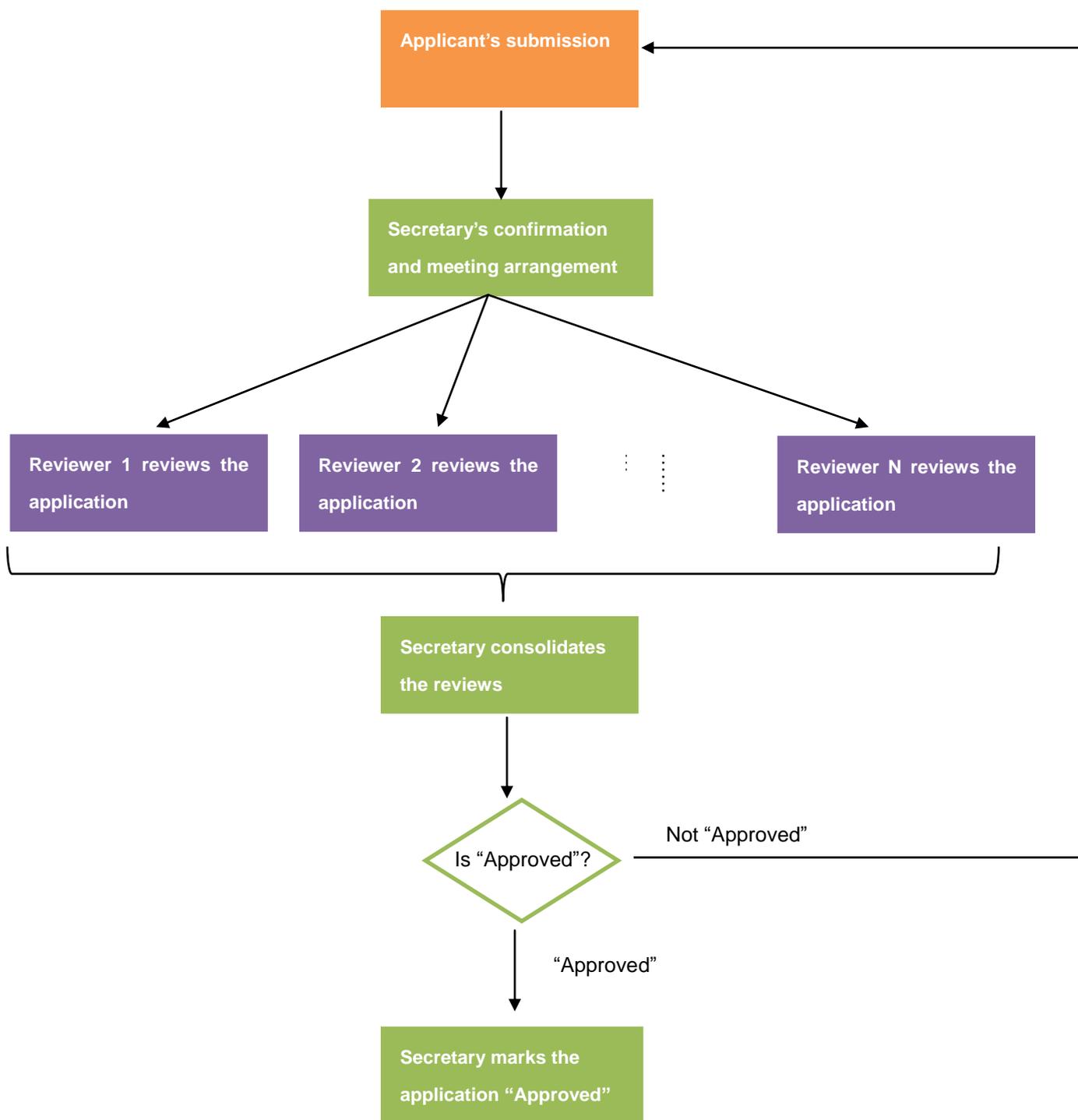
The Hospital Authority Clinical Research Ethics Review consists of two main parts:

- **Initial Application Approval (Pre-Approval)**
- **Report Review (Post-Approval)**

Report Review can be started only when the Initial Application Approval in the Pre-Approval stage is “Approved”. Once it is approved, applicant will upload reports for review and begin the Post-Approval stage of the application.



For Pre-Approval, the workflow looks like this:

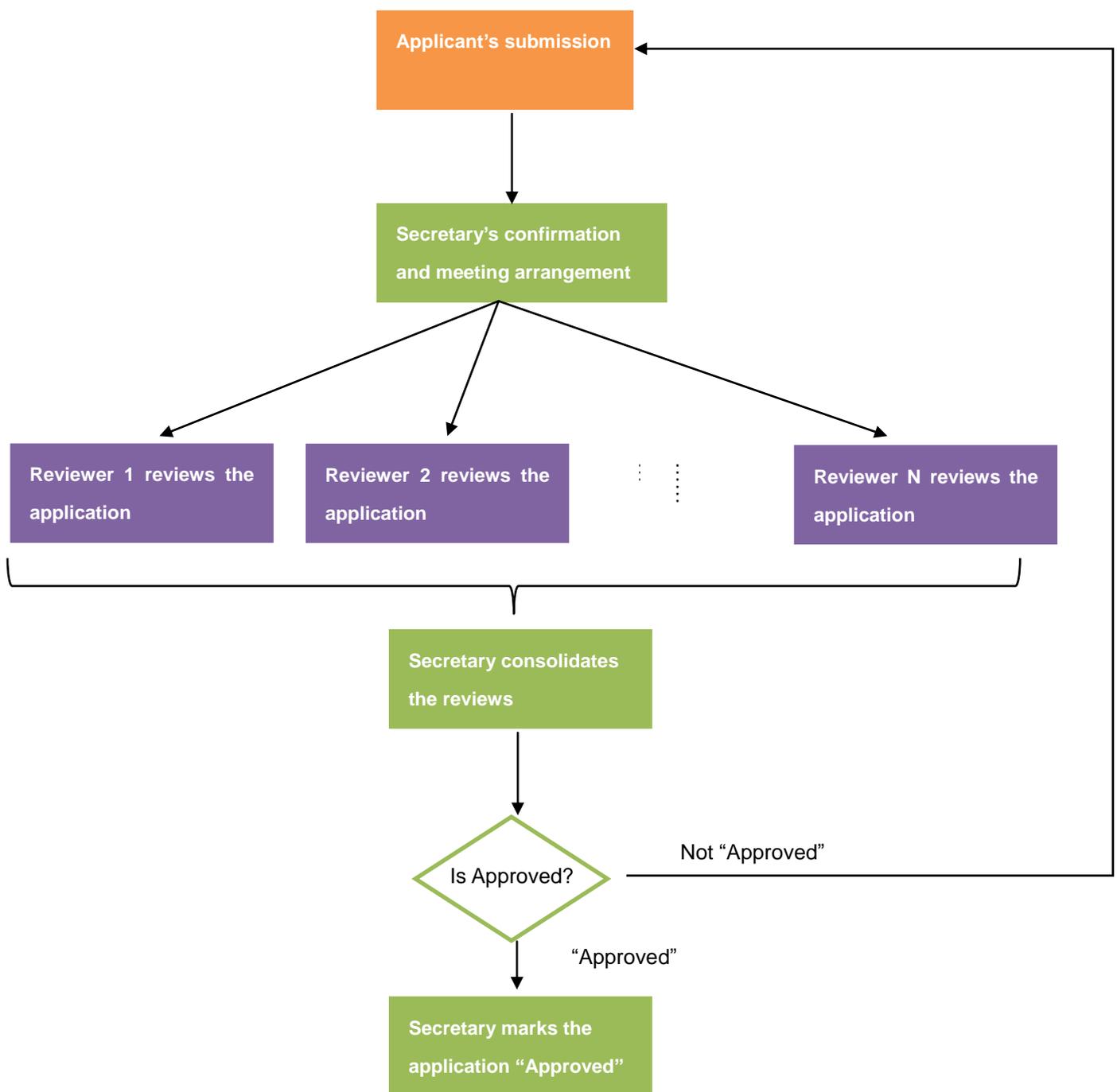


Once the application is confirmed by Secretary, the application will be passed to reviewer(s) for review. Once reviewers have finished reviewing, secretary will consolidate the reviews and mark whether the application is approved. If it is not approved, secretary will return the application to the applicant for resubmission.

Once the Pre-Approval stage is over, the applicant will submit reports. This is called the **Post-Approval** stage. In Post-Approval, seven types of report review applications could be submitted:

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

For each type of report review application, the workflow also looks like this:



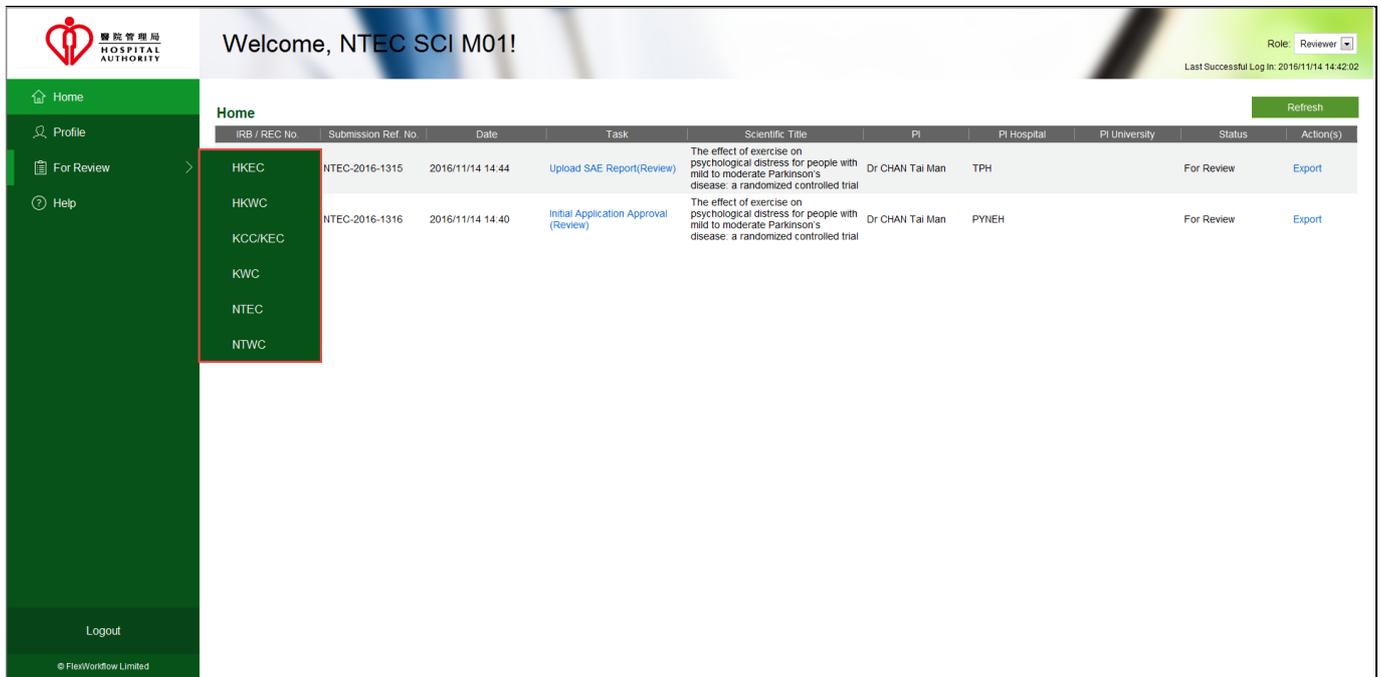
Once the **"Final Report"** is approved, the entire Hospital Authority Clinical Research Ethics Review will be "Completed":

6. Initial Application Approval Review (Pre-Approval)

As a reviewer, you may receive an e-mail notification if there is a new application pending for your approval.

