Navigating Ethics & Compliance Online System (ECOS) User Guide

Institutional Review Board (IRB) Module

(ECOS User Guide – IRB Module, Ver 1, 9 May 24)

National Healthcare Group
Adding years of healthy life

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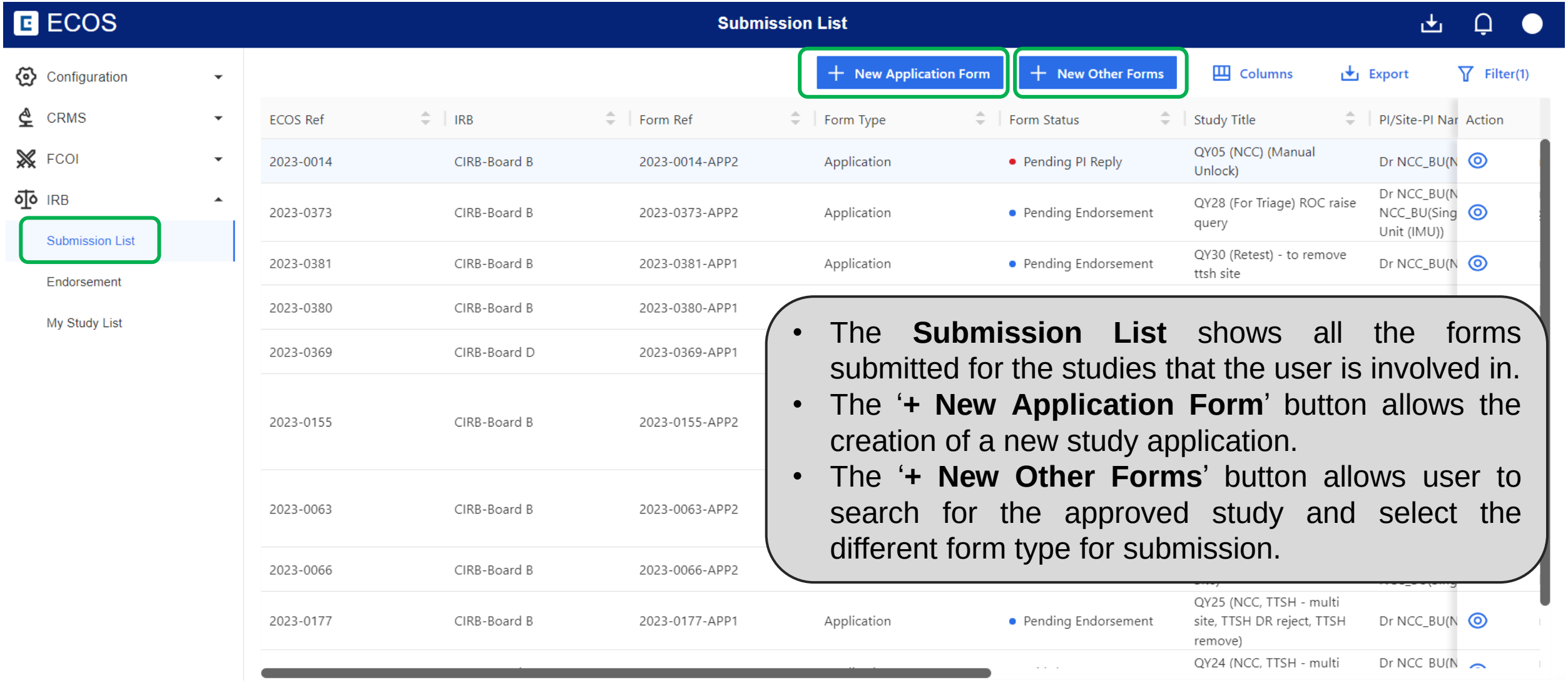
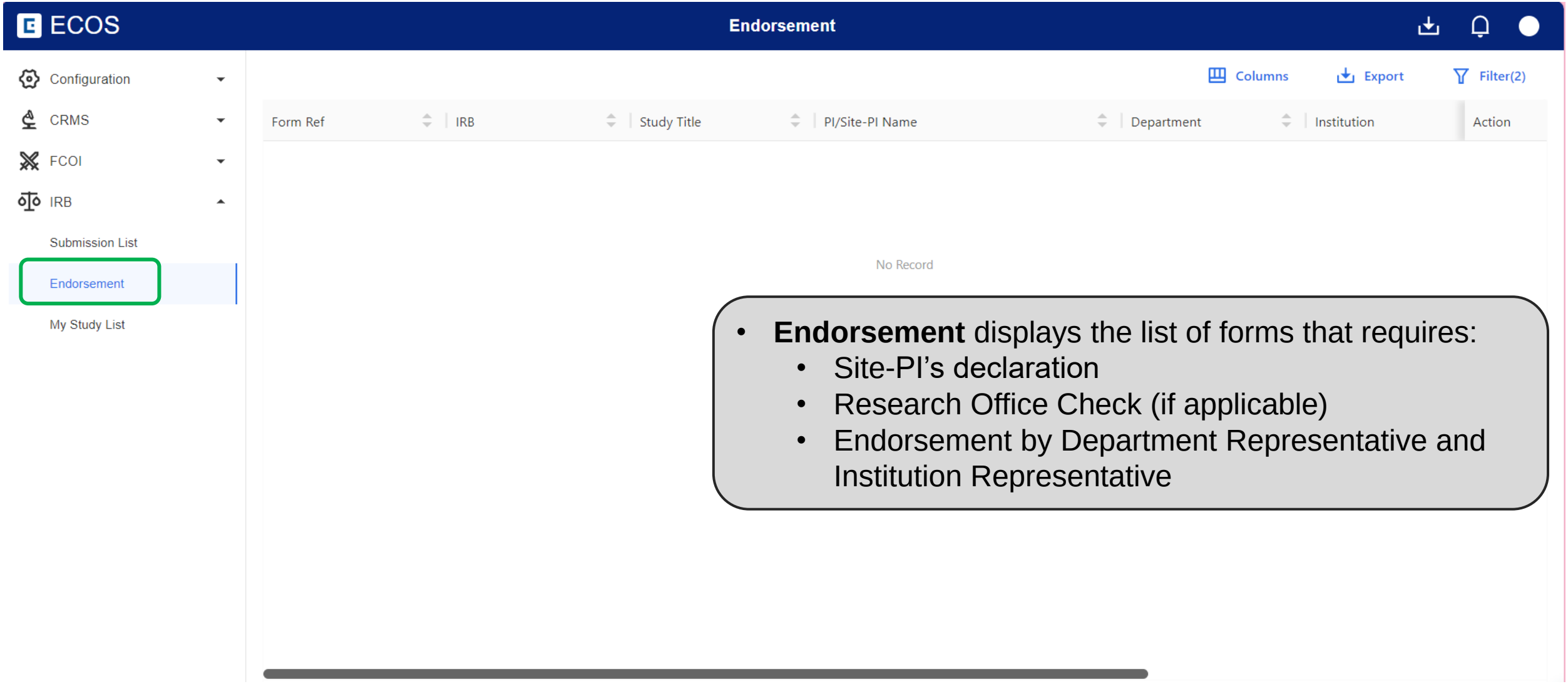
IRB Dashboard – Submission List



