ECOS

IRB Guidebook:

Migrated studies (CIRB)

Version 1 dated: 20 May 2024

SingHealth
Defining Tomorrow's Medicine

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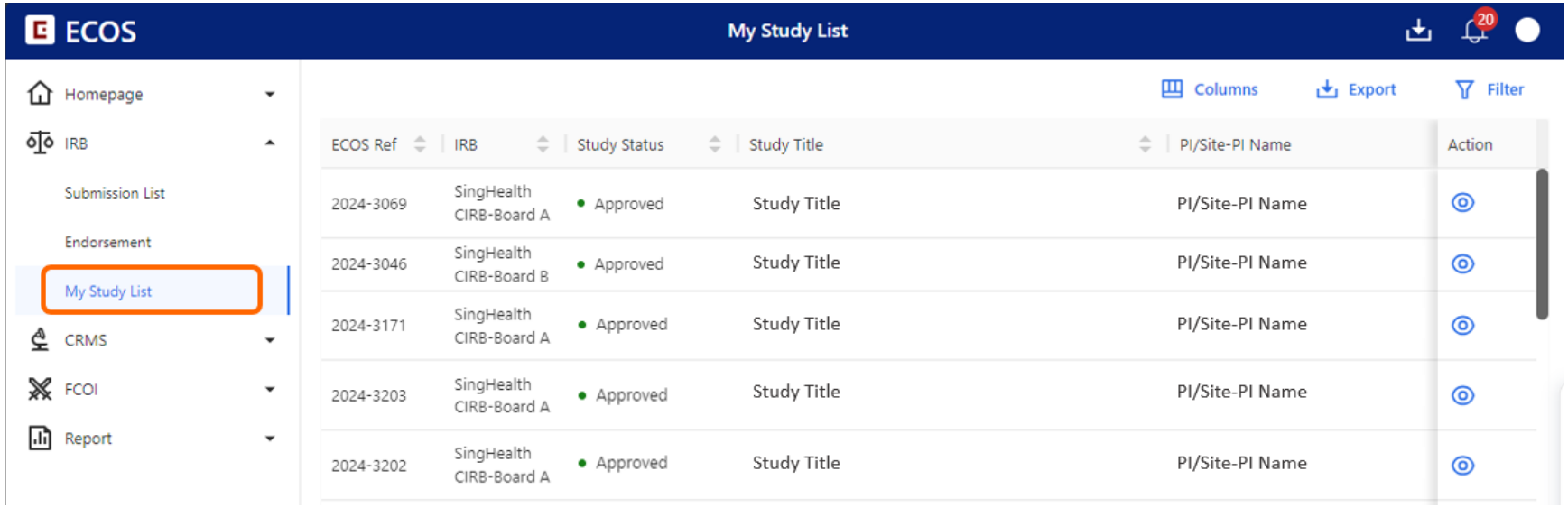
Migrated On-going Approved Studies ("Migrated Studies")

Migrated Studies refer to studies which were approved by CIRB on iSHaRe prior to launch of ECOS and the studies status is "Approved" as of 28 Mar 2024. All Migrated Studies retain the CIRB Reference Number. The CIRB Reference Number would be the ECOS Reference Number. The slash (/) in the CIRB Reference Number will be replaced by dash (-). Please quote the ECOS Reference Number in your communication with IRB.

1.1 Studies approved by CIRB

- **My Study List**

To locate the Migrated Studies: Click on "My Study List" and click "" to view the study summary.



