ECOS

Questions and Answers from ECOS Trainings

The questions are from the following trainings:

- The New IRB Application Form and Minimum Training Requirements (8, 13 and 21 Mar 2024 in SingHealth, KKH and CGH respectively)
- Navigating the Ethics & Compliance Online System (23, 26 and 30 Apr 2024 in KKH, CGH and SingHealth respectively)

Version dated 8 May 2024

SingHealth
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General

1. **Is ECOS a merging of online systems or a merging of IRBs (CIRB and DSRB)? If CIRB and DSRB remain separate, would submission and reporting requirements follow CIRB or DSRB guidelines?**

   ECOS is a merging of SingHealth iSHaRe and NHG ROAM online systems. CIRB and DSRB remain as separate IRBs. Please follow the submission and reporting guidelines of the reviewing IRB. CIRB and DSRB has harmonized the application form and other forms. Investigators will use the same form with a common set of questions for submissions to either CIRB or DSRB.

2. **Can ECOS be accessed using personal devices?**

   Yes, ECOS is internet facing and can be assessed using personal devices.

3. **Will ECOS be a whitelisted website, so download/upload can be done using corporate devices?**

   Yes, ECOS is whitelisted and accessible through Healthcare Virtual Browser (HVB).

4. **Since ECOS can be accessed through the Internet, can anyone (e.g. medical students) register for an account before being part of specific research projects?**

   You may create an account, but please assess whether you need to be added to the IRB application. There is no need to create an ECOS account if you are not the PI, Site-PI or Co-I of the research. ECOS accounts expires after 90 days and your password needs to be updated regularly to prevent expiry.

5. **Would there be any restriction on the type of file downloads/uploads?**

   File size limit is 400MB. When uploading the various file types, e.g. pdf, doc, png, jpeg, etc. Please ensure the file extension is in lowercase, i.e. png instead of PNG. Upload of video is discouraged.

6. **I have both iSHaRe and ROAM accounts, will the studies I am involved in from both accounts be ported over?**

   Your login credentials will be determined based on your primary employment. For instance, if your primary appointment is under SingHealth, your login ID will be your SingHealth M365 email address. If you have studies in both iSHaRe and ROAM, they will be consolidated into a single account. For example, if you are a SingHealth user having both iSHaRe and ROAM accounts, your M365 email address in iSHaRe must also be the email address in ROAM account. This allows the studies from both systems to be migrated to the same account.

7. **For PIs with multiple appointments (e.g. SingHealth Institution and Duke-NUS), is there a preferred appointment and email address to be added in their CRMS profile?**
   If you have a SingHealth appointment, you should use your M365 ID to log in. Some persons may have multiple appointments, but they should only have one M365 login account. When using the M365 email to create their user ID, they can include multiple appointments in that particular login.

   For instance, if a doctor has appointments at a SingHealth Institution and Duke-NUS, both appointments should be added to their profile. We encourage setting up 2 different accounts. One account using M365 given by SingHealth and another account using the Duke-NUS email address. Should the person cease employment with SingHealth, studies in the Duke-NUS account is not affected.

   For studies conducted under the SingHealth appointment, the SingHealth appointment should be selected, and it will be routed to the SingHealth ROC for check and DR/IR for endorsement. Similarly, if the study is conducted under the Duke-NUS' capacity, the doctor's profile under their Duke-NUS appointment should be added/selected.

8. **For sponsors' user accounts, must we create a new account on ECOS using the email linked to iSHaRe?**
   For non-PHI users, if you previously had an account in iSHaRe, you may use the email address with the 'Forgot Password' feature to reset your password.

9. **The same sponsor may authorise different CROs to manage different trials. Does it mean each CRO must create an individual account in CRMS for each sponsor we work with?**
   We understand this is a common practice where the sponsor will engage different CROs to manage different trials. For each trial, the respective CRO personnel, e.g. CRA, can be added as needed to the User Authorisation List (UAL) in the CRMS module. There is no need to create a separate account for this. Please refer to the FAQ section on CRMS – User Authorisation List and Study Member Review to understand more related questions.

   If the sponsor engages different CROs to manage different aspects of the same trial, for example, CRO-A for the start-up portion, and CRO-B for monitoring/operation portion, both CRO personnel can be added to the UAL of the same study. However, please first ascertain the need to be added to the UAL, i.e. access requirement to IRB and CRMS modules. Please also keep the PI/Site-PI well-informed about this arrangement, this will also aid them when performing user endorsement on the Study Member Review page. A gentle reminder for the

study team to deactivate users who no longer require access to the IRB or CRMS modules, e.g. consider deactivating CRO-A personnel once the start-up portion has been completed.

10. **Can ECOS be assessed by non-SingHealth/non-PHI individuals for example by CRO/Sponsor via Microsoft Authenticator to provide support in application form submission and review?**
    Sponsors will continue to have access to the Application Form/ECOS to support the PI. However, you will need to be added and approved by the PI in CRMS before you can have access to the Application Form. ECOS can also be accessed via internet.

11. **Will non-SingHealth co-investigators be able to register for an ECOS account?**
    Non-SingHealth co-investigators will be able to register for an ECOS account. However, please assess if the external user needs to be added to the study. If the person will not be performing research activities at the study site, they do not require IRB approval and do not need to be added to the study.

12. **What will happen if my ECOS account is disabled due to 90 calendar days of user login inactivity?**
    You would not be able to login to ECOS. Please refer to the ECOS Account Registration Guide for more information.

13. **For download center, what does it mean by downloaded files will only be available for downloading to local for 7 days only?**
    The files in download center are stored for 7 days only. If you wish to download the file in local, you will have to perform the export function again.

14. **When will the track changes and export function be available?**
    Both functions will be available in Q3 of FY2024.

15. **What are the potential risks that might occurr with the use of track changes and export function before they are fully developed?**
    As both functions are still under development, there might be missing or inaccurate information in the track changes or PDF output. The functions are retained in the system for users who may still find them useful in the meantime. However, please do not use the outputs as official copies.

16. **Will it be possible to download the query list and responses as PDF files in July for ISF/ETMF filing purposes?**

The export function is still under development, please use it with caution. Queries currently will be exported in Excel format, and may require editing for clarity. However, in the final product, queries will be exported as PDF files, allowing for clearer visibility of both the questions and responses.

17. Will there be recordings of the trainings available?

The recordings of all ECOS trainings are uploaded in SingHealth eLearning Portal and accessible to SingHealth staff only.

Minimum Training

1. **Are the minimum training requirements applicable only to PI or is it applicable for Co-I and Site-PI as well?**
   Please refer to RICE website for the training requirements.

2. **Could you confirm that the PI, Site-PI and all Co-Is need to complete the minimum training requirements to access and create application forms?**
   For access to ECOS or to start a draft, you can do so even without completing the minimum training requirement. However, the draft application/amendment cannot be submitted if the minimum training requirement is not met. It must be completed before an IRB application/amendment can be submitted.

3. **Are the minimum training requirements for study team members the same?**
   Please refer to RICE website for the training requirements.