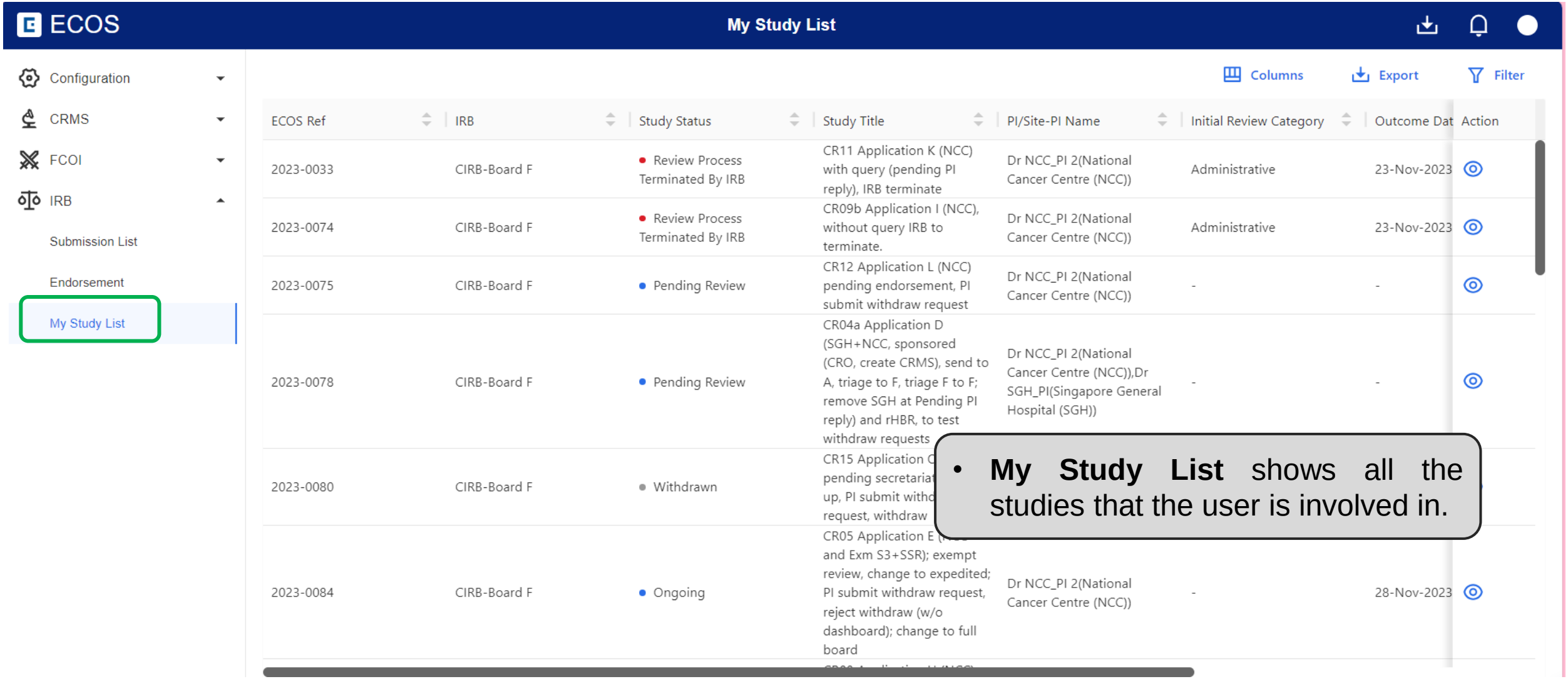
- The **Submission List** shows all the forms submitted for the studies that the user is involved in.
- The '**+ New Application Form**' button allows the creation of a new study application.
- The '**+ New Other Forms**' button allows user to search for the approved study and select the different form type for submission.

