HKU Med LKS Faculty of Medicine
Clinical Trials Centre
香港大學臨床試驗中心



IISupreme

Investigator-Initiated Clinical Study One-Stop Platform

User Guide

Version 03

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List of General Abbreviations/Defined Terms

CTC	Clinical Trials Centre of HKU
DAG	Data access groups
EDC	Electronic data capture
ICMJE	International Committee of Medical Journal Editors
IISs	Investigator-initiated clinical studies
IRB	Institutional Review Board
HKU	The University of Hong Kong
HKUMed	Li Ka Shing Faculty of Medicine of HKU
HKWC	Hong Kong West Cluster of Hospital Authority
PI	Principal investigator
PID	PI's delegate
REDCap	Research Electronic Data Capture
WHO	World Health Organization

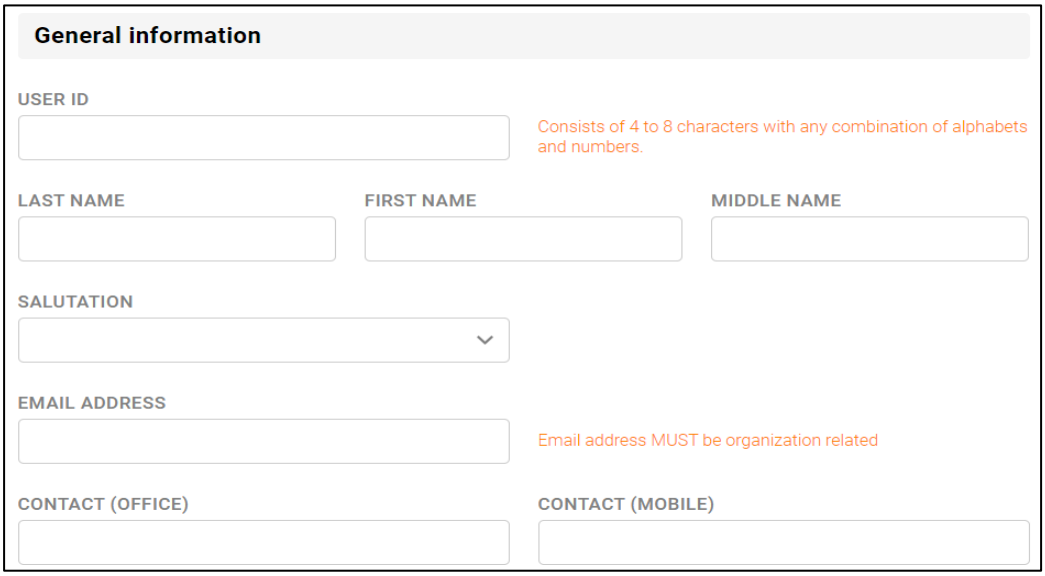
1. User Types and Clinical Trial Services Entitled

User Type	Type 1	Type 1 (Completed EDC Training Course(s))	Type 2	Type 3
User Description	HKUMed staff or HKWC staff with HKU honorary appointment		HKWC staff without HKU honorary appointment	Other institutions' staff with nomination by PI/PID
Useful Resources	✓	✓		
Training Program Related to Clinical Trial	✓	✓	✓ (EDC training course(s) only)	✓ (EDC training course(s) only)
Clinical Trial Insurance Management Service	✓	✓		
Clinical Trial Agreement Vetting Service	✓	✓		
EDC Service		✓		