4. **Regarding minimum training, would study team members like nurses, pharmacists, radiologists, and study coordinators need GCP and CITI certification by 1 April 2024?**
   There are no changes in the requirement for CITI Biomedical Research Investigators and Key Personnel certification as it applies to all study team members. However, previously, GCP certification was only mandatory for the PI and Site-PI. Starting from 1 Apr 2024, it will apply to all study team members. For more details, please refer to the CIRB update (1 Feb 2024). A PnP document regarding the minimum training and requirements for investigators and study team members is also linked in the update, specifying that GCP training is mandatory for all study team members conducting research-related activities in a clinical trial.

5. **Can CRCs help the PI and Co-I to update their minimum training certificates on CRMS? Or must the PI do it themselves?**
   The PI and Co-Is will need to upload the certificates through their profile page. The profile page is accessible by the account owner only.

6. **Will Study Team Members be able to view the profiles of other users? For example, to check whether the PI and/or Co-Is have included the necessary details?**
   Yes, STM/SA/SS can view the profiles of other users and ensure they have completed the necessary training.

7. **Can PI endorse STMs that have not completed the minimum training?**
   The PI is responsible for the conduct of the study and that study team members involved have completed the minimum training required. It will be a non-compliance if study team members who conducts research activities do not have the minimum training requirements. We advise the PI to take the appropriate actions as required.

8. **As PI is now responsible to ensure that the investigators and study team members met the minimum training requirement, how do the PI check this information?**
   PI can either review the study team members' user profile on ECOS or have their minimum training certificates filed in the Investigator Site Files (ISF).

9. **If the CITI certification for a study team member has expired, will the minimum training secretariat/CIRB reject the application and return it to PI?**
   There is no validity check on the certifications for now. However, the requirements may change. It's a good practice to maintain a valid (non-expired) certificate.

10. **Do non-PHI Co-Is and study team members need to submit HBRA certification in ECOS?**
    Non-PHI Co-Is must also complete and submit the CITI Biomedical Research Investigators and Key Personnel certification in ECOS. If they are taking part in studies on site under the purview of HBRA, the SingHealth HBRA Essentials training certificate or equivalent must be submitted. If they are taking part in the clinical trials on site regulated by HSA, ICH-GCP course certification must be submitted.

11. **Is there cross-institutional recognition of the HBRA training cert?**
    HBRA training certificates from other institutions will be recognised.

12. **Do NHG investigators need to provide CITI training certification for studies intended for submission to CIRB, even if it's not a requirement under NHG's minimum training standards?**
    For NHG Site-PIs and Co-Is, their minimum training will be reviewed based on NHG's requirements by NHG Minimum Training Secretariats even the studies will be reviewed by CIRB.

13. **Could you explain more about the minimum training for clinical trials again? Are the GCP courses FOC now?**
    SingHealth staff can access the CITI GCP course on the CITI platform for free. A certificate of completion from any ICH-GCP course providers (including online providers) is acceptable.

14. **Which e-learning platforms include local elements in the GCP course material?**
    In general, a GCP certificate from any provider is acceptable. Please refer to RICE website for more info.

    However, you will need to cover the local GCP elements with your study team members separately (i.e., during site initiation) so that everyone is aware of the local requirements. The RICE slides Guide for Site Initiation Visit (SIV) Training for an Investigator-Initiated Trial (IIT) contains the local elements, please consider using it to supplement your site initiation meeting.

15. **For the minimum training requirements regarding GCP certification, can local GCP certificates be used? Can GCP certificates from 2010 be used?**
    SingHealth has aligned with HSA's practice to accept GCP certification from any providers. e-Learning courses may be utilised to complete the GCP certification requirements. However, it is important to note that if you are conducting a clinical trial in Singapore, knowledge of the local elements of GCP is essential. To ensure all your study team members are aware of the local requirements, we recommend that a refresher is conducted at every project site initiation.

    You may use the RICE slides Guide for Site Initiation Visit (SIV) Training for an Investigator-Initiated Trial (IIT), which contains the local elements, for this purpose.

    Regarding certificates obtained in 2010, it is unclear which version of GCP was applicable at that time. Currently, SingHealth adheres to the E6(R2) guideline for GCP. Please note that ICH GCP E6(R3) is set to be introduced internationally by the end of this year. The updated version will entail significant changes. We anticipate that HSA will align with these changes and may require everyone to undergo training for E6(R3).

16. **In ECOS, the GCP certificate has no expiry date. However, if a sponsor requires the GCP to be renewed every three years, would the site need to upload the latest certificates in ECOS?**
    ECOS does not keep track of the GCP certificate expiry currently, following the institution's policy which may change to include valid-till date for certification when there are new guidelines from HSA, considering the upcoming ICH GCP E6(R3) guidelines. The same practice will also apply to sponsored studies. However, sponsors' requirements must be fulfilled, as necessary, and maintained in the Investigator Site File.

17. **Do Study Team Member (STM), Study Administrator (SA) and Study Sponsor (SS) needs to fulfill the minimum training requirement?**

    For STM, SA, and SS, if the training certificates are not uploaded in ECOS, this will not affect the submission of the IRB application form in the IRB module. However, the minimum training requirement for STM will still apply if they are involved in the conduct of the study. The PI is responsible in ensuring all study team members have met the minimum training requirements. STM may continue to upload the minimum training certificates on ECOS to allow PIs and those listed in the user authorization list to view the certificates. Their training certificates should be filed in the Investigator Site Files (ISF) and compliance with the minimum training requirements will be reviewed during monitoring, audits and inspections.

    Training certificates of SS are not required to be uploaded to ECOS. For SA who are typically helping with administrative matters of the study management are usually not delegated, hence training records are not required for monitoring/audit/ inspection.

18. **Do PI, Co-I and Site-PI need to submit their CV, GCP or medical license?**

    ECOS does not require the uploading of CVs. When users first log in, the system will prompt them to fill in the Minimum Training Profile with details including their primary/secondary appointments, academic qualifications, and minimum training certifications (for example CITI Key Biomedical Personnel, HBRA, GCP). A medical license is not required to be submitted on ECOS.

19. **CV is no longer required to be submitted on ECOS. Does a copy of CV still need to be maintained in the ISF?**

    Yes, CVs are still required to be filed in the ISF, in accordance to ICH E6(R2) GCP.

20. **Must the CV still be renewed every 2 years?**

    ECOS only requests for a small amount of information, such as employment and training history. Until the current requirement for CVs is changed, there is no need to renew the CV every 2 years.

    However, a current/ up-to-date CV should be maintained in the Investigator Site File, thus CV should be reviewed regularly (e.g. every 2-3 years) or updated when there are significant changes. It is recommended that CV is signed and dated.

    While the IRB and ECOS requirements pertain to study application, it's essential to adhere to cluster, institution and/or sponsor's policies as well. These policies may dictate additional requirements for various reasons, and it is crucial to ensure compliance with them.

21. **Why is it still necessary to maintain hard copy CVs, minimum training certificates, email correspondences, IRB application forms, etc?**
    At current, the available systems used to store electronic records (e.g. network shared folders) do not meet the regulatory requirements for electronic records. Until a validated system is available, paper records should be maintained in the Investigator Site Files.

22. **How much time does it take for the Minimum Training Secretariat (MTS) to review the minimum training certificates?**
    MTS is from the institution's Research Office. Please check with your Research Office on the review time.