IRB Dashboard – Endorsement



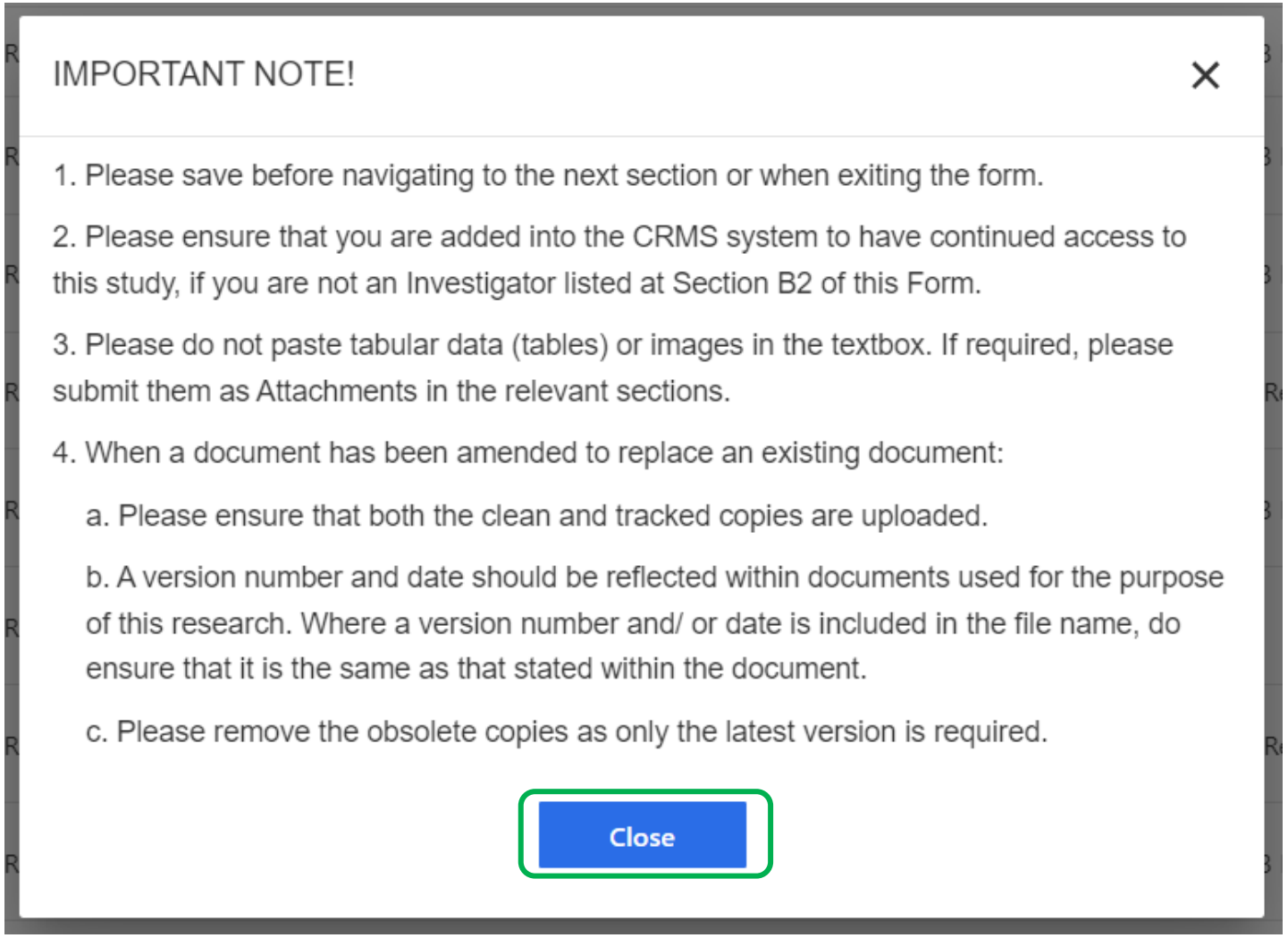
- **Endorsement** displays the list of forms that requires:
  - Site-PI's declaration
  - Research Office Check (if applicable)
  - Endorsement by Department Representative and Institution Representative