2. Registration

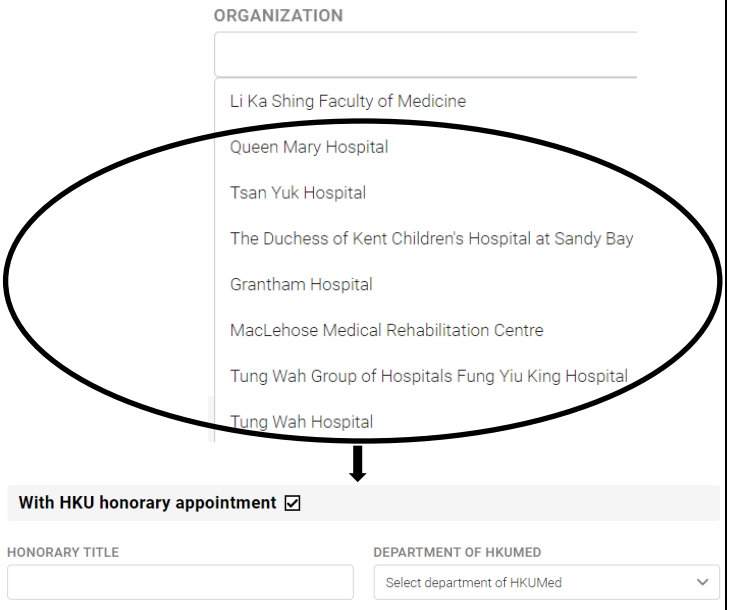
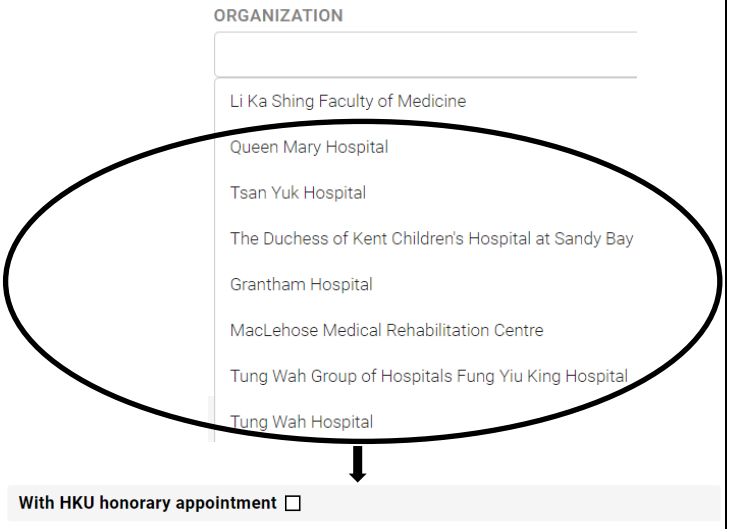
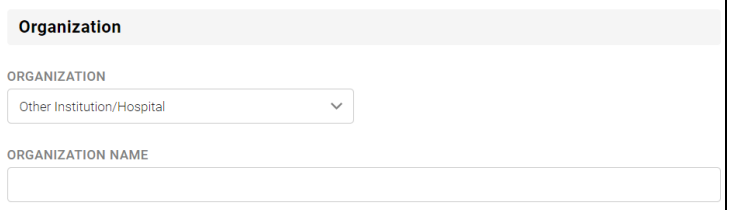
2.1.1 Read this user guide and 'Terms of Use'.

2.1.2 Visit 'Register' and input general information.



2.1.3 Based on your user type, choose your corresponding affiliation under 'Organization'.

HKUMed staff: 1. Choose Li Ka Shing Faculty of Medicine under 'Organization'. 2. Select your affiliated department under HKUMed.	ORGANIZATION Li Ka Shing Faculty of Medicine DEPARTMENT OF HKUMED Select department of HKUMed

HKWC staff **with** HKU honorary appointment: 1. Choose your affiliation under HKWC under 'Organization'. 2. Check the box of 'With HKU honorary appointment'. 3. Type your honorary title and select your department of HKUMed.	
HKWC staff **without** HKU honorary appointment: 1. Choose your affiliation under HKWC under 'Organization'. 2. Uncheck the box of 'With HKU honorary appointment'.	
Other institutions' staff with nomination by PI or PID (PI's delegate): 1. Choose 'Other Institution/Hospital' under 'Organization'. 2. Type your institution's name.	

2.1.4 Check the box 'I have read and agreed the Terms of Use.' before submission of the application to IISupreme administrator.

2.1.5 An acknowledgement email will be sent to users once submission is done.

3. User Login, Password, Profile Change and Logout

3.1.1 If registration is approved, login information including user ID and initial password will be sent to user by email.

3.1.2 Login/Logout button can be found from the top right corner of the webpage. Next to the Login/Logout button, please click 

to change your password after first login.

3.1.3 User account will be locked and access will be denied after eight (8) password failure attempts. Under normal circumstances, user account will be released automatically after 30 minutes.

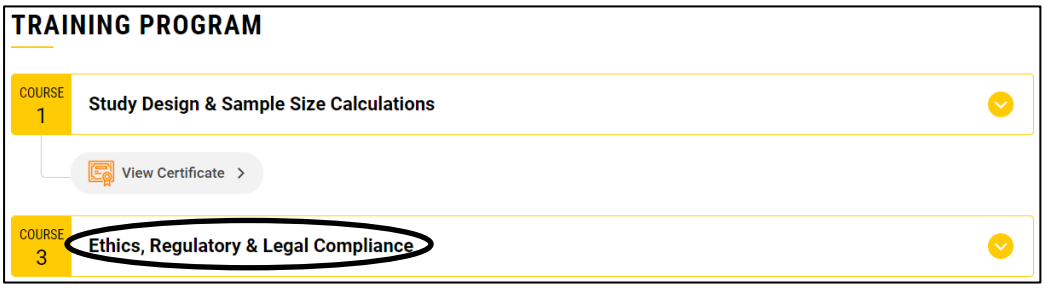
3.1.4 If you forget the user ID or password, please visit 'Forgot User ID/Password', and enter your user ID or email address used for registration. Your user ID and a link to reset password will be sent to your registered email address.

