

User Manual for Principal Investigator

Version 01

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1. What is PEARS?

1.1 Background

PEARS is an internet based, 24-hour security controlled, 21 CFR 11 (U.S. Code of Federal Regulations Title 21 Part 11) compliant electronic platform developed for multiple users submission of SAE (serious adverse event). PEARS is a validated system, which allows sponsors and/or CROs (contract research organizations) to submit SAE reports to investigators and CTC (Clinical Trials Centre of HKU) electronically for the purpose of HKU/HA HKW IRB (Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster, in short “IRB”) submission.

Through PEARS, investigators can review and endorse SAE submission documents electronically upon receipt of automatic email notification. The preparation and submission process under PEARS are properly tracked. PEARS users can monitor the progress of SAE submission of their assigned study on a real-time basis. In brief, PEARS enables:

- (a) sponsors and/or CRO dispatch SAE reports to investigators electronically for review;
- (b) sponsors and/or CRO dispatch SAE reports to CTC electronically for review and compilation;
- (c) investigators review and endorse SAE reports submission electronically; and
- (d) sponsors, CROs, investigators and CTC to monitor the SAE reports preparation and submission progress electronically.

2. How to Apply a PEARS Account?

2.1 Create Account

PEARS administrator will create a study record at PEARS when the study is approved by the Ethics Committee. He/ She will contact the PI (principal investigator) for the following procedures:

- (a) arrange a training for using PEARS;
- (b) assist the PI to complete the PEARS User Account Form (CTC-FOM-SMOS-PEA-0070); and
- (c) assist the PI to complete the PEARS User Electronic Signature Certification Form (CTC-FOM-SMOS-PEA-0020).

After verification and approval, an automatic email from PEARS Administrator (Re: “Your PEARS User Account”) will be sent to the user indicating the user name and password.

3. What are PEARS Functions?

3.1 Login

Procedures


1. Browse PEARS link at <http://pearshk.com> to display the login page
2. Type in user name and password
3. Click <Log In>



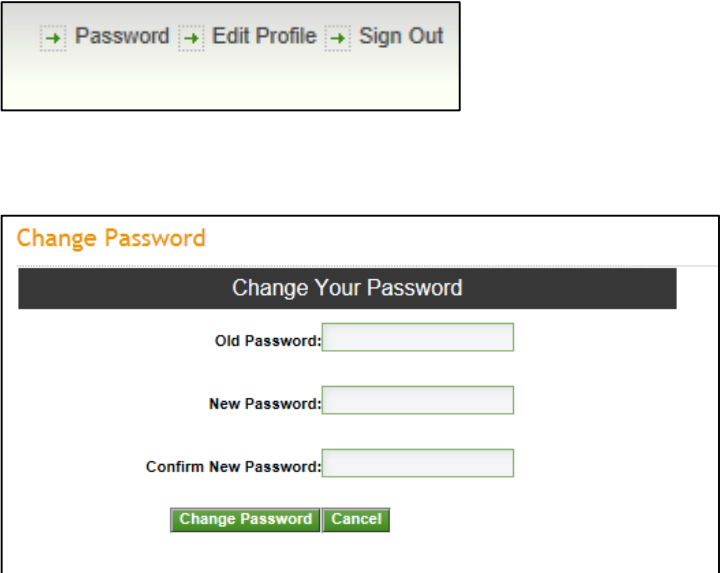
Remarks:

1. A user account should be locked and no user access should be allowed if the user cannot enter the correct password after six (6) attempts.
2. Warning message will be prompted if user unable to provide valid authentication information (maximum login attempts: 6). If user forgot his/her password, he/she could either:
 - (a) click <Forgot Password?> to request for a new password. PEARS will send a new password to the user via email automatically; or
 - (b) call Administrator for help. New password will be sent to the user via email automatically.

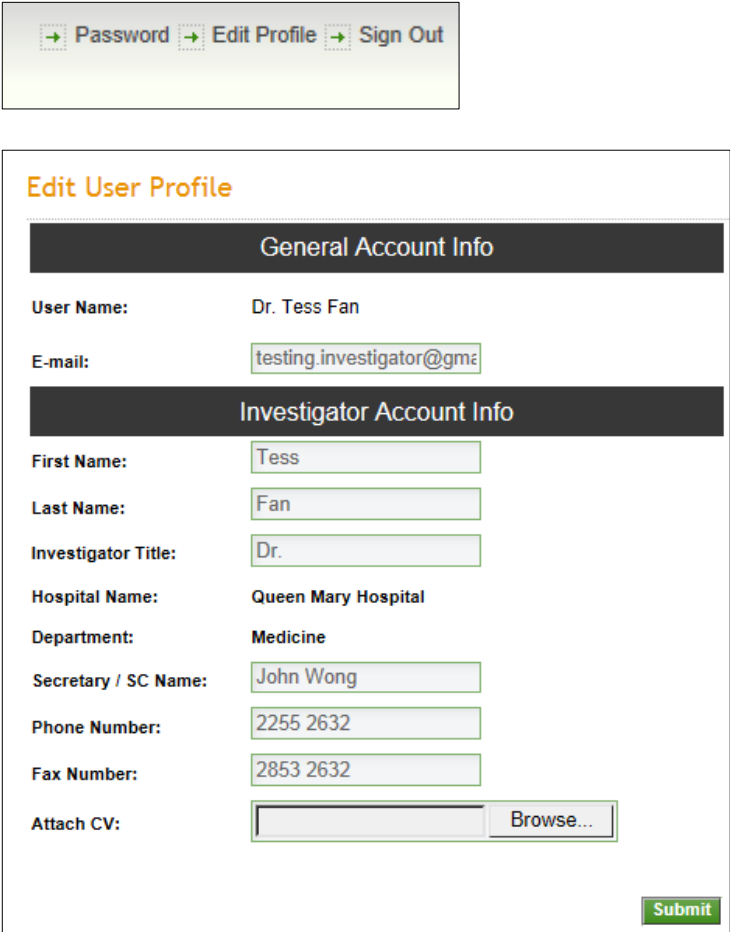
3.2 Logout

Procedures	
1. Click <Sign Out> on the top right hand corner of the webpage	
Remarks: 1. User should always sign out PEARS after use.	