IRB Dashboard – My Study List



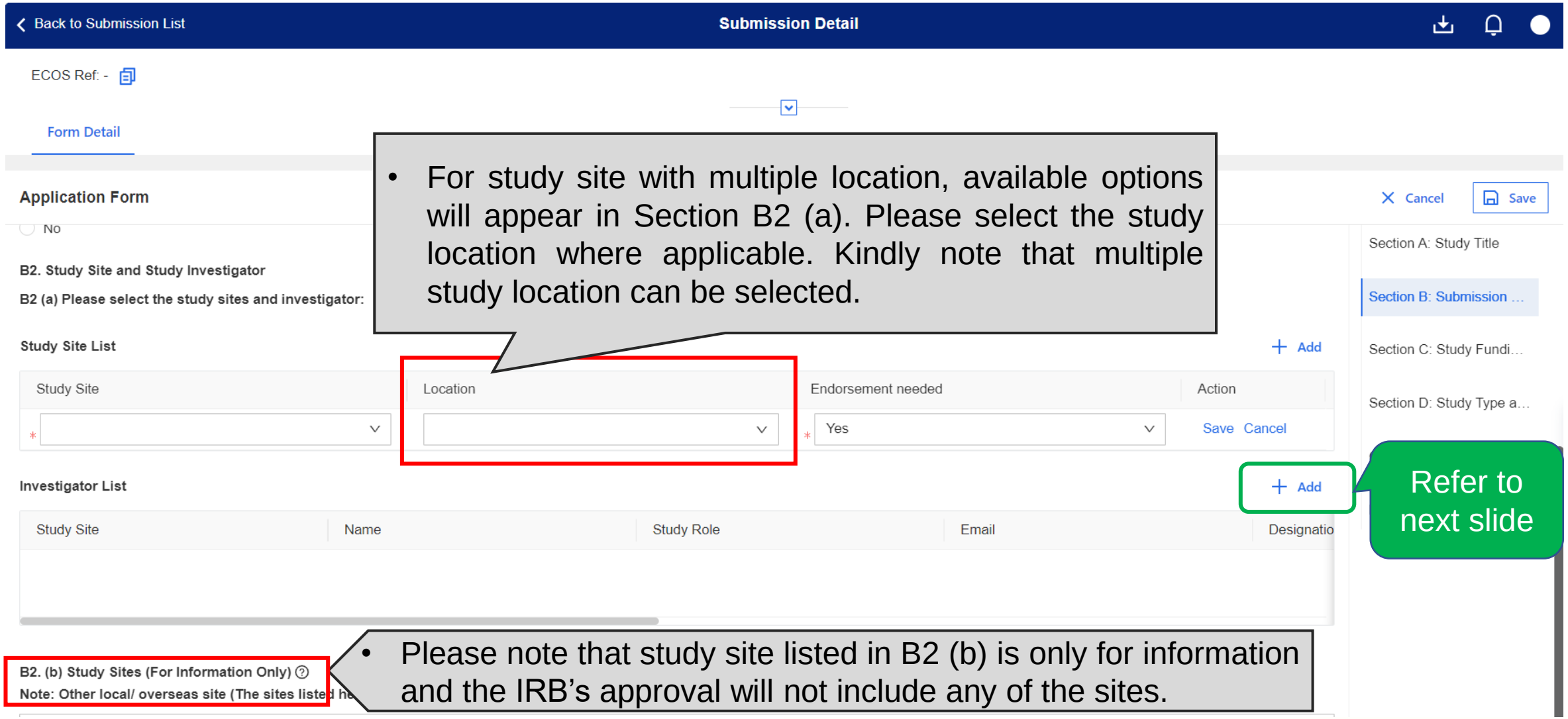
- **My Study List** shows all the studies that the user is involved in.