3.1.5 Users must inform the administrator immediately if there are any changes in your user profile. Please visit 'User Profile Change' (https://iis-ctc.hku.hk/user/profile) to provide your most updated information. An acknowledgement email will be sent to users after user profile change application is submitted. Users will receive another email once their information is updated.

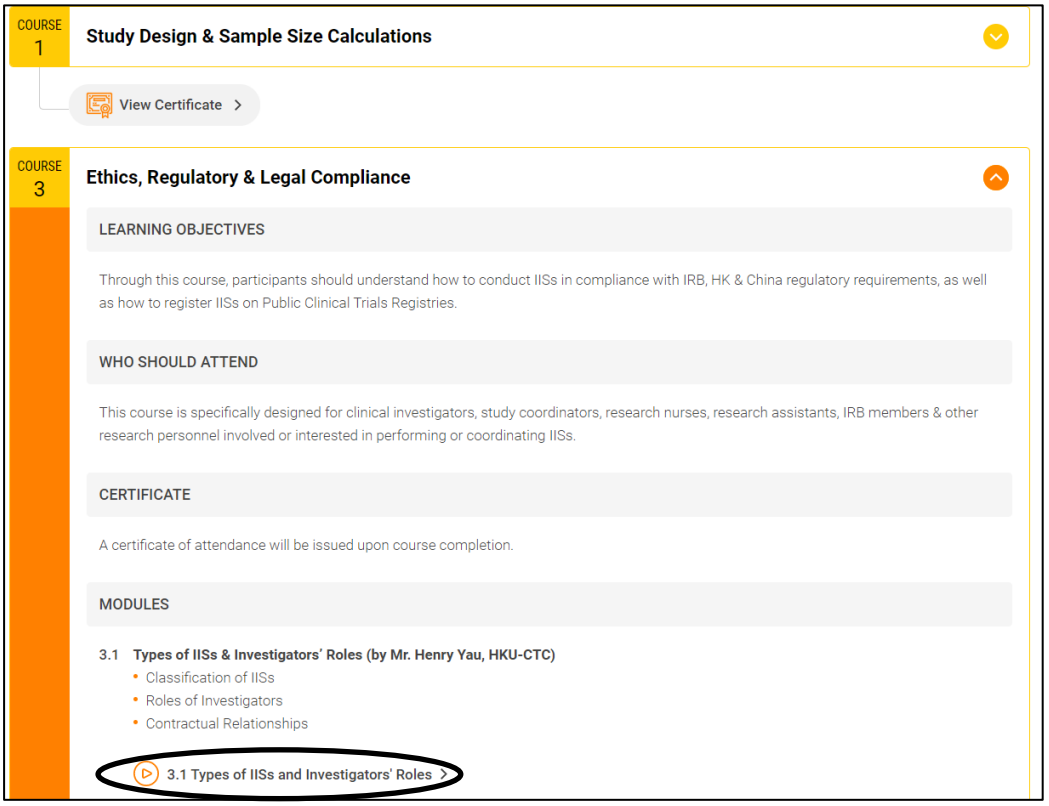
3.1.6 User account will be logout automatically after 30 minutes if it is left unattended. However, please always logout after use.

4. Training Program Related to Clinical Trial

4.1.1 Under 'Training program' (https://iis-ctc.hku.hk/training-program), users will have access to different clinical trial training courses based on their user types. You can choose the course you are interested to attend.

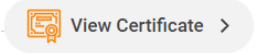


4.1.2 Select the module you would like to complete, and start watching the video.

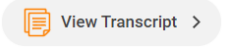


4.1.3 After watching each video, users must click 

to record their training progress.

4.1.4 After watching the video of all modules under each course, users will get a Certificate of Attendance, please click 

to preview or download the certificate.

The complete training record can be obtained by clicking 

.

5. Service Request

5.1 Starting a New Service Request

5.1.1 Study the flowchart (Appendix 1) and make sure the following information and documents are ready before starting a new service request.