- **Study Summary**

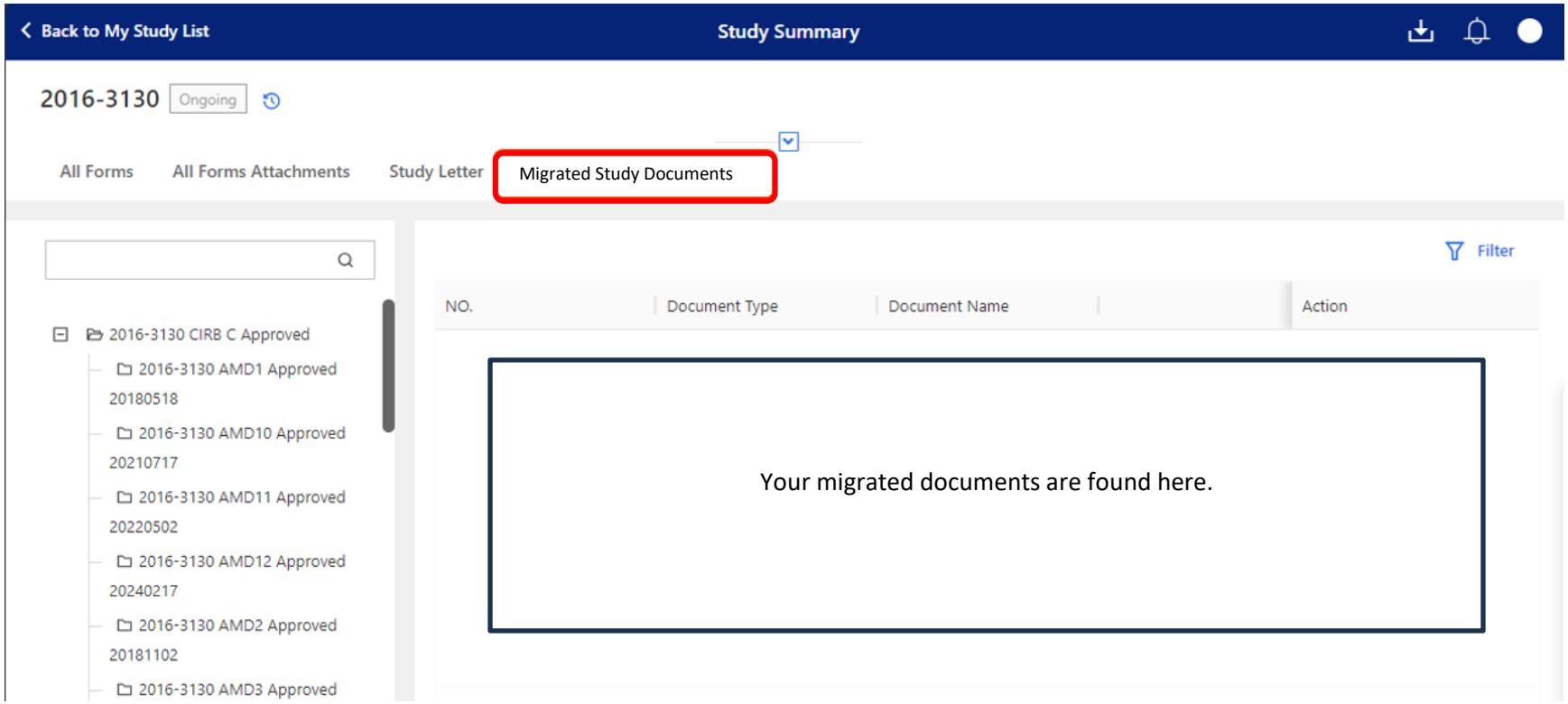
The latest approved or acknowledged Application Form or Amendment Form from iSHaRe will be migrated as “Smart Form”. You can view the migrated form in the Study Summary Page, under “All Forms”.

Note:

1. As the ECOS Application Form is different from the iSHaRe Application Form, there are new data fields which are displayed as blank and data fields in iSHaRe which are not migrated. When the first Amendment Form of migrated studies is created, the PI/study team members are expected to complete all mandatory fields.
2. The latest approved or acknowledged Application Form or Amendment Form are migrated “Smart Form” so that subsequent amendments can be submitted in ECOS. Do not use the migrated “Smart Form” as reference. Do refer to the Migrated Study Documents for the PDF of the iSHaRe Application Form or Amendment Form.
3. The CIRB decision letter for the latest approved or acknowledged Application Form or Amendment Form will not be available under “All Forms”. Decision letter can be downloaded from the Migrated Study Document if required.

- **Migrated Study Documents**

All other Forms reviewed by CIRB previously are migrated to ECOS as PDF. The documents can be found under “Migrated Study Documents”.