You may be appointed by multiple clusters. Outstanding items of each cluster that require you to review will be shown in the corresponding cluster page.

- Choose application under the corresponding cluster;



The screenshot displays the Hospital Authority system interface. At the top left is the Hospital Authority logo. The main header shows 'Welcome, NTEC SCI M01!' and the user's role as 'Reviewer'. A 'Last Successful Log In' timestamp is also visible. On the left, a green sidebar menu contains options: Home, Profile, For Review (selected), Help, and Logout. A sub-menu for 'For Review' is open, listing clusters: HKEC, HKWC, KCC/KEC, KWC, NTEC, and NTWC. The main content area shows a table of pending applications under the 'Home' tab. 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 applications are listed, both with a status of 'For Review' and an 'Export' action.

IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Status	Action(s)
	NTEC-2016-1315	2016/11/14 14:44	Upload SAE Report(Review)	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	Export
	NTEC-2016-1316	2016/11/14 14:40	Initial Application Approval (Review)	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		For Review	Export

Select **[For Review]** -> **Cluster** on menu

- The application will not be shown on the task list after it is submitted or approved.

6.1. Email Notification

As a reviewer, you may receive an e-mail as notification if there is any application is pending for your review. Below is the email template:

Subject: Review of Clinical Research Ethics Application

Dear Reviewer(s),

Please review and approve the following application:

Scientific Title: %StudyTitleFull%

Principal Investigator: %PIName%

Department / School: %PIHaDepartment% %PIUniDepartment%

Hospital/ University: %PIHaHospital% %PIUniUniversity%

Portal Address: <http://cre.home>

Yours faithfully,

%ClusterName% Cluster REC/IRB

You may ignore this request if you have already submitted the required printed copied of the application dossier

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

6.2. View Application Details

1. Go to **[For Review]** and select your cluster.

The screenshot shows the Hospital Authority system interface. The top left features the Hospital Authority logo and name. A navigation sidebar on the left includes 'Home', 'Profile', 'For Review', and 'Help'. The 'For Review' menu item is highlighted with a red box, and its sub-menu is also highlighted with a red box, listing clusters: HKEC, HKWC, KCC/KEC, KWC, NTEC, and NTWC. The main content area displays a welcome message 'Welcome, Peter Chan!' and a yellow box with instructions on how to create a new application and perform post-approval activities.

2. In the “Task” column, click “Initial Application Approval (Review)” to open the application to review.

The screenshot shows the application review table. The table has columns for IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Review Due Date, and Action(s). The 'Task' column contains the text 'Initial Application Approval (Review)', which is highlighted with a red box. The 'Action(s)' column contains an 'Export' link. The table is titled 'NTEC' and includes a 'Refresh' button.

IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Review Due Date	Action(s)
	NTEC-2016-1319	2016/11/18 01:29	Initial Application Approval (Review)	(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		01/12/2016	Export

Open the application to review

3. At the bottom, you can click the tabs to view their content.

Welcome, Peter Chan! Role: Reviewer

Submission Reference No.(For Office Use) NTEC-2016-1319
 Status For Review

HOSPITAL AUTHORITY
 Hospital Authority
 Clinical Research Ethics Review Application Form

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

Instructions to applicant

- 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.
- 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. 4x10³ 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.
- 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
- The handling and storage for data containing personal identity must comply with HA Clinical Data Policy Manual and other prevailing HA policies and if applicable university policies.
- Selected information will be passed to the HA's and University's Central Register of Clinical Research for the purpose of central

Instructions | **Part I** | Part II | Part III | Part IV | Part V | Part VI | Clinical Study Categorization Form | Application Log | Document Log | Comment Sheet | Declare Conflict of Interest

Comment Box

4. "Part VI" contains the documents uploaded for the application.

Welcome, Peter Chan! Role: Reviewer

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: 2

Upload Date	Created By	Document Type	File Name	Suggested Print Name	Upload Times
13/11/2016 2:03:26 PM	ntec.app1@gmail.com	Research Protocol	_WON-20161109-0214_20161109.pdf		1
18/11/2016 1:14:58 AM	ntec.app1@gmail.com	Research Protocol	test (2).bit	protocol	1

28. Subject Informed Consent Form* (Mandatory) * Unless waived by Cluster REC
No. of attachments: 0

29. Investigator's Brochure (Supplementary) No. of attachments: 0

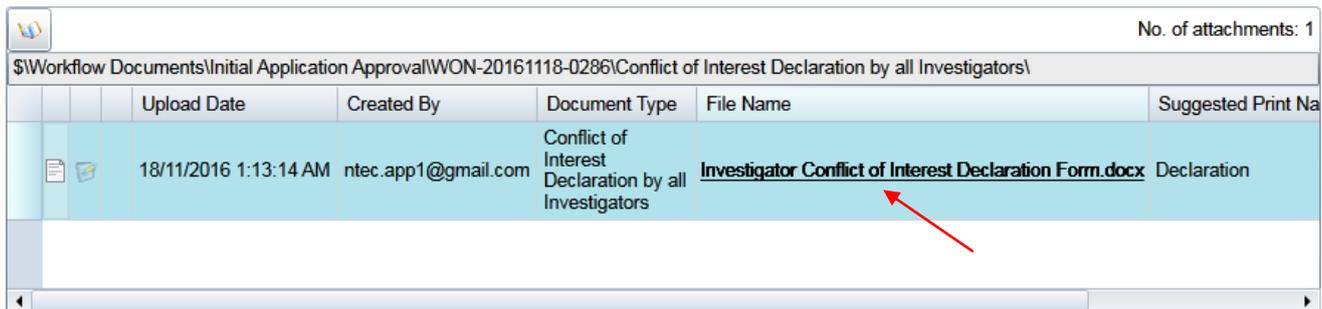
Instructions | Part I | Part II | Part III | Part IV | Part V | **Part VI** | Clinical Study Categorization Form | Application Log | Document Log | Comment Sheet | Declare Conflict of Interest

Comment Box

5. You can download the document to your computer for review.

Click on the document name in the “**File Name**” column to download the file.

33. Conflict of Interest Declaration by all Investigators (Mandatory for sponsored trial)

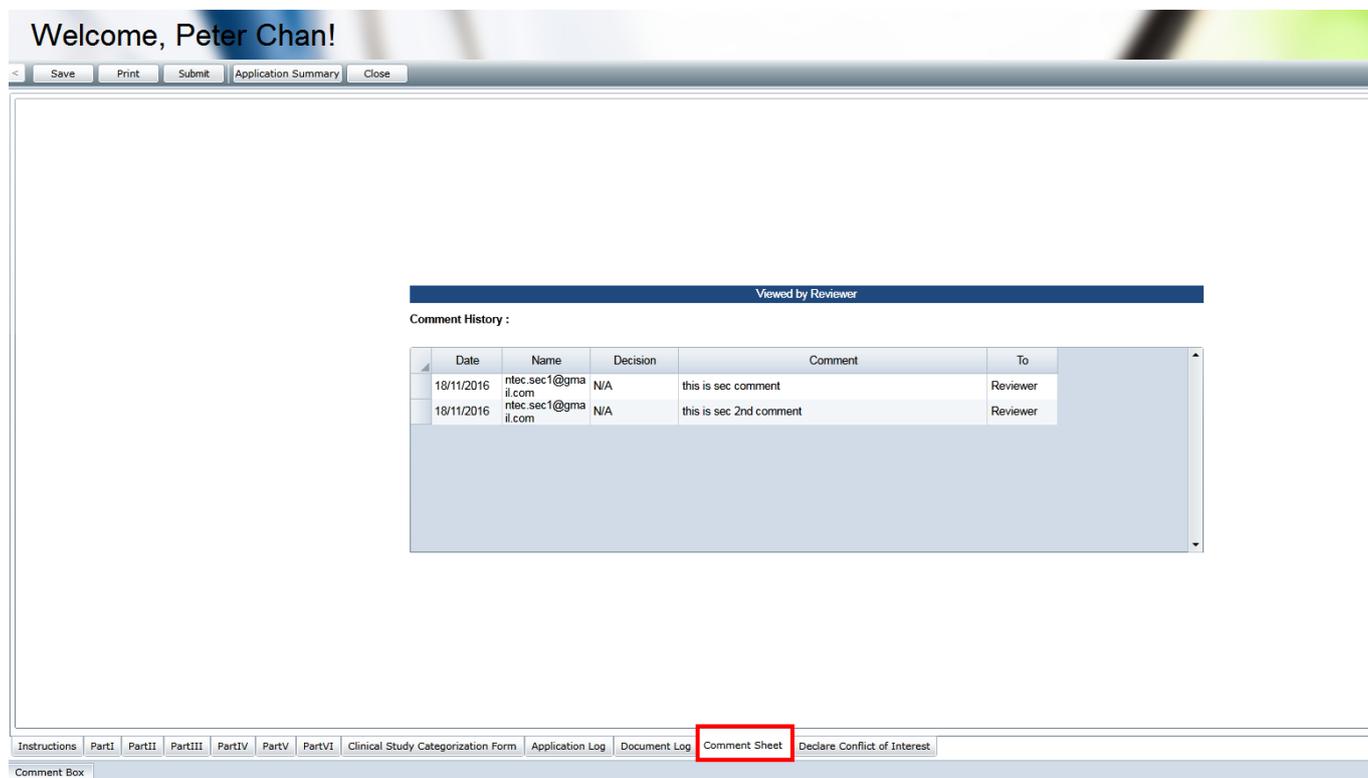


The screenshot shows a table with the following columns: Upload Date, Created By, Document Type, File Name, and Suggested Print Name. The File Name column contains the text "Investigator Conflict of Interest Declaration Form.docx", which is highlighted with a red arrow.

Upload Date	Created By	Document Type	File Name	Suggested Print Name
18/11/2016 1:13:14 AM	ntec.app1@gmail.com	Conflict of Interest Declaration by all Investigators	<u>Investigator Conflict of Interest Declaration Form.docx</u>	Declaration

6. In “**Comment Sheet**”, you can view the comments from the secretary and other reviewers of the same application.

The “Date” and “Name” columns shows you when and who left that comment.



The screenshot shows a web application interface with a navigation bar at the top containing "Save", "Print", "Submit", "Application Summary", and "Close". Below the navigation bar, there is a "Comment History" table with the following columns: Date, Name, Decision, Comment, and To. The table contains two rows of data.

Date	Name	Decision	Comment	To
18/11/2016	ntec.sec1@gmail.com	N/A	this is sec comment	Reviewer
18/11/2016	ntec.sec1@gmail.com	N/A	this is sec 2nd comment	Reviewer

At the bottom of the interface, there is a navigation bar with the following tabs: "Instructions", "PartI", "PartII", "PartIII", "PartIV", "PartV", "PartVI", "Clinical Study Categorization Form", "Application Log", "Document Log", "Comment Sheet", and "Declare Conflict of Interest". The "Comment Sheet" tab is highlighted with a red box.