23. **As the Minimum Training Secretariat assigned by my institution's Research Office, will there be a training session instructing us on how to conduct checks?**
    A separate training has been conducted for the Research Offices. You may wish to approach your colleagues for the slides or write to irb@singhealth.com.sg for assistance.

Institutional Review Board (IRB)

IRB – General

1. **Is there a downloadable soft copy application template from ECOS?**
   Yes, you may click here to download the soft copy application template.

2. **Are there any changes in the frequency of DSRB and CIRB full board reviews?**
   You can find CIRB Full Board meetings date published on the CIRB website.

3. **What is the timeline for IRB approval for new submissions in ECOS?**
   For studies that require exemption and expedited review, the review will take 30 working days **excluding** PI reply time. For studies requiring full-board review, the review would take 60 working days **excluding** PI reply time.

4. **Must it be the PI who initiates new applications? Can the study coordinator initiate it?**
   Study Coordinator can create a new application in ECOS.

5. **If the overall PI is based in NUS/NTU but participants are recruited from SingHealth hospitals, will it have to be reviewed by CIRB via submission through ECOS?**
   Please discuss with your research office if the application should be submitted to CIRB. The research sites should have a valid IRB approval for the research to be conducted at the site(s).

6. **For cross-cluster studies with a PI from NHG as the main PI, does the SingHealth PI need to complete the FCOI module?**
   Yes, the SingHealth PI will need to complete the FCOI. NHG PI as Lead PI means the study will be reviewed by NHG DSRB. FCOI information is required by NHG DSRB for the review.

7. **If the study involves both NHG and SingHealth sites, can either PI or Site-PI endorse the submission of Amendment, Study Status Reports, DNC and SAE reports?**
   For studies involving NHG and SingHealth sites, the overall PI does declaration for Amendments, Study Status Reports and Deviation/Non-Compliance forms. For SAEs, since there is a short time window for reporting, the Site-PI and Co-I can also declare and submit.

8. **Can a non-PHI user be the PI?**
   For the overall PI, he/she must be from a SingHealth Institution or an institution that is under the IRB purview.

9. **For a study conducted in the community, would the study site be the applicant institution?**
   The study site would be the institution of the PI.

10. **If the Co-I rotates between different sites, should they be added as Co-I for all sites?**
    The Co-Is must be added in both sites to perform study procedures at both sites.

11. **Under ECOS, would all members on the study site (for example investigators, coordinators, pharmacists, nurses, etc) need to be submitted as study team members in the Clinical Research Management System (CRMS)? Or would just adding the investigators be enough?**
    Investigators (PIs/Site-PIs and Co-Is) will be managed through the IRB form on ECOS, there is no need to add them in CRMS as this information will be pulled from the IRB module into CRMS. As for Study Coordinators, Nurses, Pharmacists, they can be added as Study Team Members (STMs) in CRMS if they require access to CRMS and IRB modules. Protocol administrators can be added as Study Administrators (SAs), and sponsor personnel as Study Sponsors (SSs). It is not mandatory to include all STMs in the User Authorisation List in CRMS, site can limit the number of users added to the UAL based on their needs to access CRMS and IRB modules. However, all STMs directly involved in research at the study site must be properly delegated on the delegation log.

    It is the responsibility of the PI/Site-PI to ensure that the Study Team Members who are directly involved in the research have the relevant training and are qualified to participate in the research.

12. **Is it true that no amendment is required to add new members to the study?**
    It depends on the role of the new member. Changes in PI, Site-PI or Co-I would require IRB approval and an amendment form needs to be submitted. Changes in Study Team Member and Study Administrator will no longer require IRB approval. They can be managed through the CRMS module on ECOS, if applicable.

13. **Can collaborators outside of SingHealth (such as individuals from A*STAR or Duke NUS) be added as Study members? Would they need an ECOS account as well?**
    Yes, if these collaborators are performing research activities in NHG or SingHealth sites and require access to the IRB module, they can be added in CRMS. They would require an ECOS account as well.

14. **Do statisticians that analyse de-identified data need to be included in the CRMS module in ECOS?**

    Statisticians who are only involved in the statistical analysis work need not be included in ECOS.

15. **Can Duke-NUS medical students be added as ECOS study team members as PI assign them to help clinicians extract patient information such as BMI, cholesterol from EHR to obtain a demographic table of the research participants?**

    The Duke-NUS medical students could be added if they are performing study related procedures that are not standard of care.

    The PI is responsible for the delegation of Study Team Members who are directly involved in research and documented in a delegation log. For non-Investigator Study Team Members, they may be added in CRMS module, if required.

16. **It was mentioned that the application can be unlocked for editing. At which point can it be unlocked? The period between finalisation and before the PI's declaration? Or even after PI has declared?**

    After the application form is finalized and Pending PI Declaration, those who are listed on the IRB application or CRMS can click on the "Edit" to continue with the editing and submit it again for PI declaration. Once PI has declared, the application will be routed for Research Office Check, DR endorsement and IR endorsement.

17. **If a study site is added subsequently as an amendment, does it still need to be endorsed by the research office, DR and IR?**

    If there is an addition of a study site or a change in the PI or Site-PI, the amendment form will need to be endorsed. However, differing from the iSHaRe process, when a new study site is added only the new site will need to undergo endorsement.

18. **Do non-investigators e.g. study coordinators, pharmacists and nurses, etc require CIRB approval before delegation of roles? For DSRB, there is no requirement for non-investigators to be approved before the delegation of roles.**

    With effect from 1 Feb 2024, only Investigators (i.e PI, Site-PI and Co-I) need to be approved by the CIRB. Other Study Team Members (e.g. Study Coordinators) do not require IRB approval. The PI/Site-PI should manage the Study Team Members independently. These Study Team Members may be listed in CRMS.

19. **Where can the study amendment cover note and amendment form be found?**
    Ongoing approved studies will be migrated to ECOS by end May 2024. Please raise the amendment thereafter. When you raise an amendment, the Cover Note will appear for completion before you edit the form.

20. **The buttons such as withdraw and accept rejection look alike and may facilitate accidental deletion of the form, is there an undo feature if that happens?**
    The buttons cannot be changed. Therefore, we advise users to read the text carefully.

    Please note if the PI selects the option "Accept Withdrawal" or "Accept Rejection", the form will not be deleted, but they will not be able to proceed further.

    The withdrawal button is only visible to the PI. If the form is in the endorsement stage, the PI should be cautious before clicking withdraw because it will withdraw the entire submission. However, if the submission has reached the IRB, clicking withdraw will send a withdrawal request to the IRB Secretariat for review.

    Please note that if the IRB has already initiated the review, fees may still apply even if the withdrawal request is made. Therefore, it's advised to withdraw an application as soon as possible if needed or consider carefully before submission.

21. **Will submission to CIRB and DSRB be using the same forms?**
    Yes, all forms for CIRB and DSRB will be the same except for the DSRB UPIRTSO form used to report safety events.

22. **I understand that DSRB has templates for their Investigator Site Files. Will there be standardised templates for SingHealth researchers to use for their ISFs in the future as well?**
    Please refer to Docupedia > Group Research > Office of Research Integrity and Compliance> Other Documents > Site Tools & Resources> Investigator Site File Table of Content.