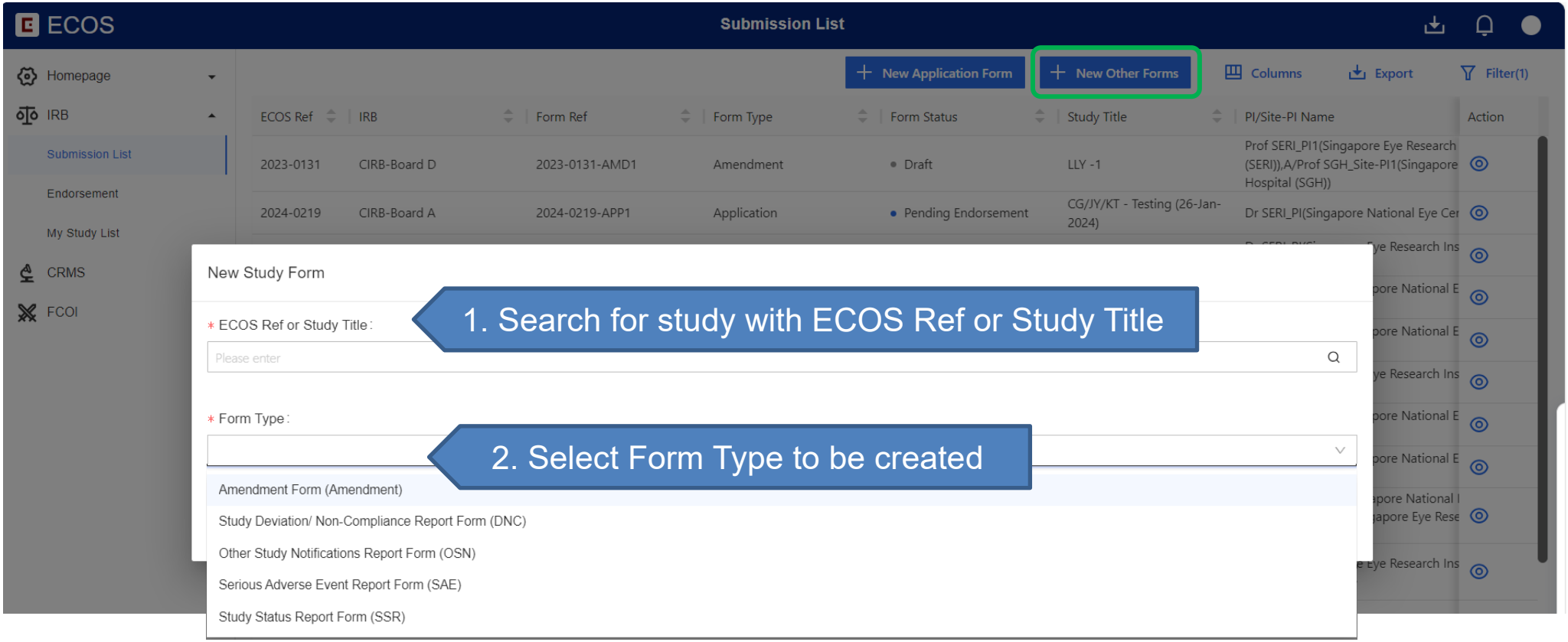


Note:

1. Study Renewal Report Form, Study Re-activation Report Form and Study Closure Report Form are reflected as SSR, SRR and SCR respectively in ECOS.
2. Local SAE Report Form is reflected as SAE in ECOS.
3. Protocol Deviation/Non-compliance Report Form is reflected as DNC in ECOS.
4. Other Reportable Event Report Form is reflected as OSN in ECOS.
5. Submissions reviewed offline would be migrated at a later stage.

1.2 How to make submission for Migrated Studies

- **Creation of Other Forms**



1. Under the IRB module, Submission List, click on the " + New Other Forms " button.
2. Search for the study with the ECOS Reference Number or Study Title.
3. Select the Form Type to be created.
4. Click on " Confirm "button.