(a) Registered email addresses or user IDs of PI and PIDs (step 5.1.3);
(b) Project information and documents for clinical trial insurance management service:
- IRB application form (step 5.2.1)
- Protocol (step 5.2.1)
- Informed consent forms in both English and Chinese, if applicable (step 5.2.1)
- Insurance policy or other supporting documents, if applicable (step 5.2.2)

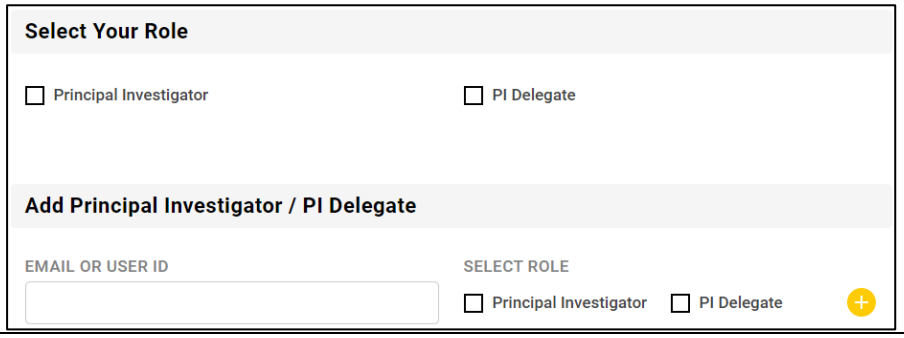
(c) Information and documents for clinical trial agreement vetting service, if applicable:
- Contact information of the supporting organization (step 5.3.1)
- Information of centres to be coordinated by HKU (step 5.3.2)
- Agreement draft in Word format (step 5.3.3)

(d) Clinical Trials Registration Identifier (acceptable to the ICMJE), if applicable (step 5.4.2).

5.1.2 Visit 'Service Request' (https://iis-ctc.hku.hk/service-request) and click NEW SERVICE REQUEST.

5.1.3 Service requester must select his/her role as either PI or PID, then add PI and/or PIDs by inputting their registered email addresses/user IDs and selecting their roles. Remember to click ⊕ to confirm the information. Wrong information can be removed by clicking ⊗.

- There must be one PI and at most two PIDs (i.e. PID1 and PID2).
- PI and PIDs must be Type 1 users.
- The PID who will be responsible for maintaining the REDCap Project(s) should be PID1.

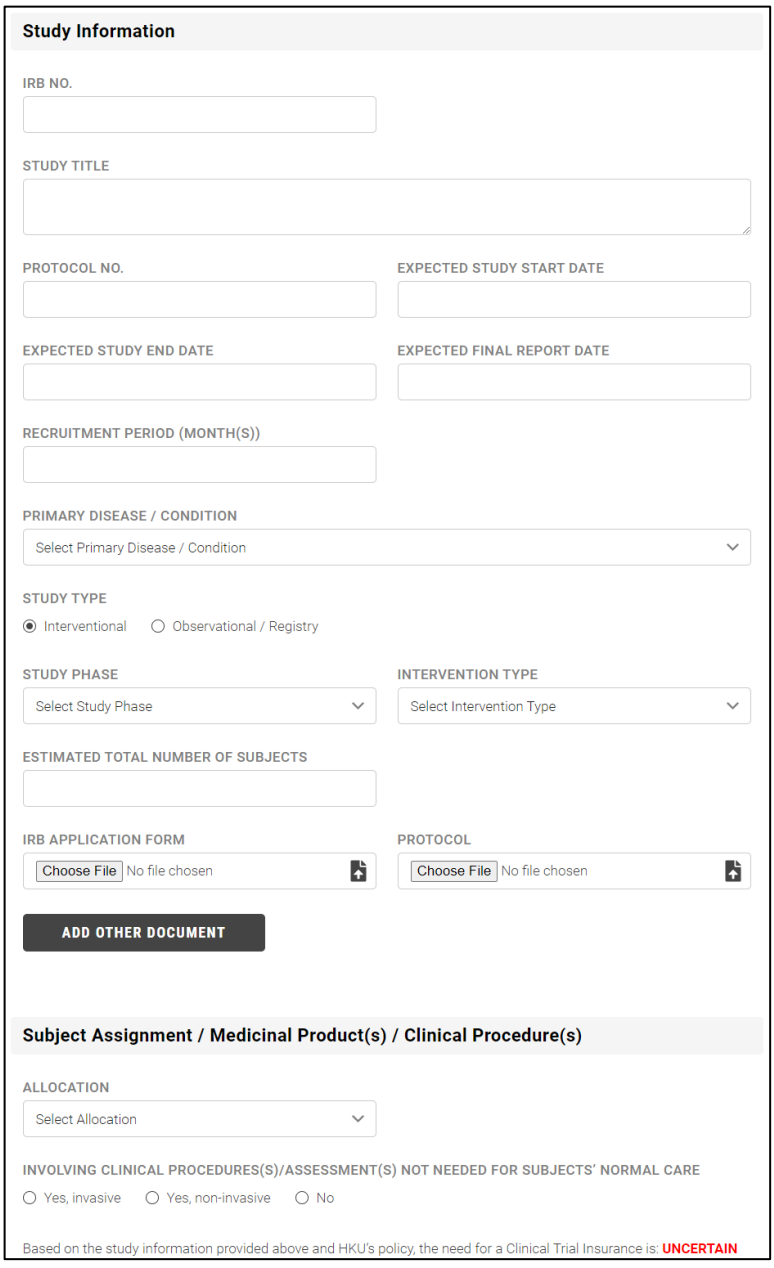


5.1.4 Remember to click SAVE to save any unfinished work as a draft. When you visit 'Service Request' (https://iis-ctc.hku.hk/service-request) again, you can find your draft and click Edit to continue.