6.3. Declare Conflict of Interest

Before submitting your review, you have to declare your conflict of interest.

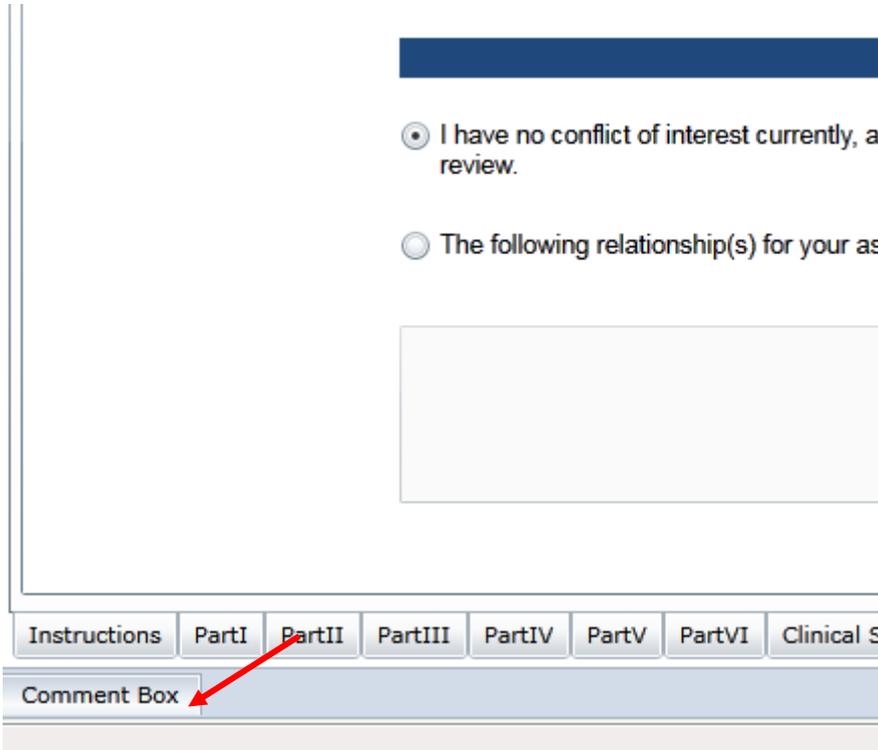
1. Go to the “**Declare Conflict of Interest**” tab page.
2. Declare whether you have conflict of interest or not. Please list the details if you do.

The screenshot shows a web application interface. At the top left, it says "Welcome, Peter Chan!". On the top right, there is a "Role: Reviewer" dropdown menu. Below the header is a navigation bar with buttons for "Save", "Print", "Submit", "Application Summary", and "Close". On the far right of this bar are navigation arrows and a dropdown menu labeled "Declare Conflict of Interest". The main content area has a dark blue header with the text "Declare Conflict of Interest". Below this header are two radio button options: the first is "I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review." and the second is "The following relationship(s) for your assessment of conflict of interest:". Below the second option is a large, empty text input box. At the bottom of the page is a horizontal menu with tabs for "Instructions", "PartI", "PartII", "PartIII", "PartIV", "PartV", "PartVI", "Clinical Study Categorization Form", "Application Log", "Document Log", "Comment Sheet", and "Declare Conflict of Interest". The "Declare Conflict of Interest" tab is highlighted with a red border. Below this menu is a "Comment Box" label.

6.4. Mark Decision and Comment

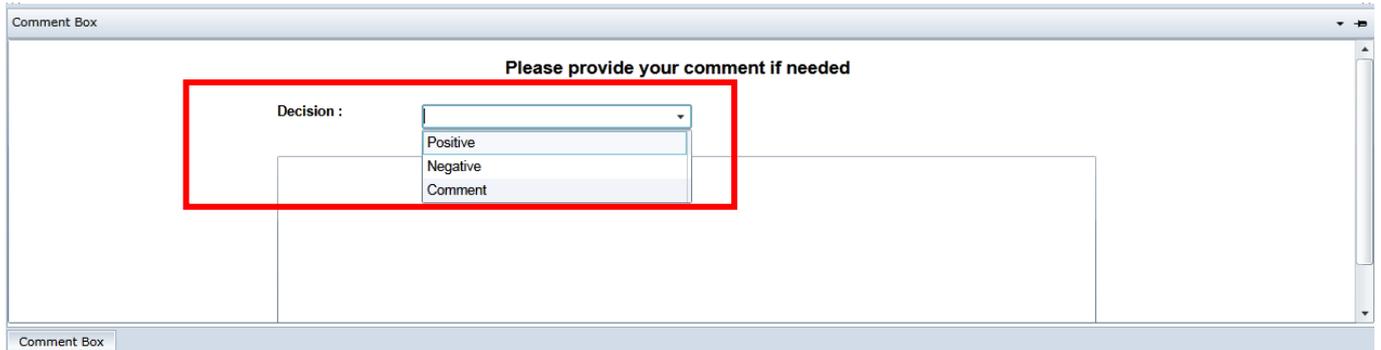
To submit your review, you have to mark your decision and your comments:

1. Move the mouse cursor to the "Comment Box";



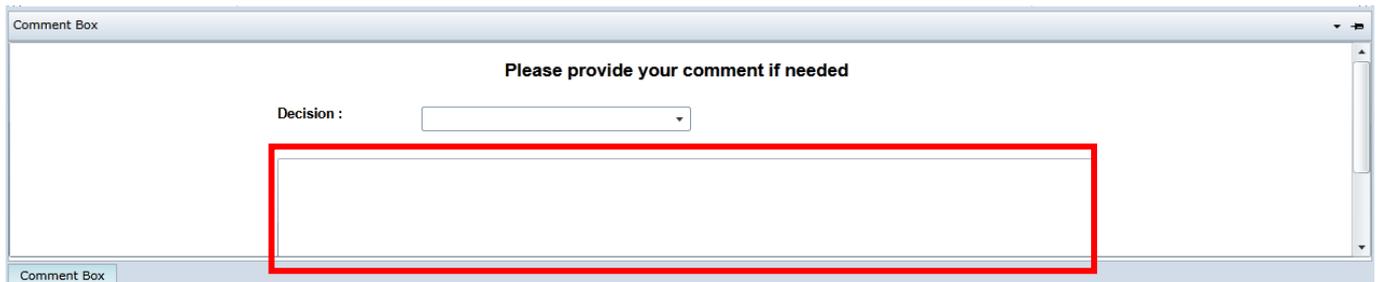
The screenshot shows a web interface with a navigation bar at the bottom containing buttons for 'Instructions', 'PartI', 'PartII', 'PartIII', 'PartIV', 'PartV', 'PartVI', and 'Clinical S'. Below the navigation bar is a 'Comment Box' button, which is highlighted with a red arrow pointing to it from the left.

2. Make your decision as "Positive" or "Negative" or "Comment";



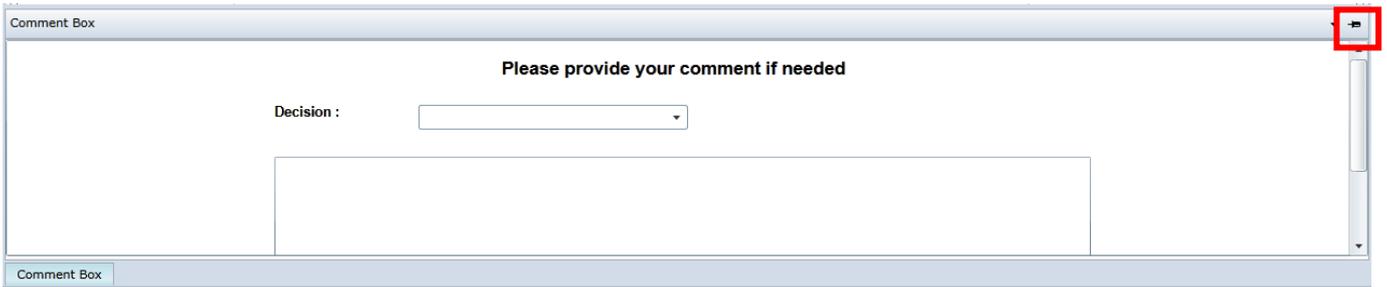
The screenshot shows a window titled 'Comment Box' with the text 'Please provide your comment if needed'. Below this text is a 'Decision :' label followed by a dropdown menu. The dropdown menu is open, showing three options: 'Positive', 'Negative', and 'Comment'. A red box highlights the dropdown menu and its options.

3. Provide your comments in the following area:



The screenshot shows a window titled 'Comment Box' with the text 'Please provide your comment if needed'. Below this text is a 'Decision :' label followed by a dropdown menu. Below the dropdown menu is a large text area for providing comments. A red box highlights this text area.

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



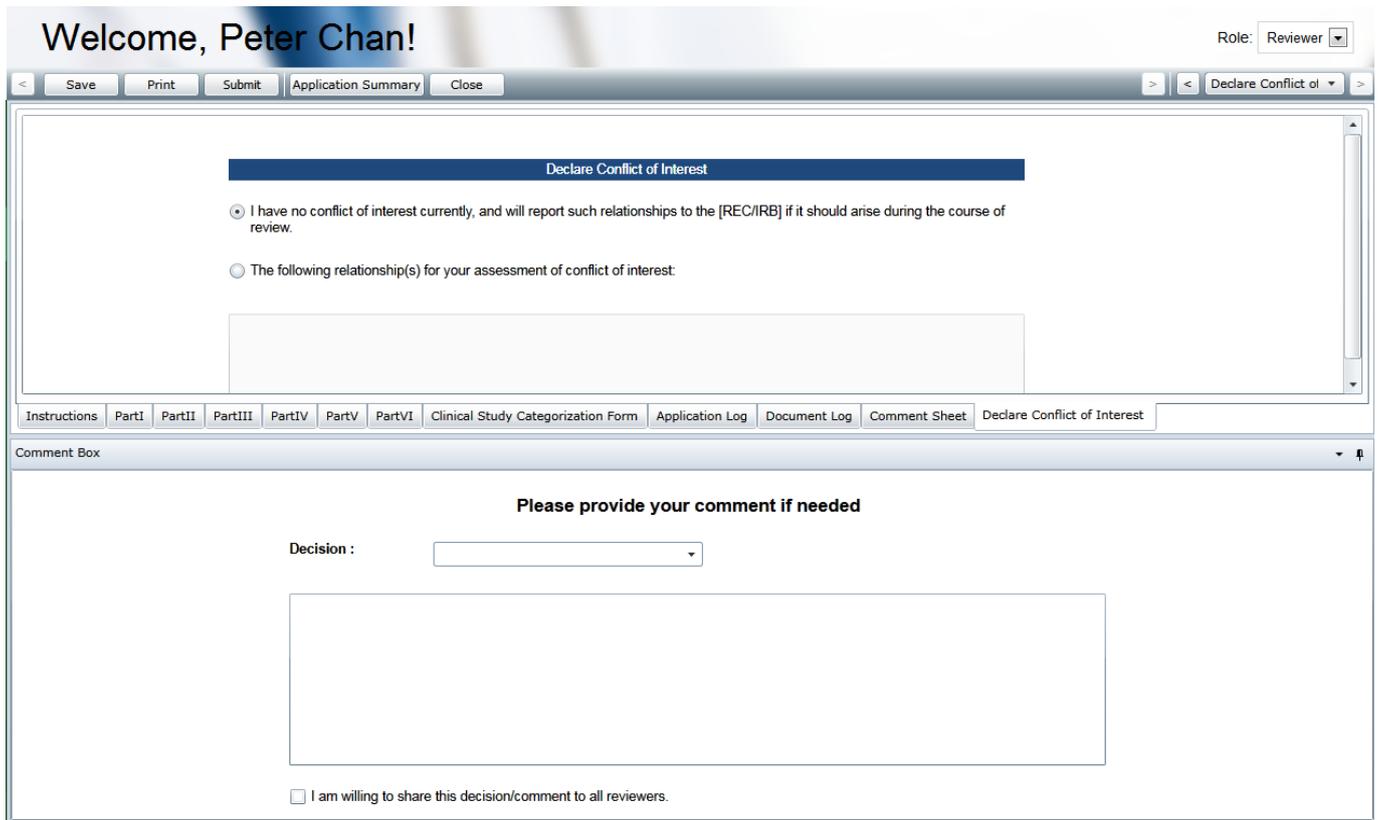
Comment Box

Please provide your comment if needed

Decision :

Comment Box

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



Welcome, Peter Chan! Role: Reviewer

Save Print Submit Application Summary Close

Declare Conflict of Interest

Declare Conflict of Interest

I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.