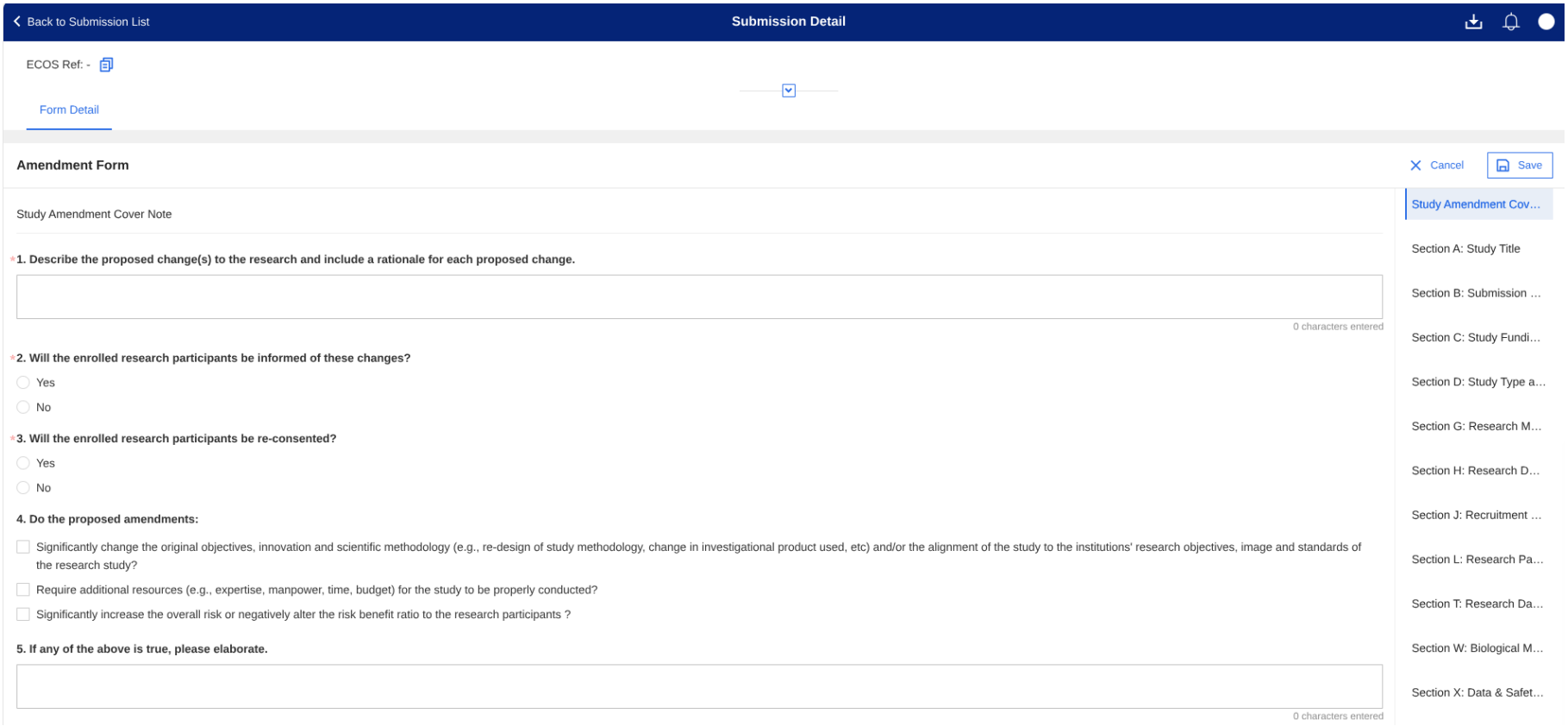
- **Amendment Form**

Due to differences between the iSHaRe Application Form and ECOS Application Form, there would be new questions when you create an amendment form. For the first time submitting an amendment form in ECOS, please ensure that all mandatory questions are answered.

Please note the following:

- Data from some sections of the iSHaRe Application Form will not be mapped over to the ECOS Amendment Application Form.
- Data from some sections of the iSHaRe Application Form may be mapped over to a single section in the ECOS Amendment Application Form.
- Some sections in ECOS Amendment Application Form have been mapped by default to a certain option to facilitate data mapping.