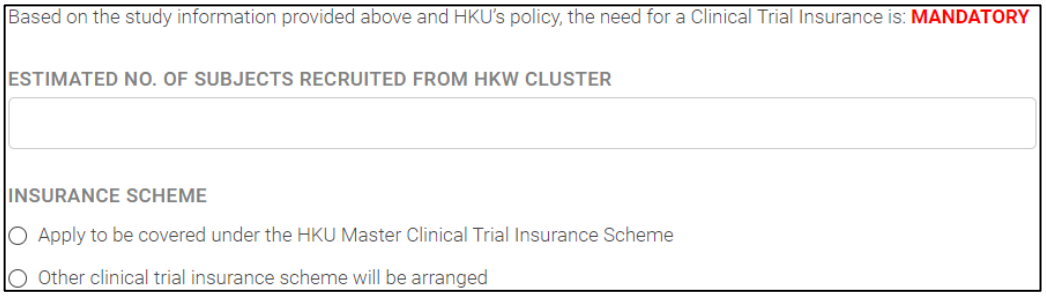
5.2 Clinical Trial Insurance Management Service

5.2.1 Study information, IRB application form, protocol and other documents (for example, informed consent forms in both English and Chinese) must be provided to evaluate:

- if clinical trial insurance is mandatory for the study; and
- if the study could be covered under the HKU Master Clinical Trial Insurance Scheme.

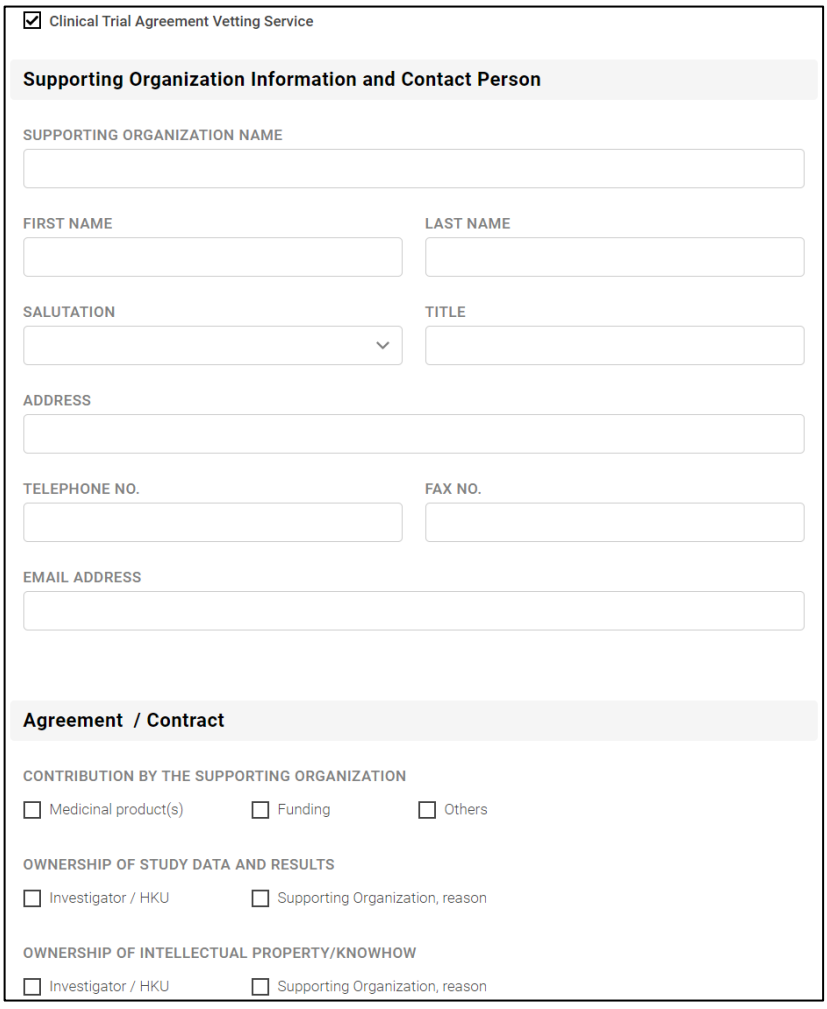


5.2.2 If insurance is **MANDATORY**, please provide the estimated number of subjects to be recruited from HKW cluster. Service requester may choose 'Apply to be covered under the HKU Master Clinical Trial Insurance Scheme' or 'Other clinical trial insurance scheme will be arranged'. If the latter is chosen, insurance policy or other supporting documents must be provided.