23. **DSRB reviews STR collection. Will IRB review STR collection as well or still need to reapply? If approval under DSRB, STR submission not required?**
    The IRB reviews the ethics of the study protocol including the types of samples required and used for analysis. Please follow the tissue bank requirements for the request of your samples from the tissue bank.

24. **With the addition of billing details on the ECOS form, does it mean that study teams will no longer need to confirm the invoice recipient via email? If so, would the invoice processing timeline change?**

    For Pharmaceutical/ Industry sponsored trials, CIRB will continue to contact the Sponsor/CRO via email to confirm the billing details before raising the invoice as the information in CRMS may not be updated in time.

    Please note that the invoice processing timeline is about two to three weeks.

25. **For Waiver of Documentation of Informed Consent, does it mean that there will be no screening or enrolment log?**

    If the IRB approves the waiver of documentation of informed consent, it means that the research participants will not be required to sign the Informed Consent Document. However, you are still required to maintain a log for your screening and enrolment activities.

26. **For multisite collaborations, a data-sharing agreement is required. Is this the case for ECOS as well?**

    Yes, there are no changes in cluster and institution policies.

27. **For ECOS, which roles are allowed to submit SAE and/or DNC forms? Some IRB online systems only allow the overall PI to submit.**

    In ECOS, PI can submit all form types. SAE Report Forms can be submitted by either the PI, Site-PI or Co-I.

28. **Can we report multiple events in one DNC form?**

    Each event should be submitted using one Study Deviation/Non-compliance Report Form. However, if the same event happened to a few participants, the PI could describe the event and list the affected participants' identifiers in one Study Deviation/Non-compliance Report Form.

29. **For studies migrated to ECOS, will the application form need to be redone to fill in data fields that are not on the current iSHaRe application form?**

    There will be additional questions on the ECOS application that are unfilled after data migration. When an Amendment form is raised, ECOS will prompt users to fill in the new questions. However, there is no need to rush to edit the application form. The additional questions only need to be filled in when an amendment form is submitted.

30. **Are there forms that we need to resubmit on ECOS once it is launched (for example forms that were submitted in hardcopy form via email)?**
    Yes, forms submitted in hardcopy via email will need to be resubmitted on ECOS.

31. **What if there are no amendments until the end of the study? Do we need to submit an amendment form to answer the new questions on ECOS?**
    No, a submission of amendment is not needed. Please submit a Study Status Report (SSR) form upon study completion.

32. **For closed studies that will not be migrated to ECOS, how should the Final Clinical Study Report be submitted to CIRB?**
    Please submit the Final Clinical Study Report to the Board Secretariat via email as an Other Reportable Event (ORE).

33. **If studies that are under different institutions for example NHG, NUHS and SingHealth have received IRB approvals from their respective IRBs, can the de-identifed data be combined for analysis as one collaborative study?**
    Ethics approval is typically granted for a specific study. For a new study (whether de-identified or combined studies), the ethical requirements for the new study will be considered separately.

34. **Is it possible to export the data entered into CRMS, such as recruitment numbers, for use in generating study status reports?**
    The information in the CRMS module is not directly linked to the IRB module. Thus, it would still be necessary to manually enter the information into the IRB forms.

35. **What is the designated timeframe for submitting Study Status Updates?**
    Study status updates should be submitted at least once a year for the annual renewal and when there are updates to report to the IRB regarding the study.

36. **Is there a specific timeline for the study team to notify the CIRB about a change in study status from ongoing to suspended?**
    The PI is required to inform the IRB by submitting the study status report form within a period of 7 days.

37. Would CIRB be willing to review private institutions as study sites if there are also sites from NHG or SingHealth?

CIRB may review studies conducted in other institutions if prior arrangements have been made. For example, a Research Institution (RI) appointing CIRB as the IRB or if SingHealth is providing RI oversight for a non-RI.

38. Will there be fees charged for the submission of amendment and renewal forms?

Yes, amendment and renewal fees are applicable to industry sponsored studies.

IRB – Application Form

1. **Who have access to edit the application form?**
   Investigators listed in Section B2 of the application form and study roles added in CRMS would have access to IRB module to edit IRB forms.

2. **To draft the initial IRB Application Form, does PI need to add the study administrator?**
   The ECOS system offers flexibility in the drafting of an IRB Application form. If the PI initiates the IRB Application Form, the PI can add STM/SA/SS to the UAL in CRMS if the PI requires assistance from the STM/SA/SS to complete the form. Alternatively, the IRB Application Form can also be initiated by a STM/SA/SS. When the form is saved for the first time, the STM/SA/SS will be prompted to select a Site and Role for the system to add the STM/SA/SS to the UAL in CRMS. This will allow the user to have continued access to the IRB Application Form in the IRB module.

3. **Could a glossary of the terms used on the ECOS form be provided? For example- What is defined as a software, what is defined as a mobile app, etc.**
   Please refer to the IRB Guidebook on the terms used in ECOS Application Form. For definition related to digital health, please refer to HSA website.

4. **If a project involves collaboration between two medical specialties, which Board should the application be submitted to?**
   Please select the specialty that you believe is the closest match to your study. If the IRB determines that the submission should be submitted to a different board, they will transfer the study if necessary.

5. **What does it mean by entering a site with different locations on the ECOS form? Is it referring to satellite sites?**
   For institutions where there are more than one location such as SNEC, the institution will determine the locations. The drop-down list of location will be provided by the research office for configuration in ECOS. Therefore, please consult your research office to determine the locations that need to be indicated for your studies, where applicable.

6. **Do we need to add all locations/sites where participants will visit for any study procedure on the ECOS form? What about non-SingHealth facilities?**
   Please first consider if the location/site is considered a research site. If the site is performing significant study procedures such as investigational product administration, the site will need to be listed as a study site on the IRB Application Form.

7. **If the IIT is international in scope, do we need to include the information from overseas sites?**

   If there are other sites involved, you may enter the information in Section B3 of the application form. However, do note that it will be for information only and not for IRB approval.

8. **Under what circumstances would the IRB request for an application form to be converted from an exemption application to a full application for a study collecting data retrospectively with waiver of consent?**

   The IRB will inform the study team if a study does not meet the criteria of the selected exemption category. In that case, the form will have to be converted from an exemption application to a study application form. Please note that the form would require re-endorsement after changing the study type.

   Some reasons why a study would be converted from an exemption application to a full application could be that for example - the study is non-exempt from HBR or the study team collects a list of identifiers at any point in the study.

9. **Would a study analysing existing blood test results of an outbreak/exposure be under the purview of HBRA?**

   The study would fall under the purview of HBR if it meets the definition of HBR as per HBRA Section 3.

10. **What is the difference between studies classified as non-HBR, clinical trials and "others"? If studies are either clinical trials (regulated by HSA) or those not regulated by HSA (HBR). What are non-HBR studies?**

    For studies that meet the definition of Human Biomedical Research (HBR), they are regulated by HBRA. Clinical trials are governed by either the HSA Health Products Act or the Medicines Act. Therefore, if you are required to submit to HSA for Clinical Trial Authorizations (CTA), Clinical Trial Notifications (CTN), or Clinical Trial Certificates (CTC), you should select "Clinical Trials" in Section D2. For studies that do not fall under the definition of HBR and are not clinical trials, they are classified as non-HBR and the option "Others" should be selected.