Do check the first ECOS Amendment Form thoroughly and update accordingly. Do ensure that you check this against the latest IRB Approved Application/ Amendment Form.



Points to note when you create your first amendment form (for migrated studies) on ECOS:

- **Section B**
  - Section B1 information cannot be updated during amendment submission.
  - Approved study sites cannot be removed. If these sites no longer involved in the research, please submit a Study Status Report Form to update the site status to either "Completed" or "Terminated".
  - If your existing studies involved study site without Site-PI in iSHaRe, the study PI has been set by default as that study site's site-PI. Please review if you need to update the Site-PI for that study site.
  - Study investigator(s) listed in Section B2 would need to complete their minimum training and obtain the required training label before the amendment form can be submitted. (i.e., clinical trial involving drug/ biologics would need the clinical trial label).

- **Section C**
  - Please review and update the Grant information and Sponsor's contact details/CRO's contact details/IRB billing information via the CRMS module. You will not be able to update this information in the amendment form. Change in Sponsor should be updated via the amendment form.

- **Section D**
  - Please review if the options mapped in Section D3 and D5 are accurate. There may be missing information as the options for these questions were expanded.
    - ❖ If your study involved Medical Device and it was not selected in Section D3, please select "Medical Device" in Section D3 and complete Section I accordingly.
    - ❖ If your study involved Software or Mobile Application and it was not selected in Section D3, please select "Software or Mobile Application" in Section D3 and complete Section V accordingly.
      Note: Screenshots of Software or Mobile Application relating to collection of data should be attached in Section E3 or G7. Attachments relating to the Software or Mobile Application should be attached in Section V (For example, mobile app user guide).
    - ❖ If your study involved combination of wavier of documentation of consent and obtaining consent, "waiver of documentation of consent" may not be selected in Section D5. Please select the "waiver of documentation of consent" and "consent will be obtained" in Section D5 and complete Section O (wavier of documentation of consent) and Section J (informed consent).

- ❖ If your study is a Clinical Trial regulated by HSA, the option “Interventions/ Invasive Procedures” should be selected at Section D3. Do not uncheck this option.
- ❖ More than 1 option can be selected for Section D3 and D5.

- The default selection for migrated study in Section D4 is “Yes”. Please review if the option selected in Section D4 is accurate. If the study does not involve recruitment, please update it to “No”.

- **Section E/G**
  - The text box in iSHaRe Application Form Section F allows for formatting and insertion of tables. The text box in ECOS only allows insertion of text (without formatting and does not support data in tabular format). Please review the response migrated for these sections. You may need to update the response.
  - Section E7/G16 – Potential Risk: The default selection is “Social risk”. Please review if the classification of risk is accurate and update accordingly. More than one option can be selected.
  - Section G7 – Response from iSHaRe Section F8, F10 and F11 was migrated to Section G7. You may need to update the response accordingly if there were repetition.
  - Section G7/G9 – Visit schedule attachment(s) was migrated to Section G7. Please review if this attachment should be moved to Section G9.
  - Section G7/G10 – Management of incidental findings were indicated in iSHaRe Section F8 (now migrated to G7). Please update Section G10 (Management of incidental findings) accordingly. Note: G10 only appears if consent will be obtained.
  - Section G13 - Please indicate the age group of the research participants if it was not already included.
  - Section G14 - If pregnant women will be excluded from the study, please indicate, if it was not already included.

- **Section J**
  - Section J4 - Response from iSHaRe Section H2 and H3 was mapped to Section J4. Please review the response and update if required.
  - Section J5 – The default selection is face-to-face consent. Please update if your study has been approved by the IRB for obtaining informed consent remotely.
  - Section J6 - Response from iSHaRe Section P1, P2 and P3 was mapped to Section J6. Please review the response and update if required.