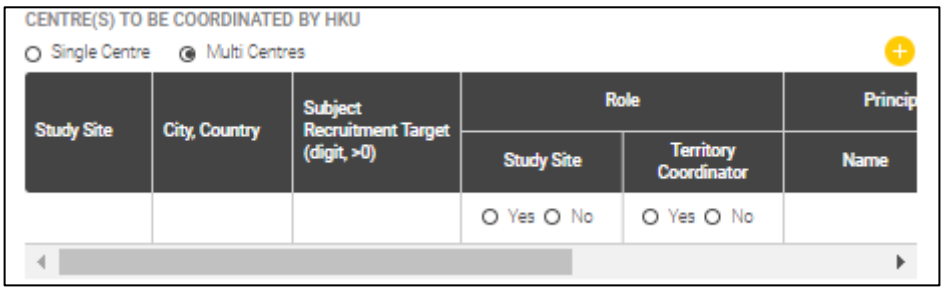


5.3 Clinical Trial Agreement Vetting Service (Optional)

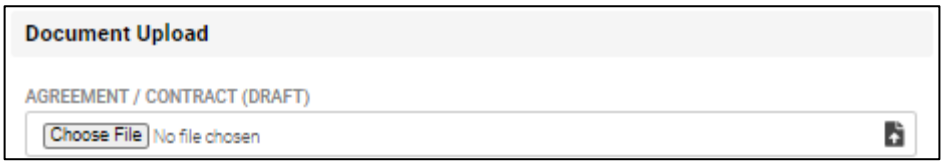
5.3.1 Please check the box of 'Clinical Trial Agreement Vetting Service', then provide the contact information of the supporting organization and details of the agreement.



5.3.2 Please indicate if it is a single-centre study or a multi-centre study. For multi-centre study, please provide the information of the centres to be coordinated by HKU.

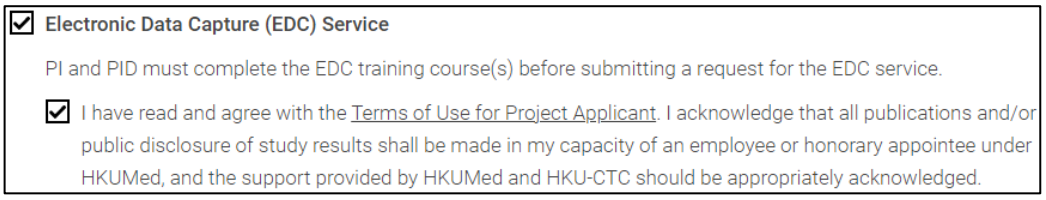


5.3.3 Please upload agreement draft(s) in Word format if there are any.

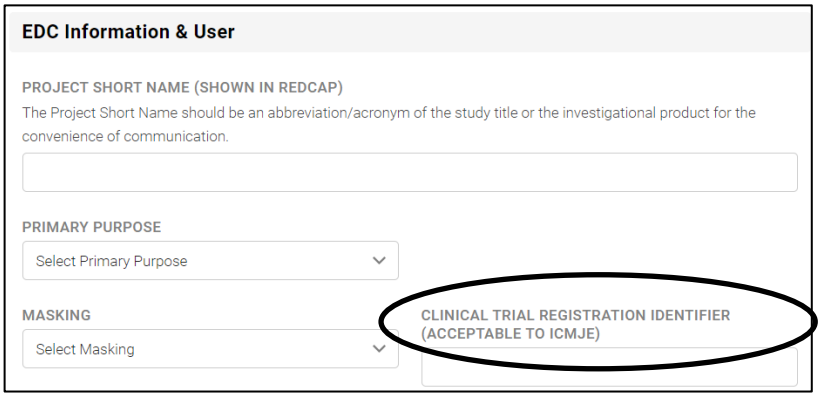


5.4 EDC Service (Optional)

5.4.1 Please check the box of 'Electronic Data Capture (EDC) Service'. This checkbox is available only if PI and PIDs have completed the EDC training course(s). The requester must also read and agree the Terms of Use for Project Applicant.

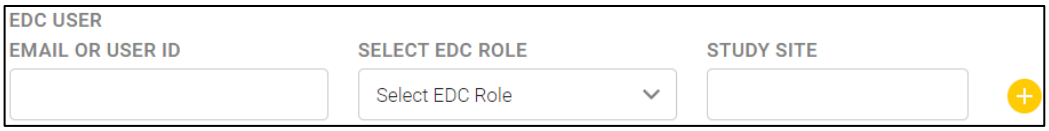


5.4.2 For an interventional study, EDC service will be provided only if the study is registered with www.ClinicalTrials.gov or other Primary Registry in the WHO Registry network and registration identifier must be provided. If you do not know how to register your study, please contact us.