Creation of New Application Form



- Click on '**Close**' button to proceed with the creation of form.
- Complete **Section A: Study Title**, **Section B: Submission IRB and Board, at least 1 Study Site and 1 Principal Investigator** to save draft.

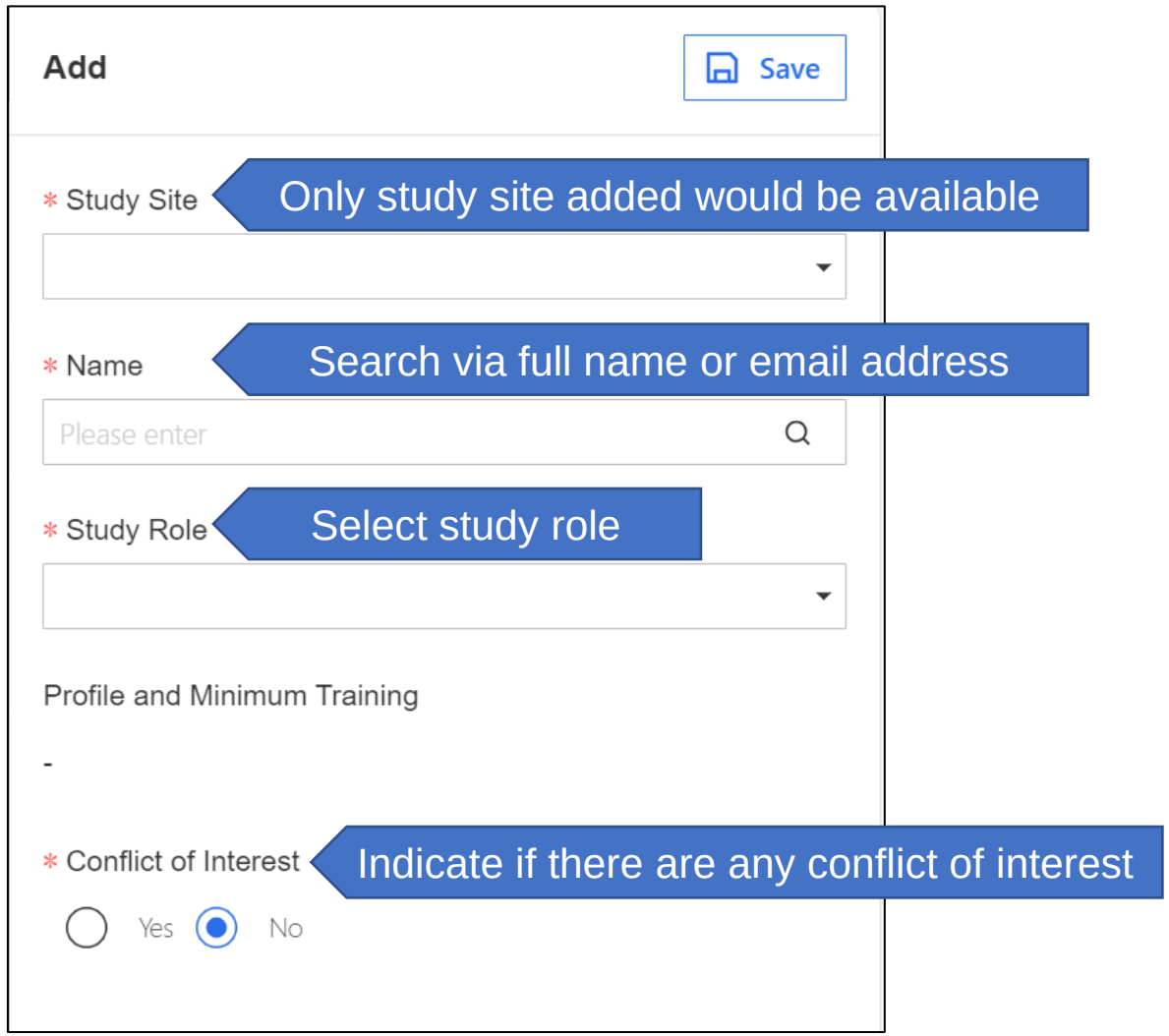
Study Site and Study Investigator

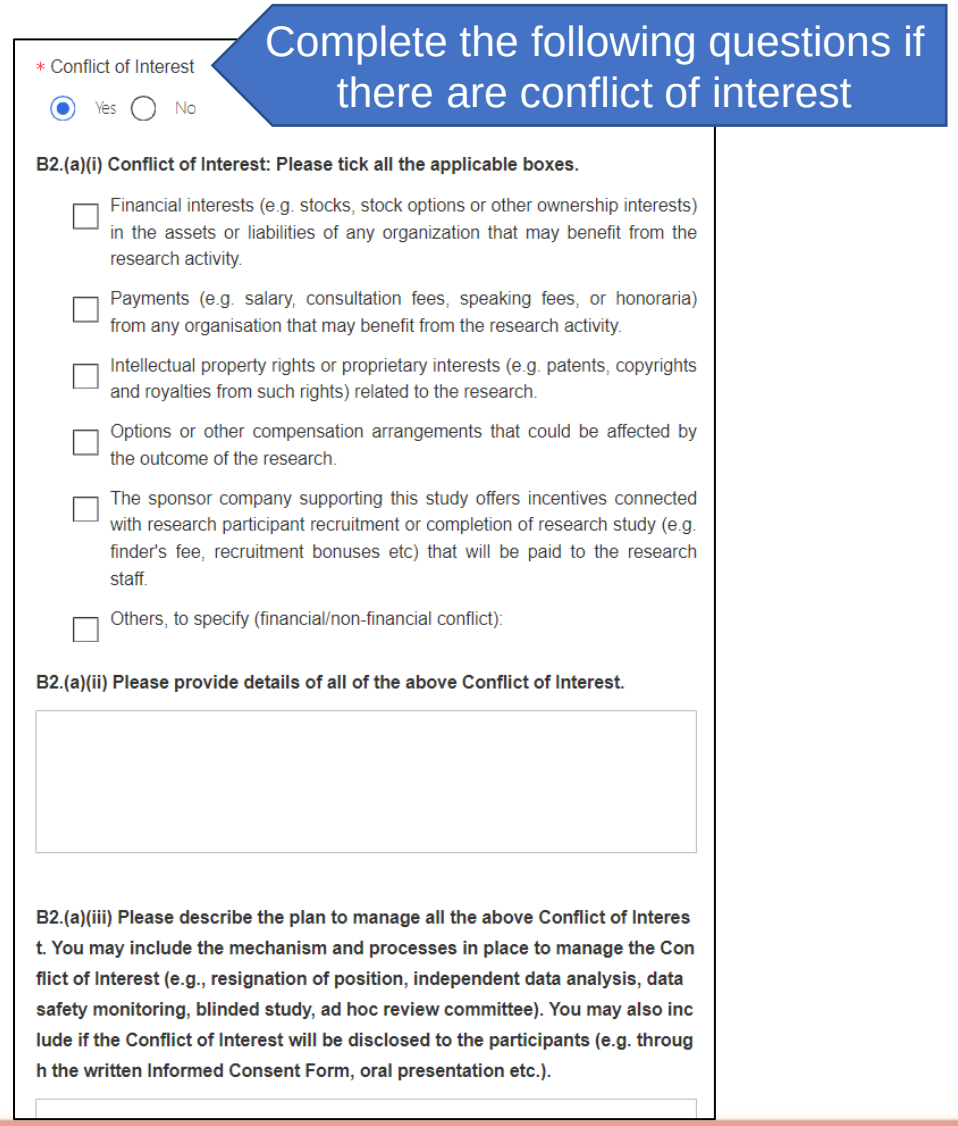