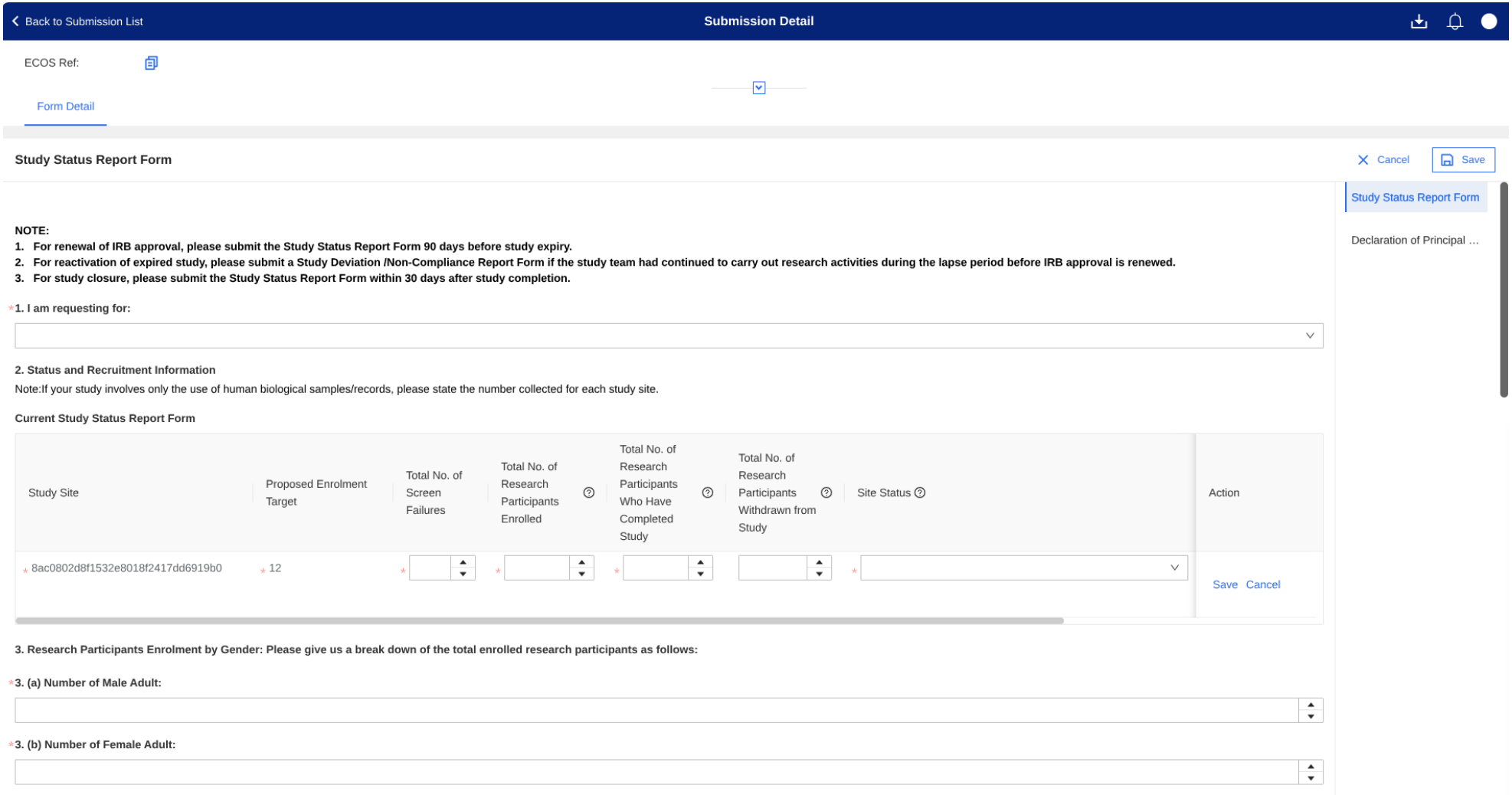
- **Section S**
    - For studies requested for wavier of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3, the default selection is "Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large". Please review if this is the correct option. Otherwise, please select the correct options accordingly.

- **Section W**
    - Please review and update Section W1 accordingly. For example, if your study involves collection of blood samples (some stored locally, some transferred overseas) and archival tumor samples. The migrated form will display them as 1 entry in prospective collection and 1 entry as existing human biological materials. Please update this section as such: The blood samples to be split into 2 different entries under the prospective collection while the archival tumor samples will be under the existing human biological materials.
- **Section X**
    - Section X2 - Response from iSHaRe Section T2, T3, T4 and T5 was mapped to Section X2. Please review the response and update if required.