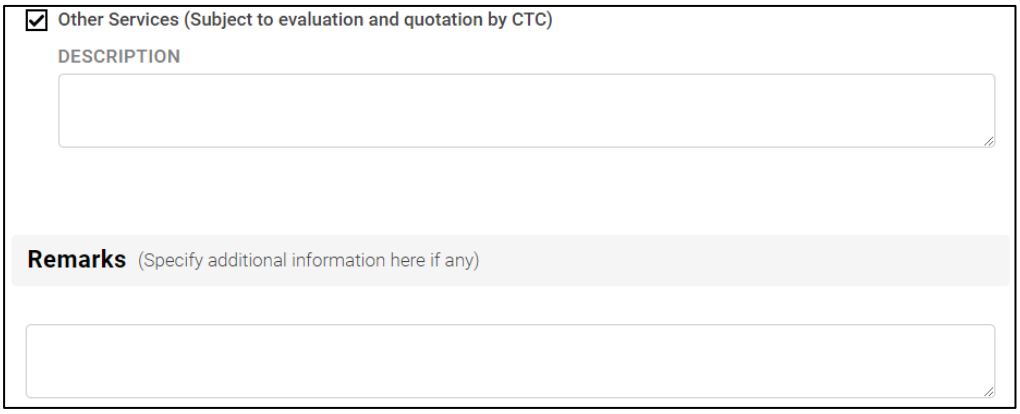
5.4.3 Please add EDC Users by inputting their registered email addresses or user IDs, then select their EDC Roles.

- For a multi-centre study: There must be at least one PID.
- For a double-blind study: There must be at least two EDC Users. At least one of the EDC Users will be unblinded. While the other EDC Users are blinded, the unblinded personnel (usually the pharmacist who prepares the study treatments) is responsible for the unblinded process of the study.



5.5 Other Services and Remarks

5.5.1 If other services are needed, please check the box of 'Other Services (Subject to evaluation and quotation by CTC)' and provide description of the request. Additional information could be provided in the 'Remarks' field.



5.6 Submitting for Verification

5.6.1 After providing all the required information and documents, please click SUBMIT FOR VERIFICATION. An acknowledgement email will be sent to PI and PIDs.

5.6.2 After administrator's verification, another email will be sent to PI and PIDs, asking the requester to check the service request, especially the changes highlighted in BLUE color. If the requester needs to update the information or the documents, please click EDIT and repeat step 5.6.1 until there are no more changes.

5.6.3 Finally the requester can click CONFIRM FOR VERIFICATION. An acknowledgement email will be sent to PI and PIDs. After administrator's review, results and follow-up instruction will be sent to PI and PIDs by another email.

6. EDC Service

6.1 Maintaining REDCap Project(s) for a New Study

6.1.1 If an EDC Service request is accepted, new REDCap project(s) will be created in production server and testing server within three (3) working days. The testing account information will be then emailed to PID1 (or PI if there are no PIDs).

6.1.2 PI and PIDs are responsible for testing and validating all data collection instruments and settings of the REDCap project in the testing server. When the testing is completed, PI and PIDs are responsible for copying all data collection instruments and settings from the testing server back to the production server.

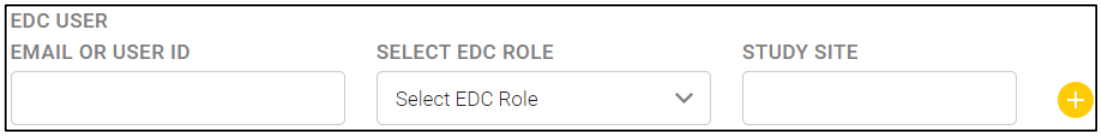
6.1.3 All EDC Users who have completed the EDC training course(s) can visit 'EDC Service' (https://iis-ctc.hku.hk/edc-service) and click View to get access to a maintenance page for the study. Only PI and PIDs can click Edit to update EDC status, EDC User, documents and other information. Some documents and data fields can only be updated by the administrator, please contact us for such changes.

Updated by PI and PIDs	Updated by Administrator
• PI Delegate • Study title • Protocol No. • Expected study start date • Expected study end date • Expected final report date • Recruitment period (Month(s)) • EDC User • Attachment • Request for Live • Close EDC	• Principal Investigator (PI) • IRB No. • Primary disease/condition • Study type • Study phase • Allocation • Estimated total number of subjects • IRB application form • Protocol • Project short name • Primary purpose • Masking • Clinical trial registration identifier • IRB approval letter • Certificate for Clinical Trial

6.1.4 Please click SAVE to confirm the changes and an acknowledgement email will be sent to PI, PIDs and EDC Users. The changes will be effective within three (3) working days.