The following relationship(s) for your assessment of conflict of interest:

Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

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

Welcome, Peter Chan! Role: Reviewer

Save Print Submit Application Summary Close Declare Conflict of Interest

Declare Conflict of Interest

I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.

The following relationship(s) for your assessment of conflict of interest:

Instructions Part I Part II Part III Part IV Part V Part VI Clinical Study Categorization Form Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box  Make Sliding

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

5. You may check the check box of "I am willing to share this decision / comment to all reviewers".

Comment Box

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

Once checked, all reviewers of the application can view your decision and comment in the comment sheet of the form during their reviews:

Viewed by Reviewer

Comment History :

Date	Name	Decision	Comment	To	ColumnHeader

Clinical Study Categorization Form	Application Log	Document Log	Comment Sheet	Declare Conflict of Interest		
Instructions	PartI	PartII	PartIII	PartIV	PartV	PartVI

Other reviewers can view your shared comment in the "Comment Sheet"

6.5. Submit Review

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

Welcome, Peter Chan!

< Save Print **Submit** Application Summary Close >

Declare Conflict of Interest

I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.

The following relationship(s) for your assessment of conflict of interest:

Instructions Part I Part II Part III Part IV Part V Part VI Clinical Study Categorization Form Application Log Document Log Comment Sheet **Declare Conflict of Interest**

Comment Box

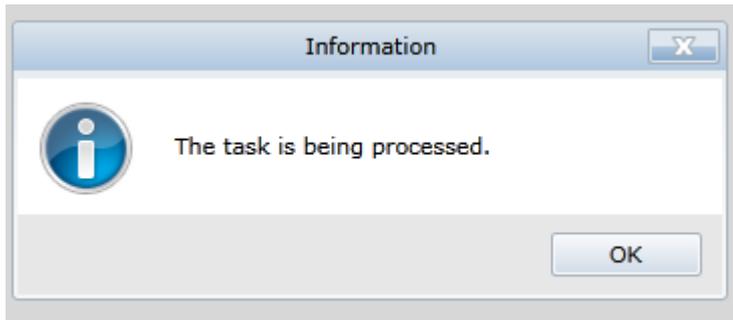
2. Click **[Yes]** in the prompted dialog:

Message

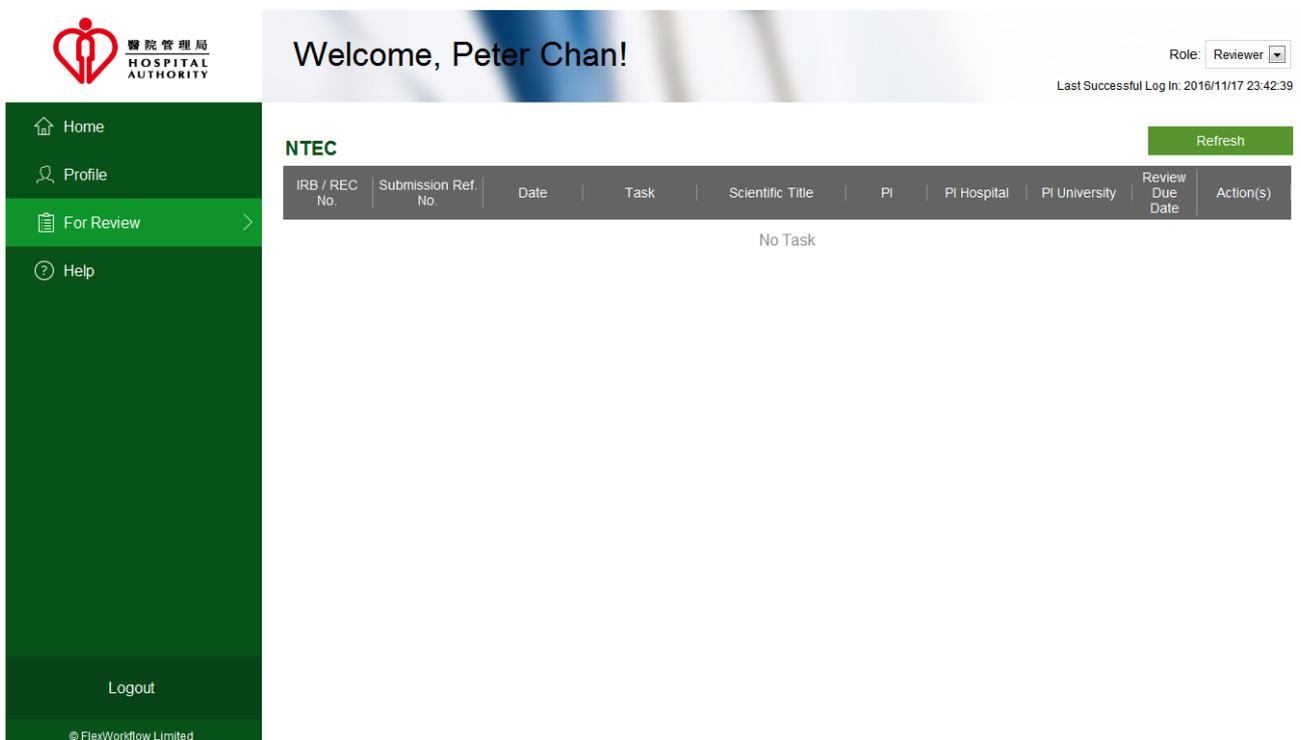
Are you sure to confirm the review?

Yes No

3. Click **[OK]** to proceed.



4. The application is removed from the task list. You have now completed the review procedures of the application.

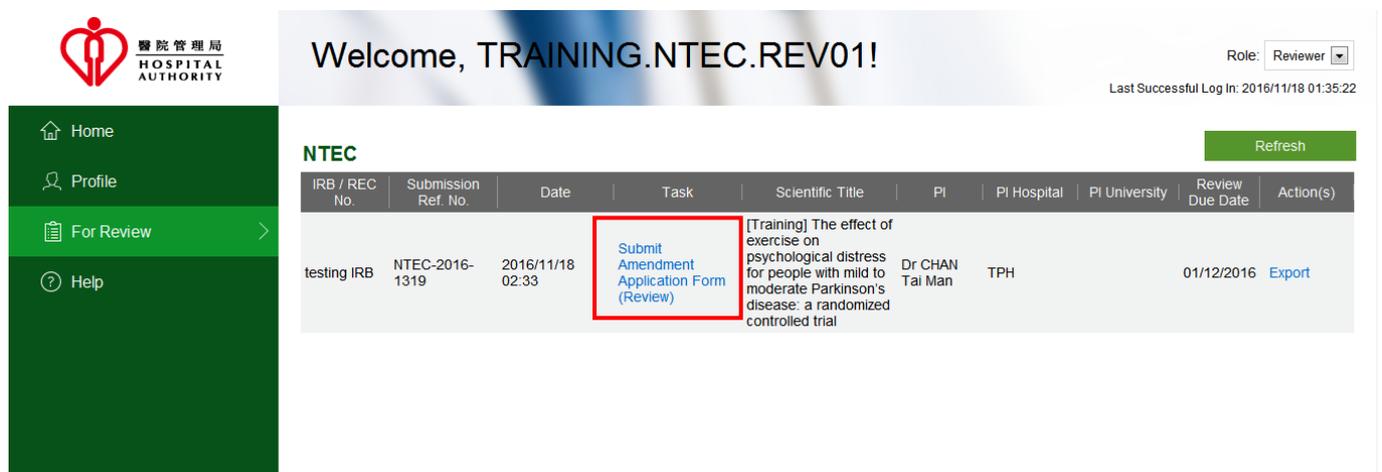
The screenshot shows the user interface of the NTEC application. On the left is a dark green sidebar with navigation options: Home, Profile, For Review (highlighted with a right-pointing arrow), and Help. At the bottom of the sidebar is a "Logout" button and the copyright notice "© FlexWorkflow Limited". The main content area has a header with the Hospital Authority logo and name, a welcome message "Welcome, Peter Chan!", a role dropdown menu set to "Reviewer", and a "Last Successful Log In: 2016/11/17 23:42:39" timestamp. Below the header is a "Refresh" button. The main area contains a table titled "NTEC" with the following columns: IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Review Due Date, and Action(s). The table is currently empty, with the text "No Task" centered below it.

7. Amendment Application Form Review (Post-Approval)

If the “Initial Application Approval” has been approved already, but the applicant wants to revise it, he/she may submit an “Amendment Application Form”. Similar to “Initial Application Approval”, after the confirmation by secretary, the task for reviewing the amendment application will be sent to reviewers.

The review procedures are also similar to those of “Initial Application Approval”. Reviewers have to review the form and its changes, declare their conflict of interest, and mark their decision and comments.

To review the form, in the corresponding cluster page, the task called “**Submit Amendment Application Form (Review)**” is shown in the task list. Click on the task to open it.



The screenshot displays the NTEC (New Technology Evaluation Committee) system interface. On the left is a dark green sidebar with navigation options: Home, Profile, For Review (highlighted), and Help. The main content area shows a welcome message for 'TRAINING.NTEC.REV01!' and a user role of 'Reviewer'. Below this is a table of tasks. The 'For Review' task is highlighted with a red box. The table includes columns for IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Review Due Date, and Action(s).

IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Review Due Date	Action(s)
testing IRB	NTEC-2016-1319	2016/11/18 02:33	Submit Amendment Application Form (Review)	[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		01/12/2016	Export

7.1. View Application Amendment

The “Amendment Application Form” tab shows you a list of amendments:

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 **Anticipated Start Date:** 30/12/2016

Principal Investigator (PI): Dr 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?
			The objective of this study is to			

Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log Comment Sheet **Amendment Application Form** Declare Conflict of Interest

Comment Box

If the field values on the form have been revised, the “**List of Amended Fields**” table shows you the amendments, with a comparison between the old values and the revised ones:

- “Field Name” shows which field has been changed.
- “Current Condition” shows the current value in the approved “Initial Application Approval”.
- “Amendment” shows the revised value.
- “Proposed By” shows who proposed the revised value.
- “Reason for Change” shows the reason for the amendment.
- “Will change increase risk to participants?” shows the change of risk to participants.