3.3 Change Password

Procedures	
1. Click <Password> on the top right hand corner of the webpage 2. Type in old password 3. Type in new password and confirm new password 4. Click <Change Password>	
Remarks: 1. User receives initial password via email. 2. User should change password at initial login, and user can change password at any time. A confirmation email will be received after changing the password. 3. Minimum password length: eight (8) characters 4. System requests user to change password every 180 days. 5. System does not allow user to re-use the previous one old password. 6. Maximum login attempts: six (6) 7. Password transactions will be recorded in system audit trail.	

3.4 Edit Profile

Procedures	
<ol style="list-style-type: none">1. Click <Edit Profile> on the top right hand corner of the webpage2. Update profile when necessary3. Click <Submit> to confirm updated information	 <p>Remarks:</p> <ol style="list-style-type: none">1. PI is not allowed to change User Name, Hospital Name and Department name. PEARS Administrator will update the required fields whenever appropriate.2. Modification on profile information will be recorded in system audit trail.

3.5 View Alert Message

Procedures	
<ol style="list-style-type: none"> 1. Click <Home> at the toolbar 2. Alert message will be shown (if any) 	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p>Home</p> <hr/> <p>Welcome back testing.corporateacc</p> <p style="text-align: center;">There is outstanding SAE report.</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p>Home</p> <hr/> <p>Welcome back Dr. Tess Fan</p> <p style="text-align: center;">! There is one SAE report waiting for your endorsement.</p> </div>
<p>Remarks:</p> <ol style="list-style-type: none"> 1. Alert message is a reminder to PI for the pending document review/endorsement. 	

3.6 SAE Submission Log

Procedures																															
<ol style="list-style-type: none"> 1. Click <alert message> at Home page 2. Click <Submission ID> to view Submission Summary Report 3. Click <SUSAR Attachment> to view individual Safety Reports dispatched by sponsor/ CRO 4. Click <View Submission Cover Letter> and <View SAE Report Form> to review submission documents 5. Click <E-signature> to endorse the IRB submission documents. An alert message will be pop-up for re-confirmation. 6. Click <OK> to re-confirm document endorsement 	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p style="text-align: center;">! There are 4 SAE reports waiting for your endorsement.</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p>Submission Report Summary</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>CTC Number:</td> <td>0525</td> <td>Message from webpage:</td> <td>X</td> </tr> <tr> <td>Submission ID:</td> <td>70</td> <td colspan="2" style="text-align: center;">? Are you sure you want to sign the SAE Submission report?</td> </tr> <tr> <td>Protocol Title:</td> <td>A phase 3 preventing</td> <td colspan="2" style="text-align: center;">OK Cancel</td> </tr> </table> <p>Dispatched Items</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Tracking ID</th> <th>Date of Dear Investigator Letter</th> <th>MFR Control No</th> <th>Report Type</th> <th>Event Name</th> <th>Date Received by Manufacturer</th> <th>Report Date</th> <th>Action Taken</th> <th>SUSAR Attachment</th> </tr> </thead> <tbody> <tr> <td>SC</td> <td></td> <td>adf</td> <td>adf</td> <td>aru</td> <td></td> <td>12 Jun 2010</td> <td>Adjusted Dosage</td> <td>SCRS0001003 SCRS0001004.pdf</td> </tr> </tbody> </table> <p style="text-align: center;">1 of 1 1 - 20</p> <p style="text-align: center;"> <input type="button" value="E-Signature"/> <input type="button" value="View Submission Cover Letter"/> <input type="button" value="View SAE Report Form"/> </p> </div>	CTC Number:	0525	Message from webpage:	X	Submission ID:	70	? Are you sure you want to sign the SAE Submission report?		Protocol Title:	A phase 3 preventing	OK Cancel		Tracking ID	Date of Dear Investigator Letter	MFR Control No	Report Type	Event Name	Date Received by Manufacturer	Report Date	Action Taken	SUSAR Attachment	SC		adf	adf	aru		12 Jun 2010	Adjusted Dosage	SCRS0001003 SCRS0001004.pdf
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SC		adf	adf	aru		12 Jun 2010	Adjusted Dosage	SCRS0001003 SCRS0001004.pdf																							

Procedures

7. Click <Back> to view other pending submission logs

Remarks:

1. For e-signature, the PI will need to enter User Name and Password for re-confirmation.
2. E-signature will be recorded in system audit trail.

3.7 Tracking

Procedures

1. Click <SAE Submission Log> of a study at Home page
2. Input Protocol Number or unclick <Outstanding Only> to search for all submission history
3. Click <Search> to display the submission status

Submission ID	Company Name	Protocol Number	CTC Number	Status	Admin Submit Date	Endorse Date	IRB Submission Date
5	TESTING Limited	158221	1021HKU1	2	04 May 2016 12:31		

Status:

- 2 - Pending PI: Pending for PI Endorsement.
- 3 - Endorsed by All PI
- 4 - Submitted to IRB
- 5 - Confirmed by IRB

4. Questions

4.1 Enquiry Contact

For enquiry about PEARS, please contact PEARS Administrators at:

Name:	Ms. Karman Choi	Ms. Brenda Lui
Telephone:	2255 3956	2255 3959
Email:	pears@hku.hk	pears@hku.hk

Appendix 1: Overview of PEARS Operations