6.2 EDC Users

6.2.1 PI and PIDs can change EDC Roles and Study Sites of EDC Users by adding and removing EDC Users. Access to REDCap project(s) will only be granted to who are added as EDC Users here and have completed the EDC training course(s).



6.2.2 For a double-blind study, an additional REDCap project will be created for treatment assignment/randomization in both production server and testing server. Access to that additional REDCap project in production server will only be granted to the EDC User assigned with the EDC Role of 'Builder & Unblinded'.

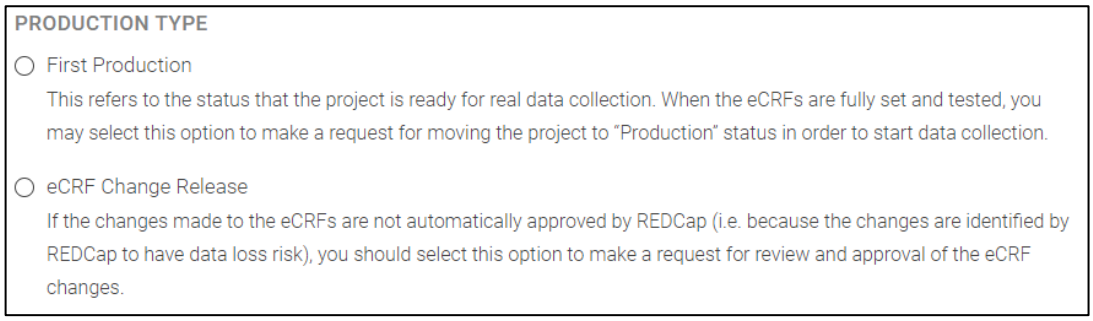
6.2.3 Please click SAVE to confirm the changes and an acknowledgement email will be sent to PI, PIDs and EDC Users. The changes will be effective within three (3) working days. Another email with information to get access to REDCap project(s) will be then sent to eligible EDC Users.

6.3 Request for Live

6.3.1 The default EDC status of a new study is 'Under Development' for development and testing. To update EDC status, PI or PID(s) must thoroughly validate all parts of the REDCap project(s), including but not limited to data collection instruments, events, randomization, user roles, DAGs (data access groups), data quality rules, etc., then click REQUEST FOR LIVE.

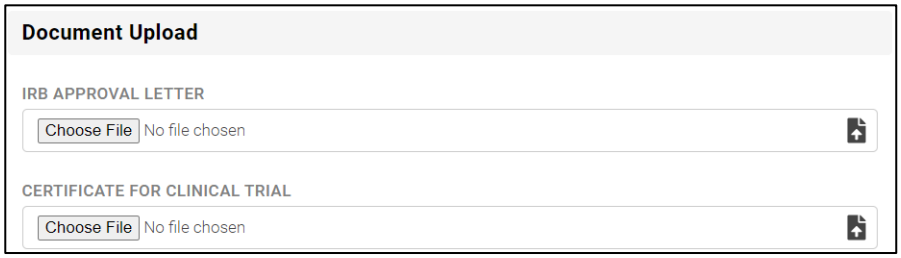
6.3.2 Select the appropriate 'Production Type':

- First Production (step 6.3.3);
- eCRF Change Release (step 6.3.4).



6.3.3 First Production

(a) IRB approval letter (and Certificate for Clinical Trial, if applicable) must be uploaded along with the request.



(b) If the request is accepted, the REDCap project(s) will be moved to 'Production' within three (3) working days. The test data will be then deleted and cannot be retrieved.

6.3.4 eCRF Change Release

(a) A request should be submitted for changes that are not automatically approved by REDCap (e.g. fields deleted, multiple-choice options deleted, field type changed, etc.).
(b) If the request is accepted, the changes will be released within three (3) working days. Any deleted data due to the eCRF change release cannot be retrieved.

6.3.5 Completing the Process of 'Request for Live'

(a) Additional information could be provided in the 'Remarks' field.
(b) After providing all the required information and documents, please click SUBMIT.
(c) An acknowledgement email will be sent to PI and PIDs. After administrator's review, results and follow-up instruction will be sent to PI and PIDs by another email.

6.4 Close EDC

6.4.1 If you do not need the EDC service for this study anymore, please click CLOSE EDC.

6.4.2 Email alert will be sent to PI and PIDs and all the REDCap project(s) related to this study will be closed within three (3) working days.

Appendix 1:
Flowchart of Service Request

Service request statuses are listed in the left column and the corresponding actions are shown in the right column. Service requesters should perform actions highlighted in yellow.