Input Information

List of Amended Fields :

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 people with PD. (revised)	applicant	test	no

If the documents uploaded to the form have been updated, the “**List of Updated Documents**” shows you the list of documents that are updated:

- “Document Section Name” shows which document has been updated.
- “Proposed By” shows who proposed the revised value.
- “Reason for Change” shows the reason for the amendment.
- “Will change increase risk to participants?” shows the change of risk to participants.

List of Updated Documents :

No	Document Section Name	Current Condition	Amendment	Proposed By	Reason for Change	Will change increase risk to participants?
1	29. Investigator's Brochure			applicant	test	no

7.2. Declare Conflict of Interest

Before submitting your review, you have to declare your conflict of interest;

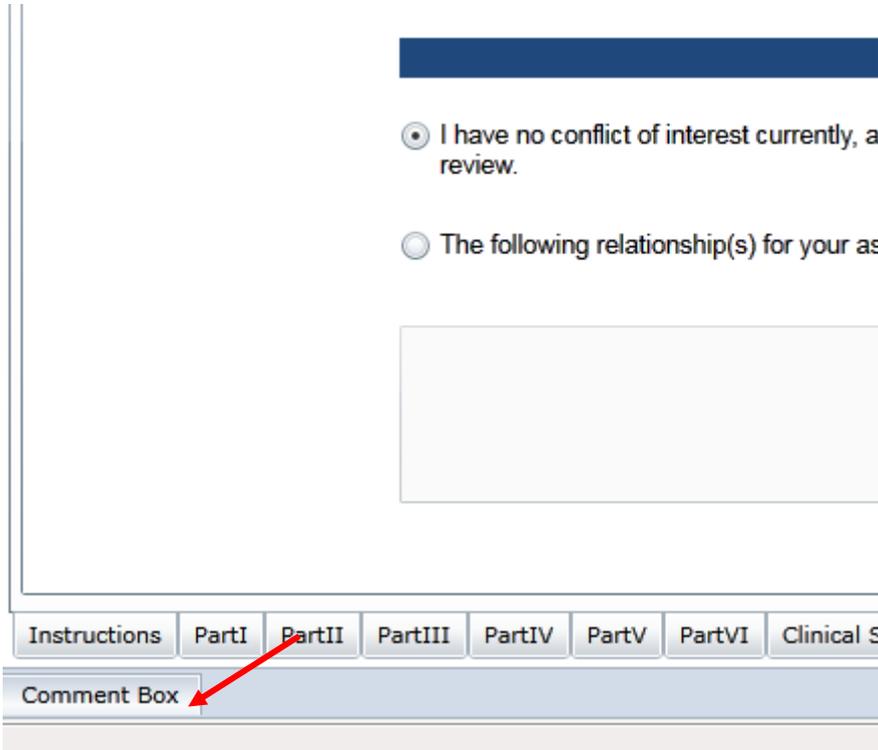
1. Go to the “**Declare Conflict of Interest**” tab.
2. Declare whether you have conflict of interest or not. Please list the details if you do.

The screenshot shows a web application interface. At the top left, it says "Welcome, Peter Chan!". On the top right, there is a "Role:" dropdown menu set to "Reviewer". Below the header is a navigation bar with buttons for "Save", "Print", "Submit", "Application Summary", and "Close". On the far right of this bar are navigation arrows and a dropdown menu currently showing "Declare Conflict of Interest". The main content area has a dark blue header with the text "Declare Conflict of Interest". Below this header are two radio button options: the first is "I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review." and the second is "The following relationship(s) for your assessment of conflict of interest:". Below the second option is a large, empty text input box. At the bottom of the page is a horizontal menu with tabs for "Instructions", "PartI", "PartII", "PartIII", "PartIV", "PartV", "PartVI", "Clinical Study Categorization Form", "Application Log", "Document Log", "Comment Sheet", and "Declare Conflict of Interest". The "Declare Conflict of Interest" tab is highlighted with a red border. Below the menu is a "Comment Box" label.

7.3. Mark Decision and Comment

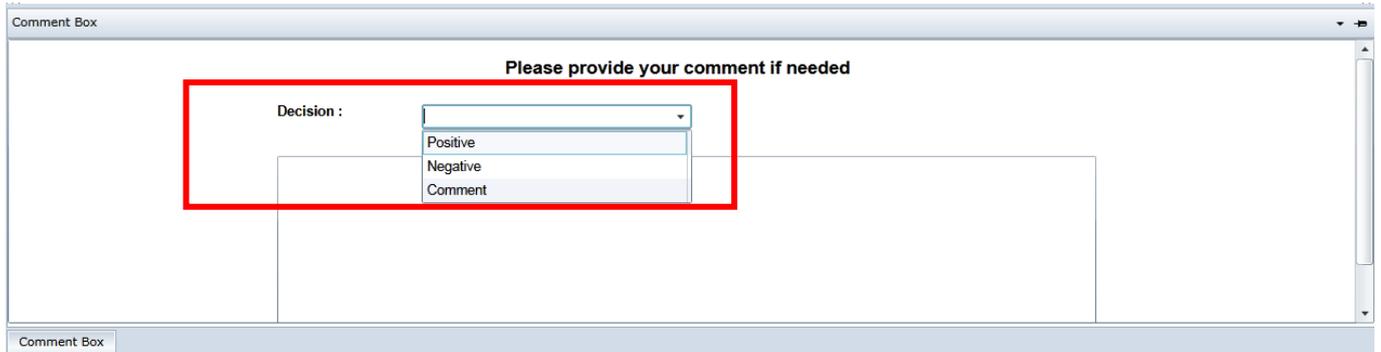
To submit your review, you have to mark your decision and your comments:

1. Move the mouse cursor to the "Comment Box".



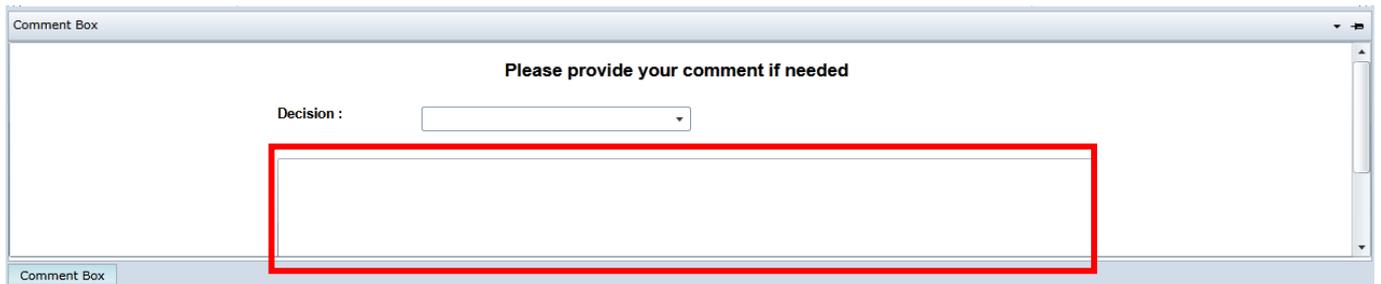
The screenshot shows a web interface with a navigation bar at the bottom containing tabs: Instructions, PartI, PartII, PartIII, PartIV, PartV, PartVI, and Clinical S. The 'Comment Box' tab is highlighted in blue, and a red arrow points to it from the left. Above the navigation bar, there is a dark blue header bar, two radio button options, and a large empty text area. The first radio button is selected and is labeled 'I have no conflict of interest currently, a review.' The second radio button is labeled 'The following relationship(s) for your as'.

2. Make your decision as "Positive", "Negative" or "Comment".



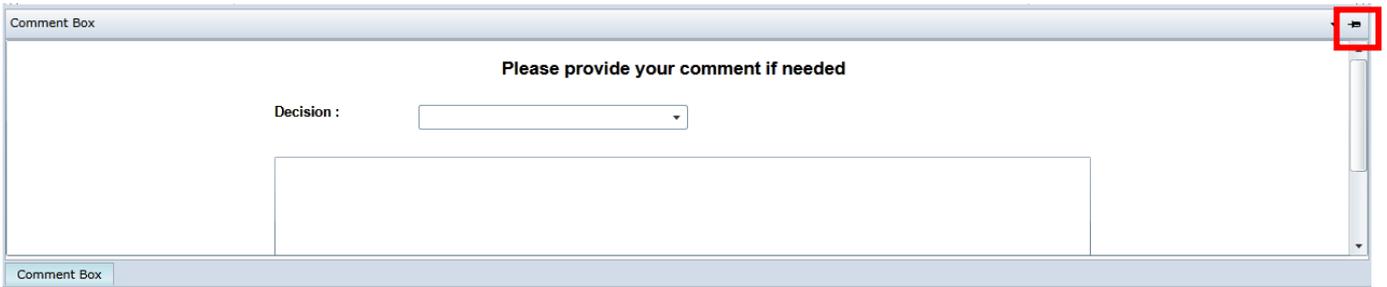
The screenshot shows a window titled 'Comment Box' with a scrollable area. At the top of the scrollable area, it says 'Please provide your comment if needed'. Below this, there is a 'Decision :' label followed by a dropdown menu. The dropdown menu is open, showing three options: 'Positive', 'Negative', and 'Comment'. A red rectangle highlights the dropdown menu and its label. Below the dropdown menu is a large empty text area for comments.

3. Provide your comments in the following area:



The screenshot shows the same 'Comment Box' window. The 'Decision :' dropdown menu is now closed. A red rectangle highlights the large empty text area below the dropdown menu, indicating where to provide comments.