- For study site with multiple location, available options will appear in Section B2 (a). Please select the study location where applicable. Kindly note that multiple study location can be selected.

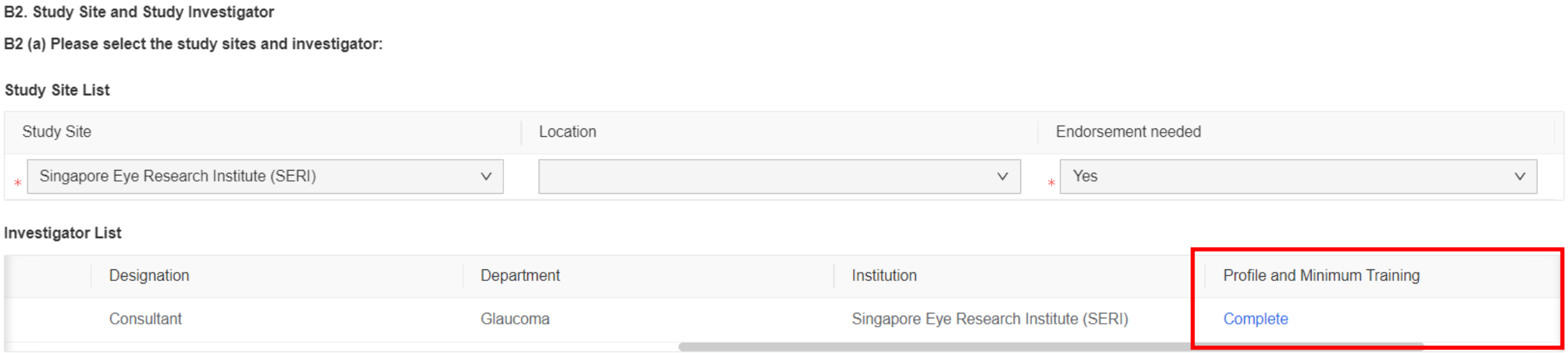
- Please note that study site listed in B2 (b) is only for information and the IRB's approval will not include any of the sites.

