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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.
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](image-url)
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)

   Dear Sir/Madam,

   Welcome to Hospital Authority Clinical Research Ethics Review Portal. Your account has been created. Please click the below link to activate the account to enable you to log in to the Portal and we strongly recommend you to change the password after your first logon.

   Please click **here** to activate your account.

   **Account information:**

   Email: testing@flexworkflow.com
   Password: uDAu=35KKSv
   Portal Address: https://hacrer/Portal

   Yours faithfully,
   Clinical Research Ethics Review Portal
   Hospital Authority

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

   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.

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

![Login Page Screenshot]

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 Screenshot]
4. Introduction of Reviewer's Home Page

User name is shown at the top of welcome page

<table>
<thead>
<tr>
<th>Function Menu</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td>Display every received application.</td>
</tr>
<tr>
<td>Profile</td>
<td>Profile page of the login user. Please refer to Section 9 Maintain User Profile for more information.</td>
</tr>
<tr>
<td>For Review</td>
<td>You can filter the applications to review based on cluster.</td>
</tr>
<tr>
<td>Help</td>
<td>Useful tips and reminders about the portal.</td>
</tr>
<tr>
<td>Logout</td>
<td>Allows you to log out from the current user account.</td>
</tr>
<tr>
<td>Role</td>
<td>Allows you to swap your roles quickly.</td>
</tr>
</tbody>
</table>

*(Applicable only if you have both Applicant and Reviewer roles)*
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.
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;

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% %PIUnidDepartment%
Hospital/University: %PIHaHospital% %PIUnivUniversity%
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.

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

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

4. “Part VI” contains the documents uploaded for the application.
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.

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.
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.
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";

![Comment Box](image1)

2. Make your decision as “Positive” or “Negative” or “Comment”;

![Decision Options](image2)

3. Provide your comments in the following area:

![Comment Area](image3)
4. 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.
If you need to collapse the comment box, click the button again.
5. You may check the check box of "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:

Other reviewers can view your shared comment in the "Comment Sheet"
6.5. Submit Review

1. Click the [Submit] button.

2. Click [Yes] in the prompted dialog:
3. Click [OK] to proceed.

![Image showing a task being processed]

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

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

### List of Amended Fields:

<table>
<thead>
<tr>
<th>No</th>
<th>Field Name</th>
<th>Current Condition</th>
<th>Amendment</th>
<th>Proposed By</th>
<th>Reason for Change</th>
<th>Will change increase risk to participants?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.2 Aim of study</td>
<td>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.</td>
<td>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)</td>
<td>applicant</td>
<td>test</td>
<td>no</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>No</th>
<th>Document Section Name</th>
<th>Current Condition</th>
<th>Amendment</th>
<th>Proposed By</th>
<th>Reason for Change</th>
<th>Will change increase risk to participants?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>23. Investigator’s Brochure</td>
<td></td>
<td>applicant</td>
<td>test</td>
<td>no</td>
<td></td>
</tr>
</tbody>
</table>
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.
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".

2. Make your decision as “Positive”, “Negative” or “Comment”.

3. Provide your comments in the following area:
4. 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.
If you need to collapse the comment box, click the button again.
5. You may check the check box of "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:

Other reviewers can view your shared comment in the “Comment Sheet”
7.4. Submit Review

1. Click the [Submit] button.

2. Click [Yes] in the prompted dialog:
3. Click [OK] to proceed.

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

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:

```plaintext
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:** %PIHasDepartment% %PIUniDepartment%

**Hospital/University:** %PIHasHospital% %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 copy 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.

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)”. 
3. 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]

4. In the “File Name” column, click on the document name to download the file.

![Upload Attachment]
8.3. Declare Conflict of Interest

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

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

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

   The following relationship(s) for your assessment of 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 need

   [ ] 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

   Leave your comment
3. You may check the check box of "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:

Other reviewers can view your shared comment in the "Comment Sheet"
8.5. Submit Review

1. Click the [Submit] button.

![Submit button](image)

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 of the study:

**Background**

**Study title:** The effect of exercise on psychological controlled trial

IRB/REC Reference Number: 20161114

Proposed Study End Date: 31/07/2018

Submit after review

2. Click [Yes] in the prompted dialog:

![Yes/No dialog](image)
3. Click [OK] to proceed.

![Information dialog box](image)

The task is being processed.

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

![Welcome page](image)
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]

   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.

   ![Profile Page]

   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

   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.

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

3. After clicking the “Send” button, the following page “Request Completed” can be seen.
4. You should receive an e-mail that contains a new password. Please login the account using the new password.