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



Comment Box

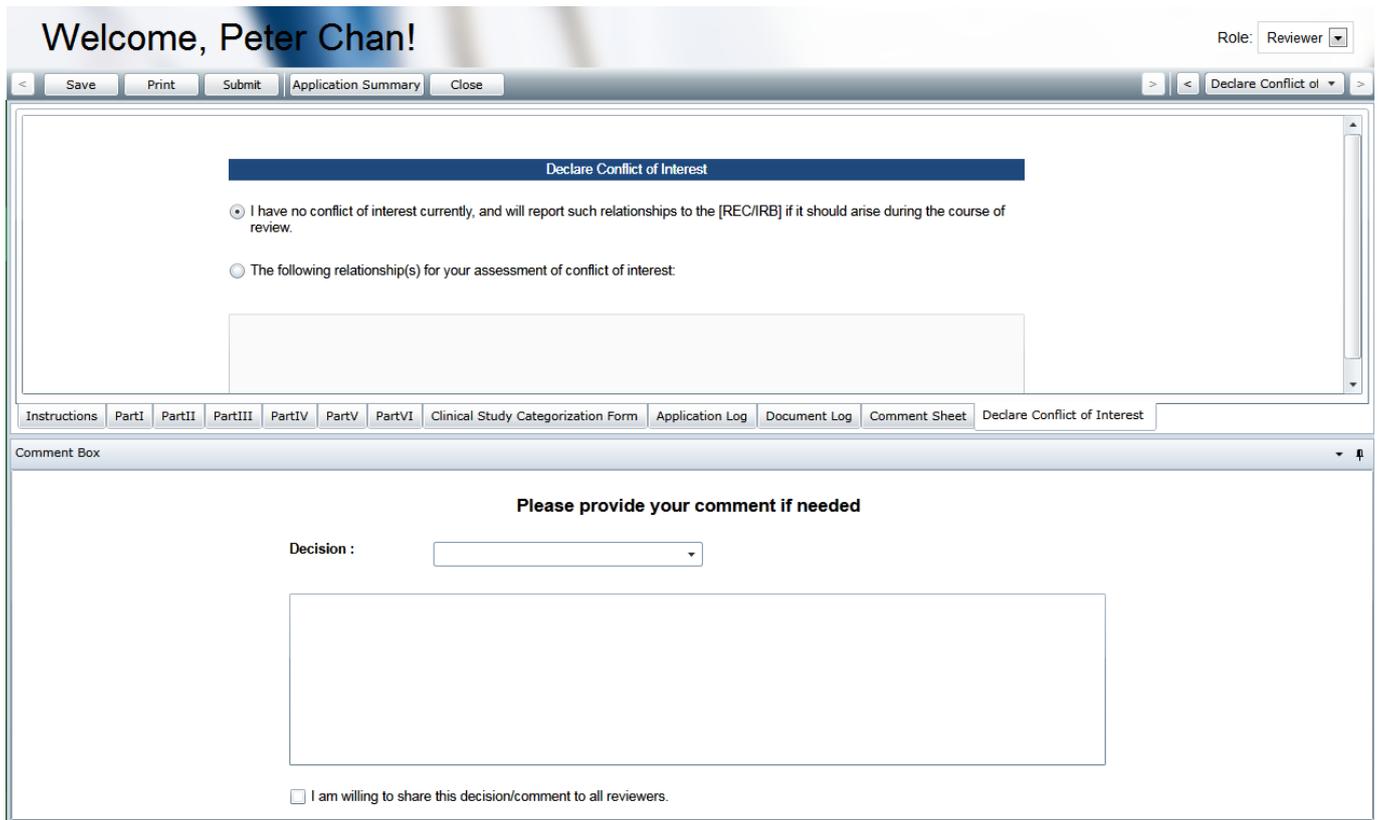
Please provide your comment if needed

Decision :

Comment Box

A red box highlights the pin icon in the top right corner of the Comment Box window.

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



Welcome, Peter Chan! Role: Reviewer

Save Print Submit Application Summary Close

Declare Conflict of Interest

Declare Conflict of Interest

I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.

The following relationship(s) for your assessment of conflict of interest:

Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

The 'Comment Box' is now pinned to the bottom of the screen.

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

Welcome, Peter Chan! Role: Reviewer

Save Print Submit Application Summary Close > < Declare Conflict of Interest >

Declare Conflict of Interest

I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.

The following relationship(s) for your assessment of conflict of interest:

Instructions Part I Part II Part III Part IV Part V Part VI Clinical Study Categorization Form Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box  Make Sliding

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

5. You may check the check box of "I am willing to share this decision / comment to all reviewers".

Comment Box

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

Once checked, all reviewers can view your decision and comment in the comment sheet of the form during their reviews:

Viewed by Reviewer

Comment History :

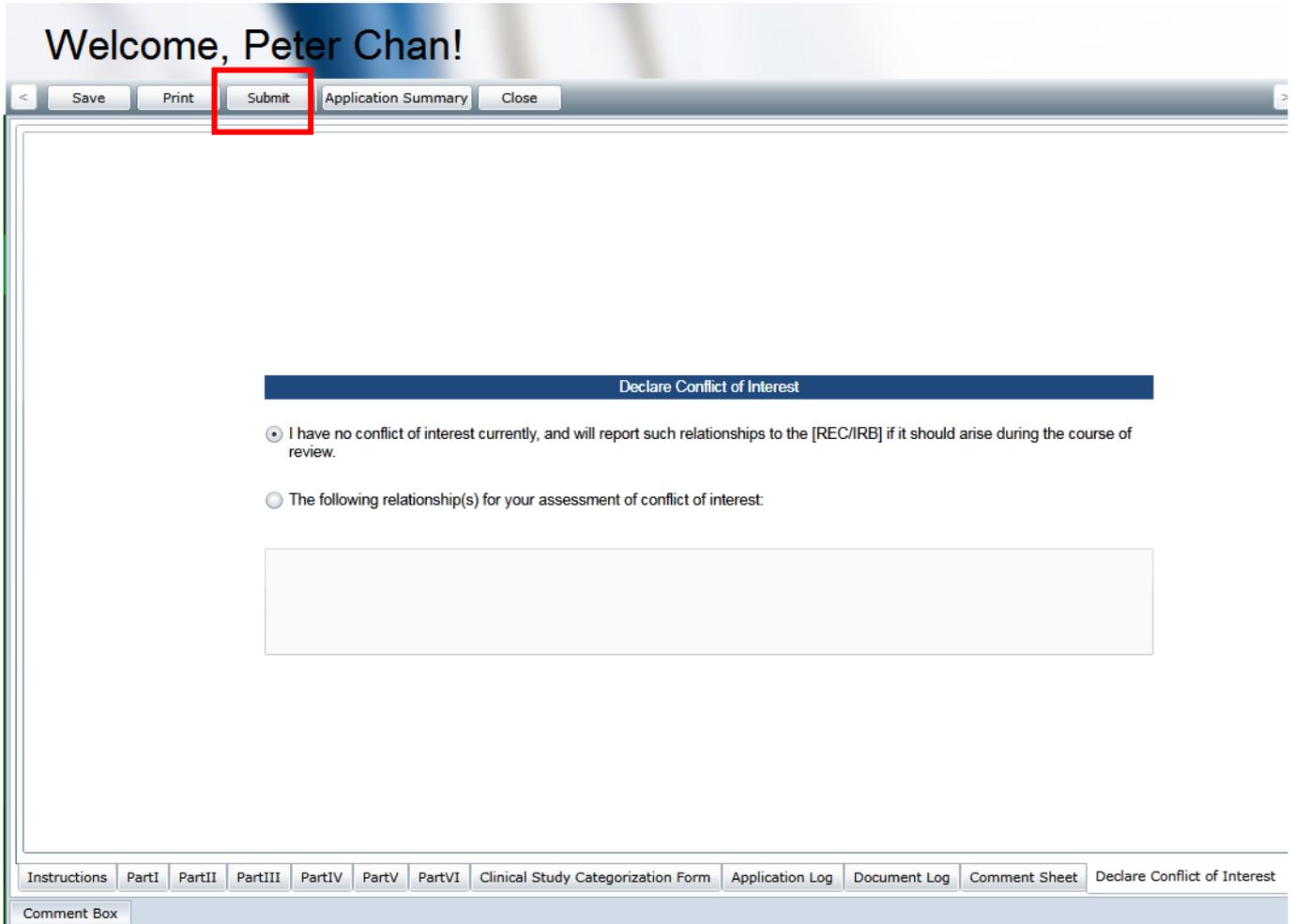
Date	Name	Decision	Comment	To	ColumnHeader

Clinical Study Categorization Form		Application Log	Document Log	Comment Sheet	Declare Conflict of Interest	
Instructions	PartI	PartII	PartIII	PartIV	PartV	PartVI

Other reviewers can view your shared comment in the "Comment Sheet"

7.4. Submit Review

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



Welcome, Peter Chan!

< Save Print **Submit** Application Summary Close >

Declare Conflict of Interest

I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.

The following relationship(s) for your assessment of conflict of interest:

Instructions PartI PartII PartIII PartIV PartV PartVI Clinical Study Categorization Form Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box

2. Click **[Yes]** in the prompted dialog:

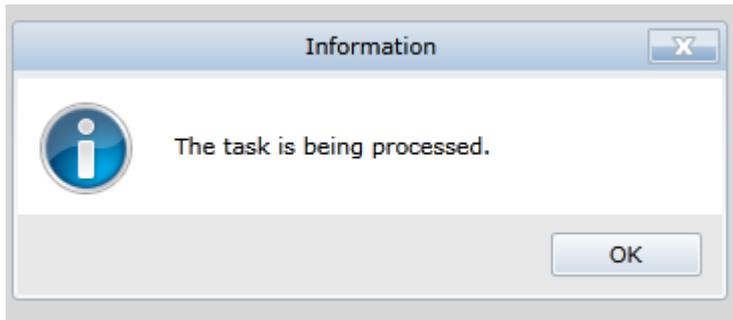


Message

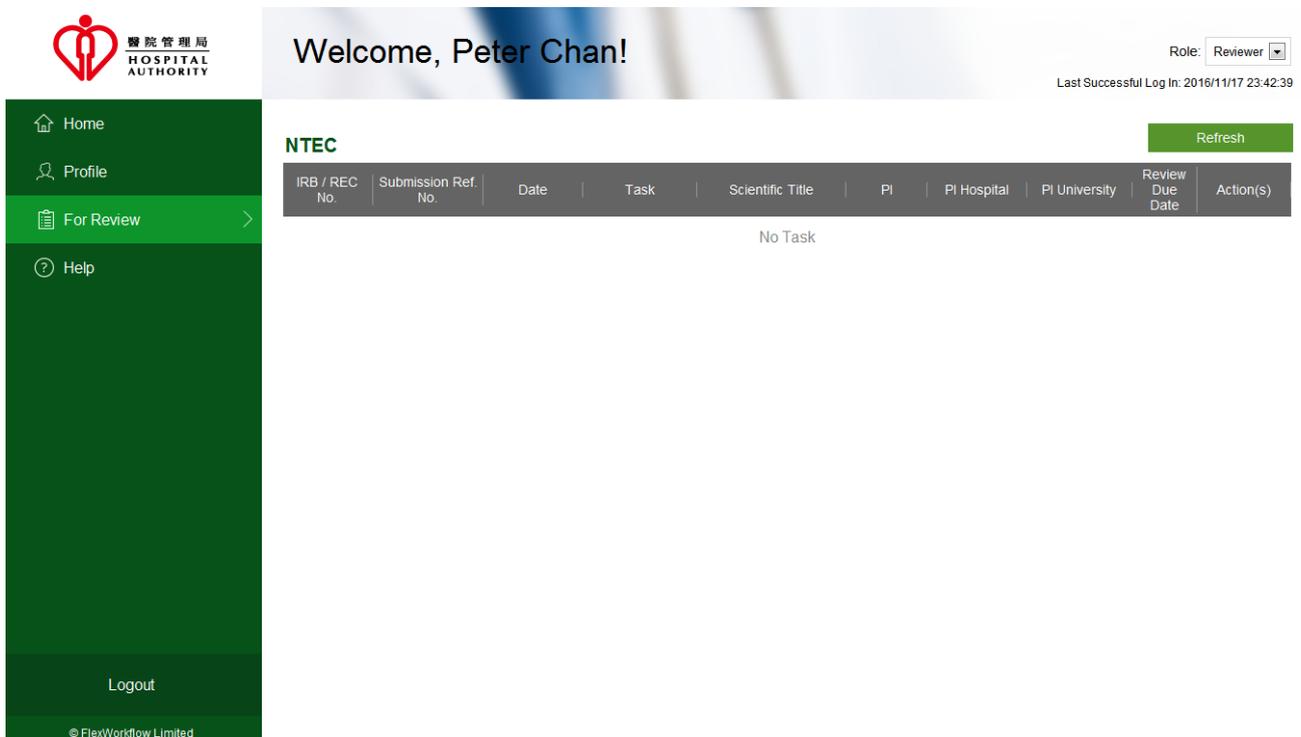
Are you sure to confirm the review?