Adding Study Investigator





Minimum Training Requirement


B2. Study Site and Study Investigator

B2 (a) Please select the study sites and investigator:

Study Site List

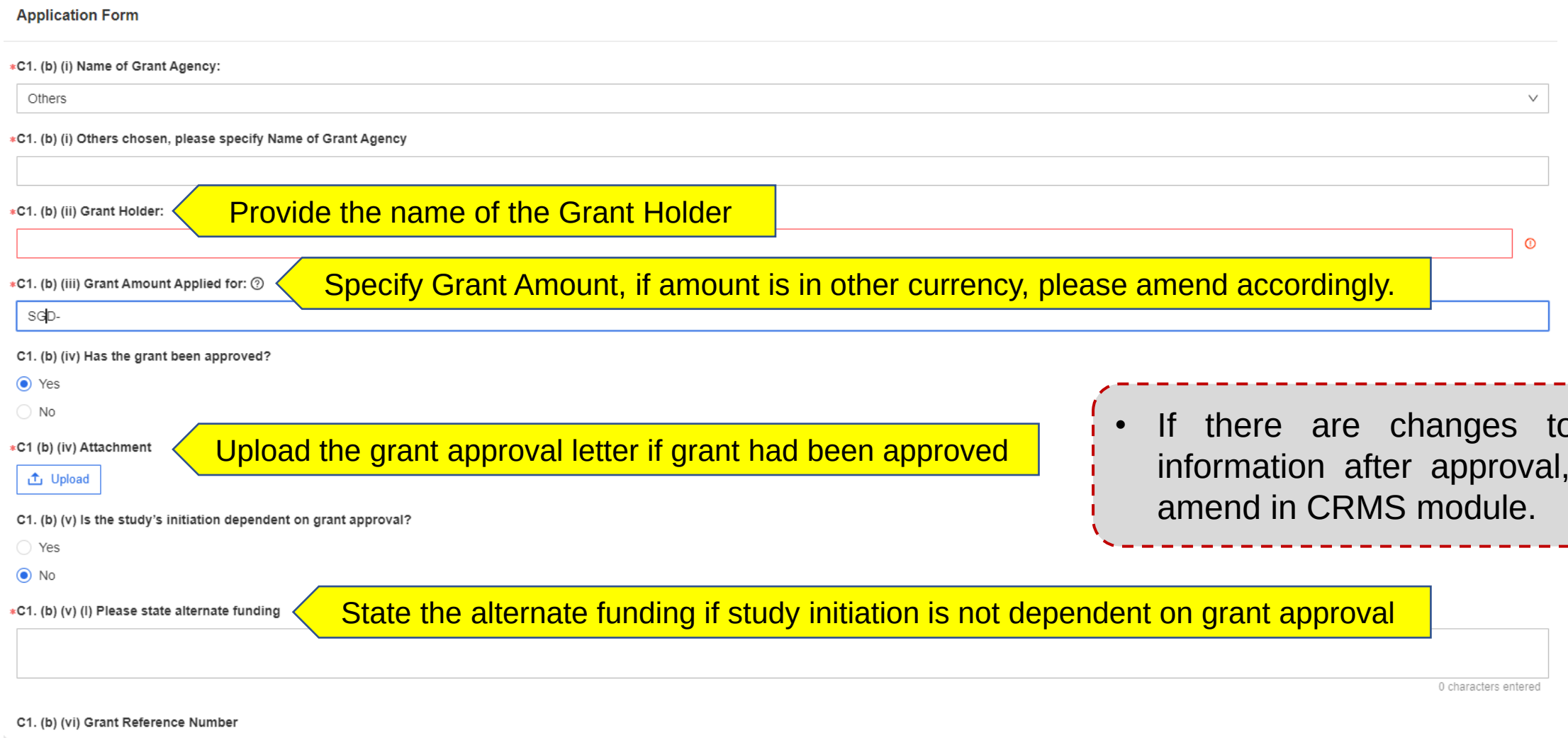
Study Site	Location	Endorsement needed
* Singapore Eye Research Institute (SERI)		* Yes

Investigator List

	Designation	Department	Institution	Profile and Minimum Training
	Consultant	Glaucoma	Singapore Eye Research Institute (SERI)	Complete

- After user is added to study team, a link to ‘Details’ will be provided to view user profile and their minimum training status.
- Do a mandatory check to find out if the user had completed the minimum training requirement to conduct the study, the status will be as follows:
  - ✓Complete: The user had fulfilled the minimum training requirement.
  - ✓Incomplete: The user had not completed the minimum training requirement to conduct the type of study (e.g. Clinical Trials, HBR, non-HBR, SBE). Therefore, the form cannot be submitted.