11. **Will a study that involves interviewing children and audio recording the interview qualify for an Exemption application?**

    Studies involving interviews with audio recordings of children cannot be exempted under any of the exemption categories.

12. **For clinical trials that involve the use of medical devices falling under the purview of HBR, do we select HBR instead of clinical trial in Section D2 Study Classification?**
    At Section D2, please select HBR as the medical device trials are regulated under the Human Biomedical Research Act.

13. **Under Section D3 of the ECOS Application Form, what does the option "medical records review" mean? Most clinical trials will require it for monitoring purposes, so should that option be selected?**
    Question D3 is asking what will be involved in the conduct of the research study. Investigators are required to select all applicable options. The option "Medical Records Review" should be selected should the research study involves reviewing/ collecting data from the medical records.

14. **What if a study involves the review of medical records? Would the retrospective review of medical records come under waiver of consent?**
    We highly recommend obtaining consent if there is a need to review identifiable data. However, if this is not possible, you may apply for Waiver of Consent. The decision is subject to the board's review and approval.

15. **If the recruitment target is a range, does the ICF have to capture the maximum or minimum of the range?**
    Please indicate the minimum number in the ICF as that should be the targeted recruitment number for the study.

16. **Is obtaining informed consent by electronic means allowed? If yes, what would be the relevant section in the application form to fill in?**
    Yes, it is allowed. Please select "Consent will be obtained remotely (remote consent)" in Section J5 of the application form. To sign the informed consent form electronically, the e-signature must comply with the ETA (Electronic Transaction Act). Section J should be completed with the details and platform used.

17. **If consent is obtained from participants and questionnaires are conducted on participants remotely through Zoom or Microsoft Teams, do we need to declare Zoom or Microsoft Teams as a software used in ECOS?**
    Yes. In addition, if you are using a specific platform to obtain electronic signatures, the platform used should also be indicated.

18. **What is the difference between a telehealth medical device and telehealth wellness device?**
    A Telehealth Medical Device is a device intended for medical purposes by the Product Owner (PO), will be classified as a medical device and will be regulated by HSA.

    Telehealth Wellness Device achieve its intended purpose by encouraging users to improve or maintain a healthy lifestyle.

19. **What is the definition of a medical device with significant risk? Based on the elaboration in point 3 of Section I1, it seems applicable for most medical devices.**
    More information can be found on the HSA website regarding the general risk classification system of medical devices.

20. **If a software or mobile app that is not commercially available is used for data collection only, would it be a telewellness device?**
    According to HSA, the definition of a "Telewellness device" is a software or mobile app designed to encourage the user to adopt or maintain a healthy lifestyle, or for the user's general well-being, but not for any specific medical purposes. However, if the software or mobile app is being used solely for data collection purposes, it should be categorised as "Others" in Section V1.

21. **For studies involving medical devices, under Section O1- Waiver of Documentation of Informed Consent, should category A or B be selected?**
    For studies involving medical devices, waiver of documentation of informed consent is unlikely to be granted by the IRB.

22. **Do translated ICFs need to be submitted for review?**
    An announcement was made on September 15, 2020, stating that CIRB no longer requires translated documents to be submitted.

IRB – Notifications

1. **Will email notifications be sent to site PIs for endorsements?**
   Yes, email notifications would be sent to site-PI to inform him/her of the pending declaration task. However, there is no email notification to Overall PI to inform him/her of the pending declaration task.

2. **Will a study renewal notification still be sent 6 months before the study expiry date?**
   Email notifications will be sent to PI at a frequency of 90 days, 60 days and 30 days before expiry as reminder to submit a Study Status Report for Study Renewal.

3. **Will approved users in the UAL receive email notifications when a new application is declared/submitted by PI or when it is endorsed by DR or IR?**
   Yes. However, this feature is still under development, users may only start to receive email notifications in Q3 of FY2024.

4. **Currently, email notifications are sent at the various stages of endorsement (PI, DR, IR, submitted to IRB) and the release of the IRB decision, will we still be receiving these notifications on ECOS?**
   Yes, there will be email notifications to PI and users in UAL should receive the email notification in Q3 of FY2024.

5. **Will the PI, site-PI, Co-I and roles in CRMS be notified when there are IRB queries?**
   All roles in the study team would receive system and email notifications when there are IRB queries. However, in the May launch, email notifications will only be sent to PI.

IRB – Migrated Study

1. **Are there any approved studies that may have been overlooked and not yet migrated to ECOS?**
   If a PI logs into their account and is unable to find some of the studies they are involved in, please reach out to the CIRB. It is possible that some studies may have been migrated to another account associated with a different email address of the user. The CIRB is aware of this possible issue and is working on a solution to consolidate studies into one account.

2. **Will the forms/attachments that were uploaded in the application of a study that has been approved in iSHaRe be migrated to ECOS?**
   Yes, all the study documents/attachments of an approved ongoing study in iSHaRe will be migrated to ECOS.

3. **What will happen to studies approved under Exemption Category 1 to 6 if they are not migrated to ECOS?**
   For studies approved under Exemption Category 1 to 6, if the status of the study is "Approved", it will be migrated.

4. **If a study is approved by the IRB in March 2024, will it be migrated to ECOS?**
   Yes, it will be migrated if the study is approved and ongoing in iSHaRe.

5. **Is PI only able to start drafting amendments and study renewals after study had been migrated?**
   Yes, CIRB aims to migrate all existing ongoing approved studies to ECOS by end May 2024. Please monitor the ECOS page on the RICE website for updates. Studies with expiry dates in August will be prioritised for renewal review, please ensure that your renewal submissions are completed by 21 Jun 2024, 5pm. This will allow the IRB sufficient time to process your renewal.

6. **For migrated studies, can amendments only be submitted after May 20?**
   Yes, amendments should only be submitted from 1st Jun 2024 for migrated studies. Kindly note that ongoing studies will be migrated in batches. Therefore, it is important to check that the study is fully migrated if you see that the study is available on ECOS.

7. **In order to submit amendment forms for migrated studies, will the new questions on the ECOS form need to be filled up before the amendment can be submitted?**
   Yes, all new questions on the ECOS form need to be filled up before amendment can be submitted.

8. **What is the deadline for submitting an amendment for a migrated study to be tabled at the next full board review?**
   If an amendment for a migrated study needs to be tabled for full-board review, it will be scheduled for review in June. Please note that the submission deadline for full-board review from June onwards will be the 1st working day of the month.

9. **What happens if the study renewal is not submitted by 21 June and the study lapses?**
   There is no change to the process of reactivation of a lapsed study. If there is a need to continue the study, a reactivation form and a DNC must be submitted to explain the need for reactivation and why the study approval lapsed. Research activities may not continue in the period where the study has expired and there is no IRB approval.

10. **After migration, would CRCs need to be manually added?**
    Yes, for migrated studies, CRCs would need the PI, Site-PI or Co-I listed in the application form to add them in CRMS. Once the CRC is added, the added CRC will then be able to add other CRCs for the study.

11. **Will past amendment, PDNC, and renewal forms for existing studies be migrated, or only the latest approved amendment form?**
    Only the latest approved or acknowledged Amendment form or application form will be migrated as the smart form in ECOS. All other forms will be stored in the data migration folder within the study summary.