Yes No

3. Click **[OK]** to proceed.



4. The application is removed from the task list. You have now completed the review procedures of the application.



The screenshot shows the user interface of the Hospital Authority NTEC system. On the left is a dark green sidebar with navigation options: Home, Profile, For Review (highlighted), and Help. At the bottom of the sidebar are "Logout" and "© FlexWorkflow Limited". The main content area has a header with the Hospital Authority logo and the text "Welcome, Peter Chan!". On the right of the header, it shows "Role: Reviewer" and "Last Successful Log In: 2016/11/17 23:42:39". Below the header is a table titled "NTEC" with a "Refresh" button. The table has columns for IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Review Due Date, and Action(s). The table is currently empty, displaying "No Task".

8. Report Review (Post-Approval)

After the “Initial Application Approval” is approved, Applicants can upload and submit several kinds of documents in the Post-Approval stage. After the confirmation by the secretary, the report will be sent to reviewers for review:

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

IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Status
20161115	NTEC-2016-1315	2016/11/14 14:44	Upload SAE Report(Review)	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

The review procedures are similar to those of “Initial Application Approval”. Reviewers have to review the details of documents, declare their conflict of interest, and mark their decisions and comments.

8.1. Email Notification

As a reviewer, you may receive an e-mail notification if there is a new application pending for your review. Below is the email template:

Subject: Review of Clinical Research Ethics Application

Dear Reviewer(s),

Please review and approve the following application:

Scientific Title: %StudyTitleFull%

Principal Investigator: %PIName%

Department / School: %PIHaDepartment% %PIUniDepartment%

Hospital/ University: %PIHaHospital% %PIUniUniversity%

Portal Address: <http://cre.home>

Yours faithfully,

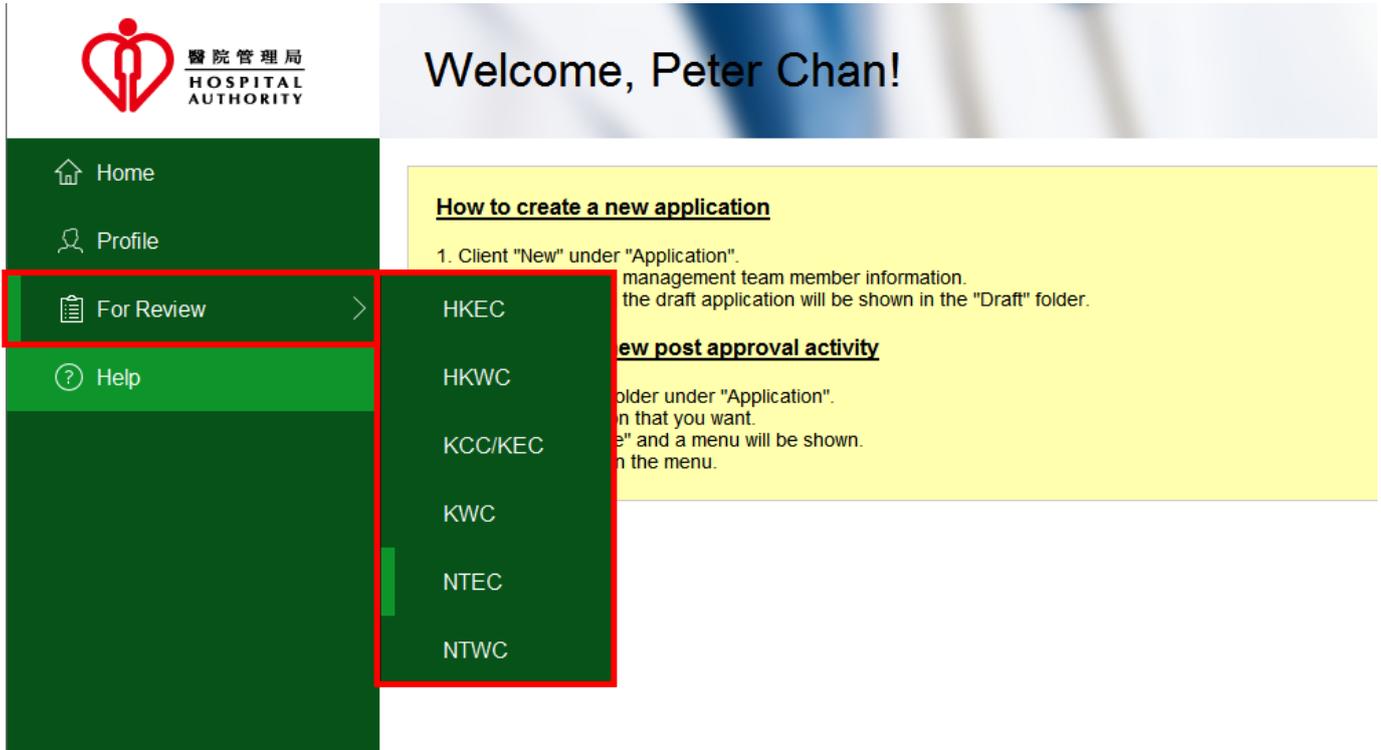
%ClusterName% Cluster REC/IRB

You may ignore this request if you have already submitted the required printed copied of the application dossier

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

8.2. View Application Details

1. Go to **[For Review]** and select your cluster.



The screenshot shows the Hospital Authority system interface. The top left features the Hospital Authority logo and name. A navigation sidebar on the left includes 'Home', 'Profile', 'For Review', and 'Help'. The 'For Review' menu item is highlighted with a red box, and a sub-menu is open, listing clusters: HKEC, HKWC, KCC/KEC, KWC, NTEC, and NTWC. The main content area displays a welcome message for Peter Chan and a yellow box with instructions on how to create a new application and perform post-approval activities.

2. In the “**Task**” column, click the task name to open the task to review.

Take Progress Report as example. The task name is “Upload Progress Report (Review)”.



The screenshot shows the Hospital Authority system interface for a user named TRAINING.NTEC.REV01. The user's role is 'Reviewer'. The main content area displays a table of tasks for review. A red arrow points to the 'Upload Progress Report(Review)' task in the 'Task' column.

IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Status	Action(s)
testing IRB	NTEC-2016-1319	2016/11/18 11:13	Upload Progress Report(Review)	[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	Export

- Review the details of the application. You are able to view the detailed application form, related documents and application history here.

Research Progress Report Form

Note to Investigator

To facilitate the REC/IRB's continuing review, please complete and submit the following Progress Report on your study to the REC/IRB prior to each deadline 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 Proposed Study End Date: 31/07/2018

Principal Investigator (PI): Dr CHAN Tai Man

E-mail of PI: ntec.app1@gmail.com Planned Sample Size: 160

Report Template: Download Initial Study Subject Recruitment Report Download Progress Report Download New Information Report

Upload Attachment

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

No. of attachments: 1

Upload Date	Created By	Document Type	File Name	Suggested Print Name	Upload Times	Tag

Progress Report Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box

- In the **"File Name"** column, click on the document name to download the file.

Upload Attachment

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

No. of attachments: 1

Upload Date	Created By	Document Type	File Name	Suggested Print Name	Upload Times	Tag
18/11/2016 11:04:01 AM	ntec.app1@gmail.com		Progress Report.docx		1	

8.3. Declare Conflict of Interest

1. Go to “Declare Conflict of Interest” page.

The screenshot shows a web application interface for a Suspected Unexpected Serious Adverse Reaction (SUSAR) Report Form. The page has a navigation bar at the top with buttons for Save, Print, Submit, Application Summary, and Close. The main content area is titled "Suspected Unexpected Serious Adverse Reaction (SUSAR) Report Form" and is divided into several sections:

- Note to Investigator:** A text box containing instructions: "To report SUSARs occurred outside study sites under the REC/IRB's jurisdiction, please complete the following form and submit to the REC/IRB all SUSARs reported from outside the your study site in accordance with the requirements set out in the SOP of the REC/IRB."
- Background Information:** Fields for Study title (The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial), IRB/REC Reference Number (20161114), Protocol Number, and Proposed Study End Date (31/07/2018).
- Input Information:** Number of SUSARs Reported to be submitted (1) and a Report Template button labeled "Download SUSAR Report".
- Upload Attachment:** A section for uploading documents, including a "Suggested Print Name" field and a table of attachments.

The "Upload Attachment" section contains a table with the following data:

Upload Date	Created By	Document Type	File Name	Suggested Print Name	Upload Times	Tag
14/11/2016 4:24:36 PM	NTEC APP01		SUSAR Report.docx		1	

At the bottom of the page, a navigation bar includes buttons for SUSAR Report, Application Log, Document Log, Comment Sheet, and "Declare Conflict of Interest", which is highlighted with a red box. A "Comment Box" is also visible at the bottom left.

2. Declare whether you have conflict of interest or not. Please list the details if you do.

The screenshot shows the "Declare Conflict of Interest" form. It features a blue header with the title "Declare Conflict of Interest". Below the header are two radio button options:

- I have no conflict of interest currently, and will report such relationships to the [REC/IRB] if it should arise during the course of review.
- The following relationship(s) for your assessment of conflict of interest:

Below the second option is a large, empty text area for providing details of the conflict of interest.

Declare your conflict of interest

8.4. Mark Decision and Comment

1. Make your decision as "Positive", "Negative" or "Comment".

Please provide your comment if needed

Decision : ▼
Positive
Negative
Comment

Good focus on the rese

I am willing to share this decision/comment to all reviewers.

Mark decision

2. Leave your comment about the application inside the comment box.

Please provide your comment if needed

Decision : Negative ▼

I am willing to share this decision/comment to all reviewers.

Leave your comment

3. You may check the check box of "I am willing to share this decision / comment to all reviewers".

Please provide your comment if needed

Decision :

I am willing to share this decision/comment to all reviewers.

Share decision and comment to other reviewers

Once checked, all reviewers can view your decision and comment in the comment sheet of the application during their reviews:

Viewed by Reviewer

Comment History :

Date	Name	Decision	Comment	To	UserID

Progress Report Application Log Document Log Comment Sheet Declare Conflict of Interest

Comment Box

Other reviewers can view your shared comment in the "Comment Sheet"

8.5. Submit Review

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

Welcome, NTEC IND F05!