For more information, please refer to the IRB Guidebook: Application Form and IRB Guidebook: Other Forms (Section A: Amendment Form).

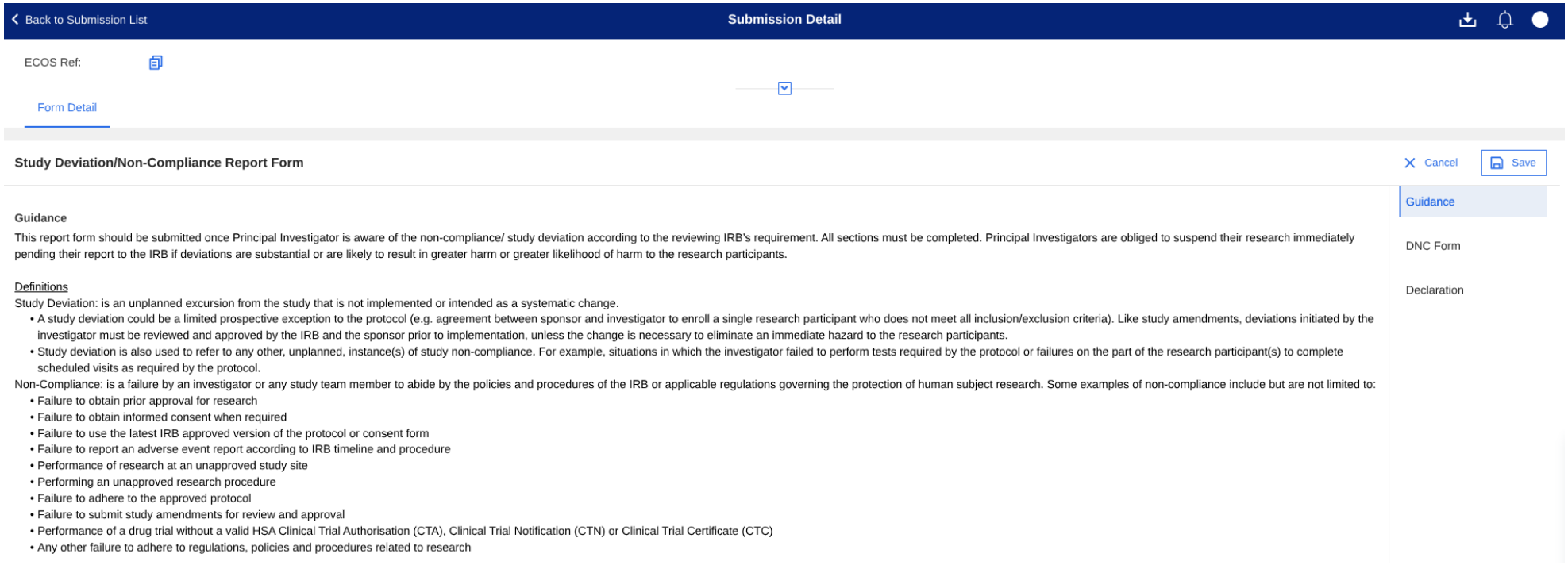
- **Study Status Report Form**

Study Renewal Report Form, Study Re-activation Report Form and Study Closure Report Form have been combined into one single form – Study Status Report Form. Please refer to the IRB Guidebook: Other Forms (Section B: Study Status Report Form) for more information.