12. **Will the DNC forms submitted via email to the secretariat be uploaded to ECOS as well?**
    Yes, they will be uploaded. However, it will be at a later date as migration of the existing data on iSHaRe will be prioritised.

13. **Will there be an extension granted for studies where the last site COV is expected to be completed in May as the submission deadline for the study completion report is required to be submitted within 4 weeks?**

    The PI should submit the Study Status Report Form on ECOS within the stipulated timeline as follows: Study Completion – within 30 days after completion of the study. Study Termination by Institution, Principal Investigator or Sponsor - within 7 days. Please refer to the IRB Submissions & Review Fees page under Study Status Report Form for more information.

    While waiting for the ongoing study to be migrated by end of May 2024, please inform the IRB secretariats of the study completion via email first. Submit the Study Status Report Form when the study has been migrated.

14. **Will a list of migrated studies be provided to the respective ROs?**

    Please write to the IRB and we will liaise with you directly. Do note that this is only applicable to the Research Office.

Clinical Research Management System (CRMS)

CRMS – General

1. **How does CRMS work?**
   The CRMS is a new research toolkit built to support researchers and clinicians to manage their clinical research projects and activities. It is a whole module by itself and is accessible via the ECOS navigation menu on the dashboard. Every study created in the IRB module will have a corresponding study created in the CRMS module. Users can enter information in the relevant pages in CRMS to plan, track and monitor submission(s), start-up, milestones, recruitment progress etc. It also contains the User Authorisation List (UAL) where access management to the IRB and/or CRMS modules for Study Team Member (STM), Study Administrator (SA) and Study Sponsor (SS) will be managed.

2. **Do all users (e.g. PI, Co-I, site administrator and sponsor administrator) with ECOS accounts need to create another profile in CRMS as well? How do we link users in CRMS to each study?**
   There is no need to create another profile in CRMS once your ECOS account is set up. Site can choose to add the selected Study Team Member/Study Administrator/Study Sponsor(s) to the User Authorisation List of each study in the CRMS module as needed..

3. **Other than user management, what is the purpose of CRMS for industry-sponsored studies given that the study sponsor will only have access to Study Information and the UAL?**
   CRMS is mainly created to help researchers and clinicians from the institutions to manage and maintain oversight over their clinical research projects and activities. PI/Site-PI, Co-I, STM and SA conducting industry-sponsored studies can use CRMS as a tracker to monitor the site-level activities. On the other hand, Study Sponsors are expected to require access to the Study Information and UAL pages to facilitate the submission of IRB Application Form and to have continued access to the IRB and CRMS modules respectively.

4. **Is it possible to export the Milestones and Participants - Recruitment Numbers to Excel?**
   Yes, information on the Milestones and Participant - Recruitment numbers can be exported to Excel. It is also possible to export the other pages as required by the user, as long as the export function is available on the page.

5. **Is data entry in CRMS mandatory for sponsored studies only?**
   CRMS is mandatory for all SingHealth studies regardless of the study funding source. Milestones, Participant - Recruitment Numbers and Site Information are the 3 mandatory CRMS pages. For Pharmaceutical/ Industry-sponsored studies, the Study Information - Basic

Information page is also mandatory. The IRB Application Form cannot be submitted if the minimum requirements on the Basic Information page are not completed.

6. **For 'Not Human Subject Research' (previously known as 'Review not Required') studies, can I confirm there is no need to update the recruitment numbers in CRMS?**
   It is not necessary to input the data on CRMS as the information is unlikely to be used for reporting. However, if the study team finds the CRMS useful as a tracking and monitoring tool, please feel free to utilise the pages.

CRMS – Study Information

1. **In the case of an IIT funded by a grant, is it acceptable for the PI to input details such as the grant's IO in the IRB Review Fee Billing Details section under Basic Information page in CRMS, allowing the IRB review fee to be billed to the IO directly?**

   There are no data fields for the entry of IO number under IRB Review Fee Billing Details on the Basic Information page in CRMS. In the case of grant-funded studies, the current work process involves the IRB billing the institution directly. Research Office colleagues may approach you for the grant details, including the IO number, hence please provide the requested information to them upon request. Nonetheless, the Site Information page in CRMS contains a dedicated section for study team to enter grant information, from which the Research Office could retrieve the necessary details without approaching the PI or study team directly. However, it is advisable to verify this process with your Research Office as the work process varies amongst different institutions.

2. **Is it mandatory to complete the regulatory information in CRMS?**

   The Regulatory Information page is conditional, SingHealth Clinical Trials Coordinating Centre (CTCC) will be releasing more information pertaining to the requirements and timeline. Please wait for the information to be disseminated.

CRMS – User Authorisation List & Study Member Review

1. **Is it mandatory to enter the complete Study Team Member (STM) list in the delegation log to the User Authorisation List (UAL) in CRMS? Or is it just for access to view the IRB-related form(s)?**

   It is not mandatory for all the STMs to be added to the UAL. Site can choose to add selected STM(s) who require access to CRMS and/or IRB modules, e.g. to enter recruitment information in CRMS, draft and submit IRB Application/ Amendment/ SAE/ DNC/ OSN/ SSR/ UPIRTSO forms. However, please note that the full list of STMs involved in the study conduct must be recorded on the site-specific delegation log.

2. **Is it possible to add Study Team Members (STMs) to the delegation log without including them in CRMS, for example, a medical student assisting with data collection for participant recruitment?**

   Yes. STMs can be added to the delegation log and not in CRMS**.**

3. **Can a Study Team Member (STM) perform study-related tasks immediately after the delegation log is signed and completed, even before the UAL is updated on ECOS?**

   Yes. Once the person has been appropriately delegated and trained in the study procedures, he/she can start performing the delegated duties for the study. UAL merely functions to manage user access to the IRB and/or CRMS modules on ECOS.

4. **For new IRB Application, will the Study Sponsor be able to add themselves to CRMS UAL, thus retaining access to the study in the IRB module on ECOS and assist in the drafting of forms? Or must this first step be completed by the PI?**

   If the IRB Application Form is initiated by a Study Team Member (STM), Study Administrator (SA) or Study Sponsor (SS), there will be a prompt triggered for them to add themselves to the User Authorisation List (UAL) in CRMS when the IRB form is saved for the first time. This will allow them to have continued access to the IRB Application Form. If the user misses this opportunity, he/she will lose access to the IRB Application Form once he/she saves and exits the form. The workaround will then involve contacting any of the investigators added to the IRB form to manually add the STM/SA/SS to the UAL.

5. **If the Study Sponsor (SS) drafts the initial application form and includes oneself to the User Authorisation List (UAL), is endorsement of this person by the PI still required?**

   Although the SS will have limited access to the Study Information and UAL pages only (before and after PI's endorsement in CRMS), endorsement is still necessary. Endorsement from the PI/Site-PI signifies an acknowledgment of the SS's involvement in the study and that they

should rightly have access to the study in CRMS and IRB modules. Thus, the user endorsement review by the PI/Site-PI is important as it concerns access to confidential study data.