< Save Print **Submit** Application Summary Close

Suspected Unexpected Serious Adverse Event

Note to Investigator

To report SUSARs occurred outside study sites under the REC/IRB's jurisdiction reported from outside the your study site in accordance with the requirements s

Background

Study title: The effect of exercise on psychological controlled trial

IRB/REC Reference Number: 20161114

Proposed Study End Date: 31/07/2018

Input In

Submit after review

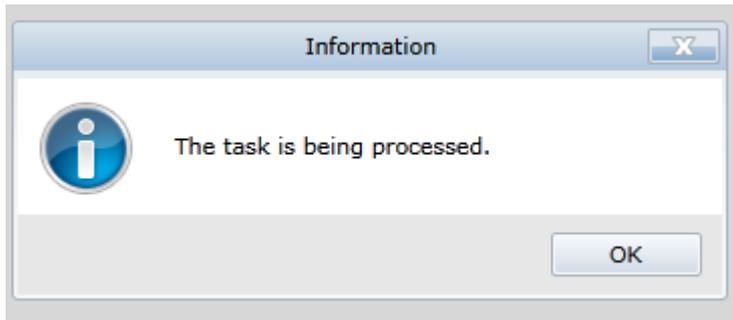
2. Click **[Yes]** in the prompted dialog:

Message

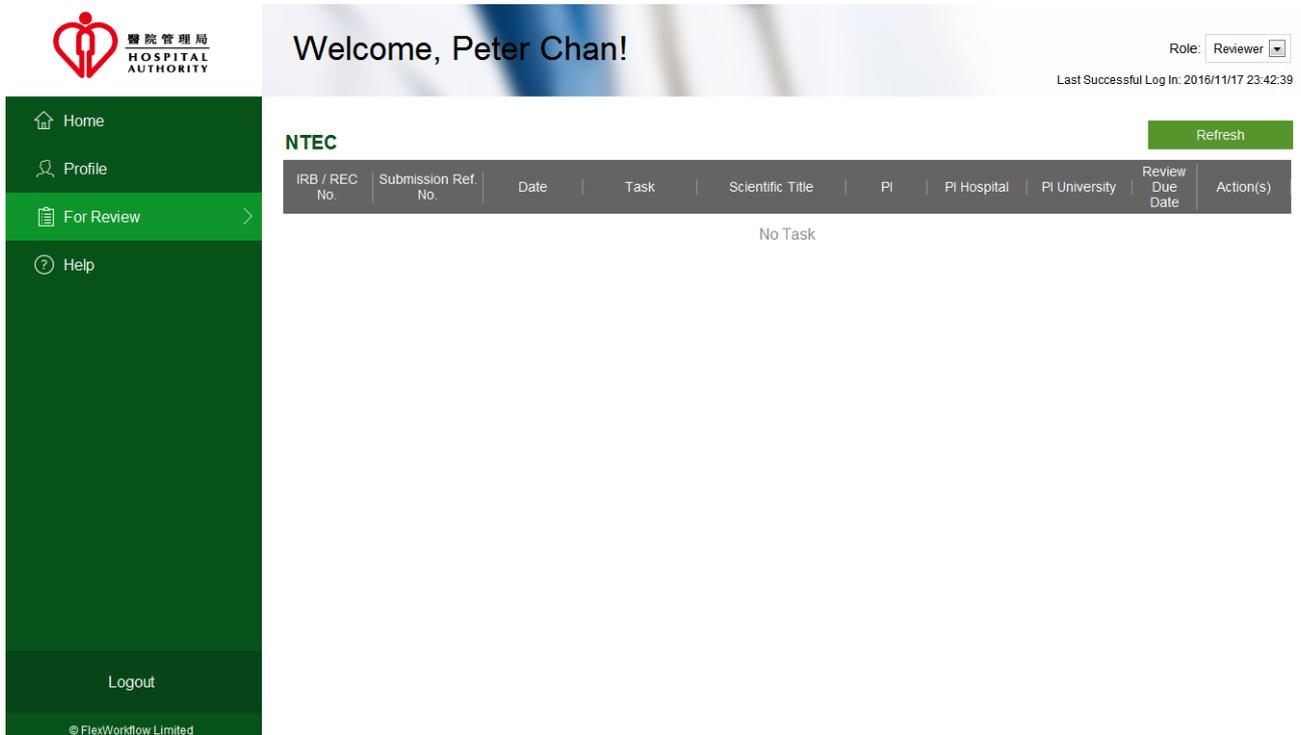
Are you sure to confirm the review?

Yes No

3. Click **[OK]** to proceed.



4. The application is removed from the task list. You have now completed the review procedures of the application.



The screenshot shows the user interface of the NTEC application. At the top left is the logo of the Hospital Authority (醫院管理局 HOSPITAL AUTHORITY). The main header area displays "Welcome, Peter Chan!" and a "Role: Reviewer" dropdown menu. Below the header, there is a "Refresh" button and a table with the following columns: IRB / REC No., Submission Ref. No., Date, Task, Scientific Title, PI, PI Hospital, PI University, Review Due Date, and Action(s). The table is currently empty, with "No Task" displayed below it. On the left side, there is a dark green sidebar menu with options: Home, Profile, For Review (highlighted), and Help. At the bottom of the sidebar is a "Logout" button and the copyright notice "© FlexWorkflow Limited".

9. Maintain User Profile

9.1. Amendment of User Profile / Change of Password

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

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



The screenshot shows the user interface for NTEC SCI M01. The top navigation bar includes the Hospital Authority logo, a welcome message, and a role dropdown set to 'Reviewer'. A left sidebar contains navigation options: Home, Profile (highlighted), For Review, and Help. The main content area shows a table with the following data:

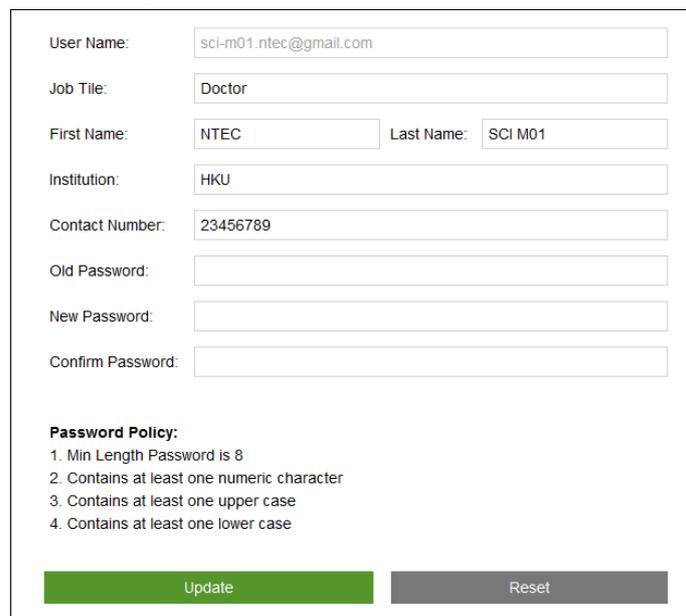
IRB / REC No.	Submission Ref. No.	Date	Task	Scientific Title	PI	PI Hospital	PI University	Status	Action(s)
20161114	NTEC-2016-1316	2016/11/14 14:40	Initial Application Approval (Review)	The effect of exercise on psychological distress for people with mild to moderate Parkinson's disease: a randomized controlled trial	Dr CHAN Tai Man	PYNEH		For Review	Export

Select **[Profile]** on menu

2. Amend your personal information.

Make sure the password entered in “New Password” and “Confirm Password” are **the same** if you are going to change your password.

3. Click the **[Update]** button to update your user profile.



The form contains the following fields and sections:

- User Name: sci-m01.ntec@gmail.com
- Job Title: Doctor
- First Name: NTEC
- Last Name: SCI M01
- Institution: HKU
- Contact Number: 23456789
- Old Password: [Empty]
- New Password: [Empty]
- Confirm Password: [Empty]

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

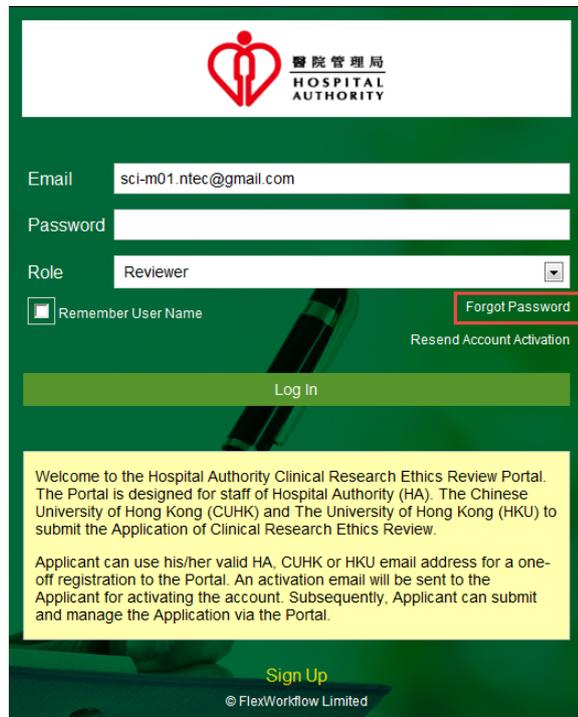
Buttons: Update, Reset

Change your personal info in profile page

9.2. Forgot Password Handling

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

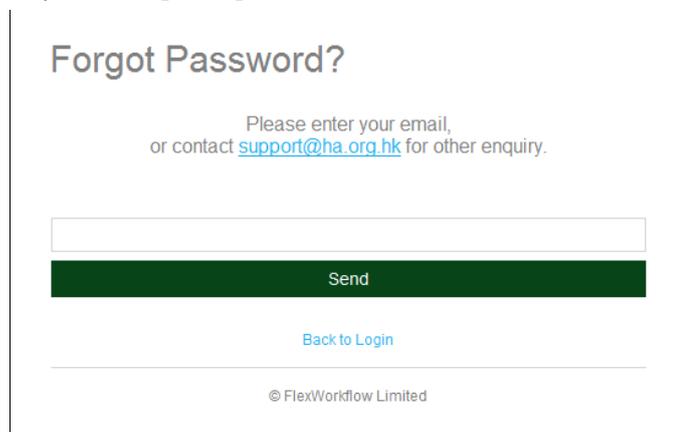
1. Click **[Forgot Password]** to proceed.



The screenshot shows the Hospital Authority login interface. At the top, there is a logo and the text '醫院管理局 HOSPITAL AUTHORITY'. Below this are input fields for 'Email' (containing 'sci-m01.ntec@gmail.com'), 'Password', and a 'Role' dropdown menu set to 'Reviewer'. There is a 'Remember User Name' checkbox and a 'Resend Account Activation' link. A red box highlights the 'Forgot Password' button. Below the login fields is a 'Log In' button. A yellow box contains a welcome message and a 'Sign Up' button. At the bottom, it says '© FlexWorkflow Limited'.

Click **[Forgot Password]**

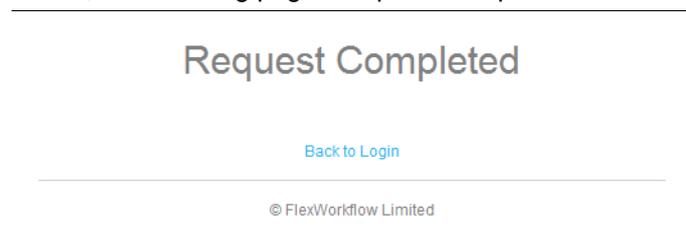
2. Enter your e-mail and then press the **[Send]** button.



The screenshot shows a page titled 'Forgot Password?'. It contains the text: 'Please enter your email, or contact support@ha.org.hk for other enquiry.' Below this is an empty text input field and a dark green 'Send' button. At the bottom, there is a 'Back to Login' link and the text '© FlexWorkflow Limited'.

Input your email

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



The screenshot shows a page titled 'Request Completed'. It contains a 'Back to Login' link and the text '© FlexWorkflow Limited' at the bottom.

Completion of request

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