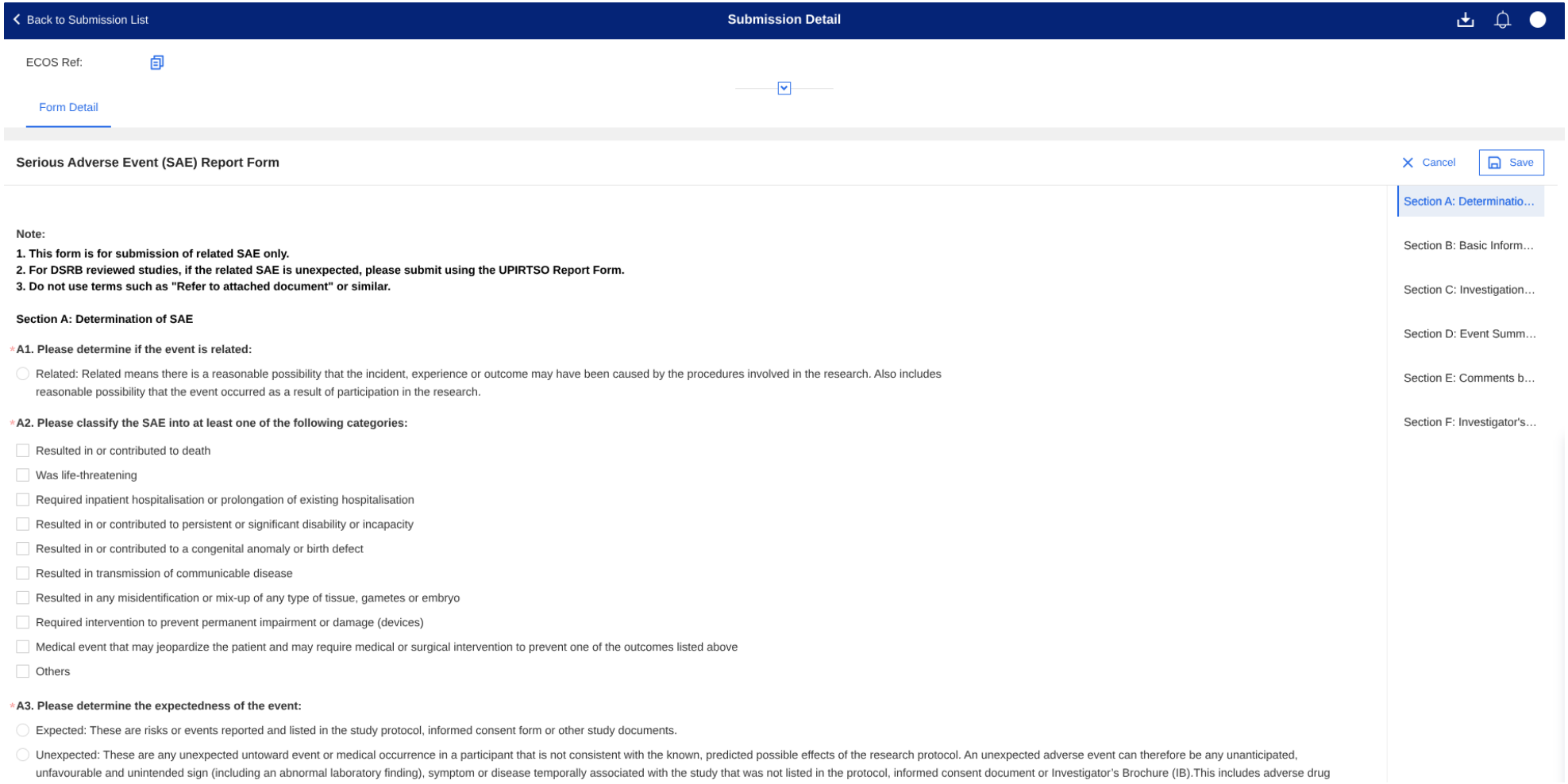
- **Study Deviation/ Non-compliance (DNC) Report Form**

DNC Report Form is for submission of Study Deviation/ Non-compliance. Please refer to the IRB Guidebook: Other Forms (Section C: Study Deviation/ Non-compliance (DNC) Form) for more information.



- **Serious Adverse Event (SAE) Report Form**

SAE Report Form is for submission of local and overseas SAE. Please refer to the IRB Guidebook: Other Forms (Section D: Serious Adverse Event (SAE) Form) for more information.



- **Other Study Notification (OSN) Report Form**

OSN Report Form is for submission of other study notifications. Please refer to the IRB Guidebook: Other Forms (Section E: Other Study Notification (OSN) Report Form) for more information.