6. **Does the PI need to endorse all users on the User Authorisation List (UAL) before the IRB form can be submitted?**
   No. There are no system logic checks involving CRMS UAL and IRB Application Form. The IRB Application Form can be submitted before the PI endorses the users on the UAL. In fact, the PI can only start endorsing user(s) after his/her role status as PI in the UAL is "Active".Please also utilise the "Mandatory Check" button on the IRB form, it will inform users of any pending action(s) before the IRB Application Form can be submitted successfully.

7. **For multi-site studies (either industry-sponsored or investigator-initiated), does the PI have CRMS access to the site-level information for all sites?**
   Irrespective whether a study is industry-sponsored or investigator-initiated, PI/Site-PI can only view site-level information of their own site. Thus, the Site-PI would have to provide the necessary information to the overall PI, if required.

8. **What is the procedure for adding a medical student as a Co-I of a study? If the PI endorses this addition, can the Co-I immediately start work on the research project without needing to wait for CIRB approval?**
   Please first assess if the medical student will be performing investigator-related tasks. If he/she is, it is correct to add this medical student as a Co-I. Any addition of Co-Is requires approval from the IRB. Please add the user in Section B2(a) of the IRB Application of Amendment Form and submit the form to the IRB for review. The user should only start performing study-related research work after the IRB has approved his/her role as a Co-I.

9. **On ECOS, who orwhich role has access to add Study Team Member (STM), Study Administrator (SA) and Study Sponsor (SS) in the CRMS module?**
   Any user who has access to the study in CRMS can add a new STM/SA/SS to the User Authorisation List (UAL). For example, if PI-1 and Co-I-2 have been added into the IRB Application Form as investigators, both can access the same study in the CRMS module to add a new STM/SA/SS. In another example, a STM/SA/SS that has been added to the UAL and thus have access to the study in CRMS, can also add another STM/SA/SS to the UAL.

10. **Would Study Team Member (STM), Study Administrator (SA) or Study Sponsor (SS) need approval from both PI and Site-PI to be added in CRMS? Or just the relevant PIs involved?**

Endorsement in CRMS is site-specific. PI/Site-PI can only endorse the STM/SA/SS added to his/her site.

11. **After the PI/Co-PI adds a** Study Team Member (STM)/Study Administrator (SA)/Study Sponsor (SS) **on CRMS, how long does it take for the approval of the new member?**
    The endorsement is immediate if the PI/Site-PI adds **STM/SA/SS** on CRMS. If the addition is performed by other roles apart from PI/Site-PI, the time to approval then depends on the PI/Site-PI endorsing this new STM/SA/SS.

    However, please be informed that all investigators and researchers including STM who are directly involved in the conduct of research must meet the Minimum Training Requirements. PI/Site-PI will be responsible for ensuring that the STM meets the Minimum Training Requirements at the point of endorsement, with the relevant certificates filed in the Investigator Site File.

12. **CRC would most likely be added under CRMS. Would they be able to perform inform consent taking for non-CT type of studies upon proper delegation and training?**
    Non-investigators directly involved in the study conduct such as CRCs, will have to be added as Study Team Members in CRMS if needed. They can take informed consent from the participants if the IRB has provided approval for this request. Please make a clear and general statement without including specific names in Section J8 (Who will take consent from potential research participants/legally acceptable representatives (e.g., PI, Co-Investigators etc.) of the IRB Application/ Amendment Form. At the same time, please check if the IRB (and institution, where applicable) has any requirement on who could take informed consent.

13. **Can a CRO personnel select the study administrator role?**
    Study Administrators are defined in general as **site personnel** not directly involved in the study conduct but provide administrative support only. There must be appropriate rationale for a CRO or sponsor personnel to be added as SA in the CRMS. Otherwise, sponsor/CRO personnel should be added as Study Sponsors in the CRMS UAL. PI/Site-PIs are advised to review the role assigned to a newly added user. If this new user should not be assigned the role of STM or SA, PI/Site-PI should then reject this user during the user endorsement review.

14. **Can external collaborators or Study Team Members (STMs) be added to the User Authorisation List (UAL) for existing and new studies?**
    For external collaborators or STMs, we suggest to have the PIfirst assess whether the external collaborator/STM performs any tasks within the study siteFor external collaborators who will be involved in the data analysis or publication writing in the future, there is no need to add

them to the UAL in CRMS. External STM performing study-specific tasks on site can be added as a STM on the UAL.

15. **Can more than one non-PHI member be added in CRMS? Can the individuals added be from the same organisation? Is there a limit to the number of non-PHI members that can be added?**

    There is no restriction to the number of users to be added in the User Authorisation List in CRMS. However, please give careful consideration before adding any user to the UAL as the site team will need to manage and keep the User Authorisation List updated, i.e. Study Team Member/Study Administrator/Study Sponsor no longer directly involved in the study should be deactivated in the list for IRB and CRMS accesses to be revoked for study data confidentiality protection purpose

16. **As study team members involved in a study will not be migrated from iSHaRe to ECOS, for past team members (e.g. Former CRCs), will the PI be required to add them back into the study? What if they have left research?**

    For Study Team Member (STM) that are actively involved in the study conduct as of current, the investigators (PI/Site-PI/Co-I) who have access to the CRMS for the migrated studies can add the STM to the User Authorisation List (UAL) in CRMS. Once added, this STM will have access to both CRMS and IRB modules. For STMs who have left the institutions or former STMs who are no longer actively involved in the study conduct (i.e. removed from delegation log), there is no need to add them to the UAL.

17. **If I am the Primary CRC on one site, but not on the other two sites, can I be added in the UAL as a Study Team Member (STM) on one site and as a Study Administrator (SA) for the other two sites?**

    If you are overseeing multiple sites and are tasked to complete the CRMS site-level pages for all sites, you can be added as a SA to the UAL of the other sites. However, please be reminded that deactivation from all sites would be necessary when the user is no longer actively involved in the study.

18. **For a multi-site, pharmaceutical/ industry-sponsored study, does Study Sponsor (SS) need to be added to the User Authorisation List (UAL) of each site in CRMS?**

    It is recommended for the SS to be added to the UAL of the lead site only. This SS would then be able to access the IRB forms and complete the Study Information – Basic Information page in CRMS as required. However, if the SS needs to help all study sites with user management (i.e. add/deactivate users), the SS can be added to the UAL of the other sites as well. Please

be reminded that deactivation from all sites would be necessary when the SS is no longer actively involved in the study.

19. **Since the User Authorisation List (UAL) endorsement is site-specific, if a Study Team Member (STM)/ Study Administrator (SA)/ Study Sponsor (SS) has been added to multiple sites, for example Site A and Site B of the same study, would each site PI need to endorse the user? Can the overall PI endorse for both sites?**
    The overall PI only has access to his/her site, hence the overall PI is unable to endorse users from other participating sites. The respective site PIs will need to endorse the STM/SA/SS.

20. **Is the UAL site-specific or study-specific?**
    The UAL is site-specific.

CRMS – Participants

1. **If the study team has existing methods of tracking monthly recruitment numbers and participants, is it still necessary to fill in the corresponding fields in CRMS?**
   Yes, completing the Participants – Recruitment Numbers page in CRMS is still required, as the information will be utilised by Clinical Trials Coordinating Centre (CTCC) for insurance coverage purposes, and by the SingHealth HQ and institutions for management purposes to maintain oversight of research within the respective institutions.

