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)

Version dated 19 Apr 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. **Will ECOS be a whitelisted website, so download/upload can be done using corporate devices?**

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

3. **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.

4. **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.

5. **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 NHG, your login ID will be the NHG login ID. If you have studies in both iSHaRe and ROAM, they will be consolidated into a single account. For example, if you are a NHG user in both iSHaRe and ROAM, your email address in iSHaRe must match your NHG M365 account. This allows the studies from both systems to be migrated to the same account.

6. **For sponsors' user accounts, must we create a new account on ECOS using the email linked to iSHaRe?**

   If you are a Protocol Administrator in an existing iSHaRe approved studies, your account will not be migrated. Only users with study roles of PI, Site-PI and Co-I listed in ongoing studies will be migrated. Please register for an ECOS account when system is up.

7. **The same sponsor may authorise different CROs to manage different trials. Does it mean that each CRO has to create an individual account in CRMS for each sponsor we work with?**

   It depends on the Sponsor and CRO's agreement whether separate accounts should be created to manage the Sponsor's studies.

8. **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.

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. **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.

7. **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 eHBRA training 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.

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

9. **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.

10. **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).

11. **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 when there are new guidelines from HSA. The same practice will also apply to sponsored studies. However, sponsors' requirements must be fulfilled, as necessary, and maintained in the site file.

12. **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.

13. **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.

14. **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.

15. **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.

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. **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.

9. **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.

10. **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.

11. **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.

12. **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.

13. **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.

14. **Could 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.

15. **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.

16. **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.

17. **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 non-Investigator Study Team Members independently. These non-Investigator Study Team Members may be listed in CRMS.

18. **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.

19. **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.

20. **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.

21. **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.

22. **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.

23. **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.

24. **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.

25. **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.

26. **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.

27. **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).

28. **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.

29. **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.

IRB Application Form

1. **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.

2. **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.

3. **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.

4. **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.

5. **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.

6. **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.

7. **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.

8. **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.

9. **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.

10. **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.

11. **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.

12. **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.

13. **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.

14. **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.

15. **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.

16. **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.

17. **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.

18. **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.

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?**
   The first renewal reminder will be sent 3 months before the expiry date. There is no change in the requirement.

Clinical Research Management System (CRMS)

1. **How does CRMS work?**
   The CRMS allows for users to be added under the User Authorisation List and for study information to be entered at the site level. Please refer to the other questions for the details of the module.

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(s) who require access to both CRMS and IRB modules.

3. **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.

4. **On ECOS, who/which role has access to add study team members, study administrators and study sponsors in the CRMS module?**
   Any user who has access to the study in CRMS can add a new Study Team Member (STM), Study Administrator (SA) or Study Sponsor (SS) to the User Authorisation List. 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. Once a new STM/SA/SS is added to the User Authorisation List, this newly added user can also start adding other users.

5. **Would study team members 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 Study Team Member/Study Administrator/Study Sponsor added to his/her site.

6. **After the PI/Co-PI adds a STM/SA/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 a Study Team Member (STM)/Study Administrator (SA)/Study Sponsor (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 Requirement. 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.

7. **Is it mandatory to submit the study team member list in CRMS? Or is it just for access to view the application form?**

   It is not mandatory for all the Study Team Members (STMs) to be added to the User Authorisation List in CRMS. Site can choose to add selected STM(s) who require access to both CRMS or IRB modules. However, please note that the full list of STMs involved in the study conduct must be recorded in the site-specific delegation log.

8. **Will study team members be able to view the profiles of other users? For example to check whether the PI or Co-I has included the necessary details?**

   Yes, Study Team Members can view the profiles of other users and ensure they have completed the necessary training.

9. **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?**

   Yes, however, please check if the IRB (and institution, where applicable) has any requirement on who could take informed consent.

10. **How to add external study team members to already approved studies?**

    For external Study Team Member (STM), we suggest having the PI assess whether the external STM performs any tasks within the study site. If the external STM is an external collaborator who will be involved in the data analysis or publication writing in the future, there is no need to add the external STM to the User Authorisation List in CRMS.

11. **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 CRMS (User Authorisation List). 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.

12. **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 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.