2. **Is it mandatory to complete the Visit Plan and Participant List under the Participants page in CRMS? For migrated studies, are study team expected to enter the existing list of participant log into the Participant List page?**
   Visit Plan and Participant List are optional pages, but we highly recommend the study team to make full use of this new tool. We would like to again gently remind that the completion of Recruitment Numbers under the Participant page in CRMS is mandatory.

   If there are no existing tools or platforms that the study team is using, we suggest entering the information into CRMS. For new studies, please start utilising the CRMS pages.

3. **Our study has recruited more than 5000 research participants. Is it still mandatory for the study team to complete the study Participant List page in CRMS as it does not seem practical?**
   Completing the Participant – Participants List page in CRMS is optional. However, the monthly numbers for the Participant – Recruitment Numbers page should be completed.

4. **In CRMS, features like the Participants List resemble some of the information required in our study logs. Is it possible to substitute our study logs with these and maintain them electronically? If not possible, perhaps export and file the printed Participants List in the Investigator Site Folder?**
   ECOS is not designed to be an electronic document repository and cannot be considered as electronic source data for any study. If the Participant List in CRMS is used as the Screening and Enrolment Log, paper records must still be maintained, i.e. the CRMS pages used as study logs should be printed and personally signed and dated before filing them in the Investigator Site File (ISF). This should be done periodically, and all previous versions of the signed and dated printed copies should be kept in the ISF to maintain an audit trail.

5. **Is the information to be entered into CRMS (e.g. monthly recruitment numbers) only applicable for studies with ongoing participant recruitment, or for all studies, including studies that had completed data collection?**

If the study is still ongoing (i.e. study has an active IRB approval/renewal and is not closed/terminated/expired), the information should be entered as insurance coverage is still required.

6. **How often do recruitment numbers need to be updated in CRMS?**
   Once a month.

7. **What happens if we forget to update the monthly recruitment numbers? Will there be a reminder sent for this?**
   Reminders regarding data entry in CRMS will not be issued by the ECOS system. It is likely to be sent outside of the system instead, e.g. reminders sent from Research Office or equivalent.

CRMS – Mandatory Pages for SingHealth Studies

1. **There seems to be a lot of information required to be entered in CRMS at the site level. Are all the fields mandatory? Or are they only for monitoring and reporting purposes?**
   There are 3 mandatory pages, they are Site Information, Milestones, and Participant – Recruitment Numbers. The remaining CRMS pages are optional, but we highly encourage research teams to use them as an organisational tool to enhance work efficiency and productivity. However, please note that each institution may make additional pages mandatory to suit its own needs Please check with your Research Office for certainty.

2. **Are the pages in CRMS also mandatory for exemption studies?**
   CIRB exempted study are studies approved under Categories 1 to 6 by CIRB. The 3 mandatory pages (Site Information, Milestones and Participant - Recruitment Numbers) should be completed for exemption studies as well. The remaining pages are optional, but we highly encourage research teams to use them.

3. **Are the pages in CRMS also mandatory for studies that do not require recruitment, such as those working with banked or legacy tissues?**
   If the study involves recruitment, the information is required to be entered in CRMS. If a target recruitment number has been stated in the IRB application form, we would expect the recruitment number in CRMS to be completed as well.

4. **What will happen if the study team does not update the mandatory information? Will the study be suspended?**
   While the study will not be suspended, PI is responsible in ensuring the mandatory information in CRMS is updated. Insufficient information may have an impact on insurance coverage as SingHealth Clinical Trials Coordinating Centre (CTCC) will extract the necessary information from the CRMS pages for the National Clinical Trials Insurance reporting. Inaccurate or absence of information may result in incorrect reporting, and this may have downstream impact such as for insurance reporting or claims. It could also be noted as an observation during internal monitoring and/or audit.

5. **Can data be imported or uploaded, for example, from an Excel spreadsheet to the Participants – Recruitment Numbers page on CRMS? This could expedite the data entry process.**
   Unfortunately, there is no import function on ECOS. The information will have to be entered manually.

6. **Are we expected to retrospectively enter the numbers into the Participant – Recruitment Numbers page? What if my study was initiated 5 years ago?**

   Please retrospectively enter the **monthly** recruitment numbers starting from January 2024. If manpower or bandwidth allows, it is preferred for all recruitment numbers (from 5 years ago) to be entered so that PI/study team can have a complete picture. If not possible nor practical, we suggest entering an aggregated annual number instead for each year in the month of December. Please see an example below. Up-to-date recruitment numbers should be entered by 30 September 2024.

No.	Month and Year	Total No. of Screen Failure	Total No. of Participants Enrolled	Total No. of Participants Who Have Completed Study	Total No. of Participants Withdrawn from Study
1	Apr 2024	0	0	0	0
2	Mar 2024	1	0	0	0
3	Feb 2024	0	1	0	1
4	Jan 2024	0	0	1	0
5	Dec 2023	3	11	2	2
6	Dec 2022	4	10	3	1
7	Dec 2021	3	15	2	2
8	Dec 2020	5	12	4	1
9	Dec 2019	3	12	3	2

CRMS – Migrated Studies

1. **Study team member and protocol administrator (including sponsor personnel) of studies on iSHaRe will not be migrated. Does it mean these users will not see any studies that they are involved in when they first log in to ECOS?**

   Yes, STM/SA/SS will not see any studies under the IRB or CRMS modules. They will have to contact the PI, Site-PI or Co-I(s) listed on the IRB Application/ Amendment Form(s) to access the UAL in CRMS and manually add the affected users to the UAL as appropriate. Minimally one STM/SA/SS should be added to the site UAL, the newly added STM/SA/SS can subsequently add more users to the UAL as required. Please note that migrated studies will progressively be migrated in batches, and the migration is expected to fully complete by end May 2024. We advise you approach the PI/Site-PI/Co-Is from 1st Jun 2024.

2. **For migrated study not requiring study amendments, will the PI be able to access CRMS to add STM/SA/SS?**

   Each study in the IRB module will have a corresponding study in the CRMS module. The PI/Site-PI can thus access CRMS to add STM/SA/SS to the UAL in CRMS.

3. **For existing studies migrated from ROAM/iSHaRe, is there a step-by-step guide on how to use CRMS. For instance, does the PI first need to add users to UAL? Subsequently, users on the UAL can add additional users as needed?**

   Yes, the PI/Site-PI or Co-investigators migrated over to CRMS should first manually add minimally **one** Study Team Member (STM), Study Administrator (SA) or Study Sponsor (SS) to the UAL. The added STM/SA/SS can then add more users as needed. PI/Site-PIs should verify the added users via the Study Member Review page accordingly. For the detailed steps to add a user to the UAL, please refer to the CRMS guidebook.

CRMS – Reports

1. **For the 12 CRMS reports, would there be mandatory forms for completion?**
   The reports have been designed to extract specific information entered in the CRMS and IRB modules to generate internal reports for the SingHealth HQ and Institution Research Offices. For now, information from Site Information, Milestones and Participant – Recruitment Numbers will be drawn from CRMS for reporting. More reports may be utilised and the requirements will then be communicated.

CRMS – Institution CRMS RO Administrators

1. **Who are the CRMS Research Office administrators that we can contact to add us STM/SA/SS on the UAL?**
   Please check with the Institution's Research Office directly.