Study Funding - Grant



- If there are changes to Grant information after approval, please amend in CRMS module.

Study Funding - Pharmaceutical/ Industry Sponsored

Application Form

*C1. (c) (i) Name of Sponsor Company

Provide the name of the Sponsor Company

- Please provide Sponsor and Clinical Research Organisation (CRO) details in CRMS module.

*C1. (c) (ii) Is the sponsor offering any incentive connected with research participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc.) that will be paid to the research staff?

- Yes
- No

*C1. (c) (iii) Will the sponsor be providing monitoring?

Indicate if sponsor would be providing monitoring

- Yes
- No

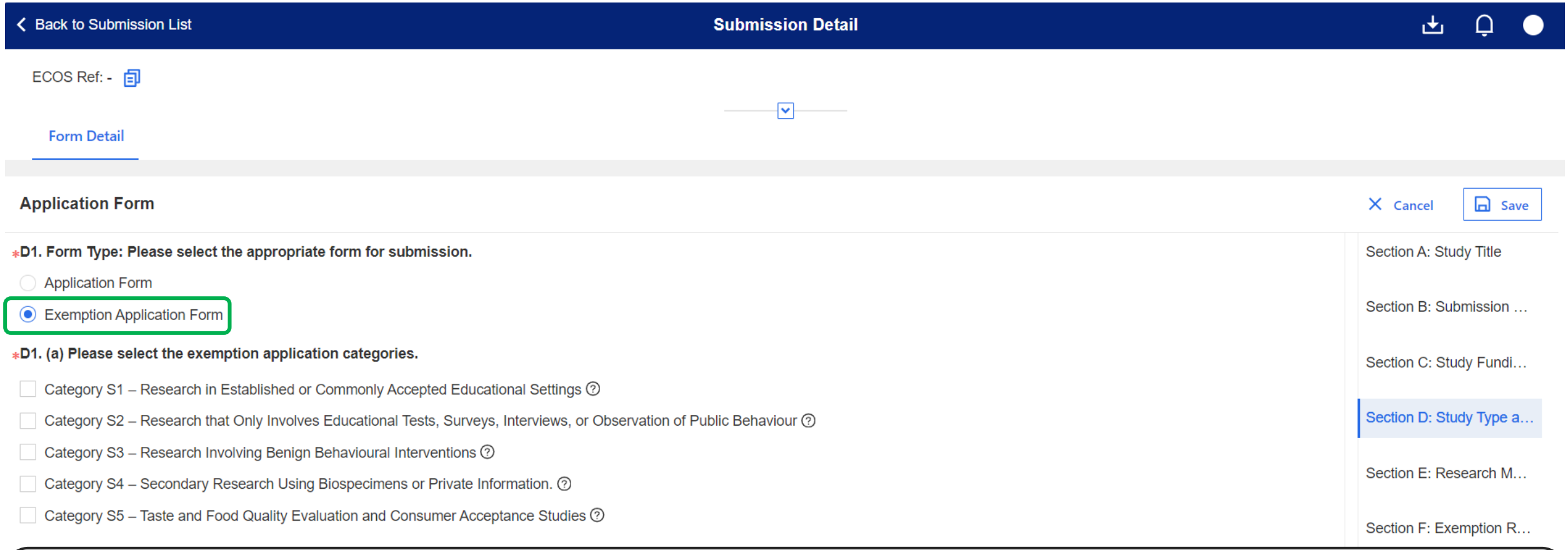
*C1. (c) (iv) Would the sponsor be responsible for the payment and compensation of injury or illness to research participants arising from participation in the study?

- Yes
- No

*C2. Will the funding/sponsor cover all research-related costs e.g., drugs, devices, procedures, tests and visits?

- Yes
- No
- Not applicable - no research-related costs

Exemption Studies



- To submit studies for exemption, choose '**Exemption Application Form**' in **Section D1** and select the exemption application categories.
- **Section E: Research Methodology & Section F: Exemption Review Criteria** will then appear for completion.

Exemption Category S1

- Research conducted in established or commonly accepted **educational settings** that involves **normal educational practices** that are not likely to adversely impact student's opportunity to learn required educational content or the assessment of educators who provide instruction.

Examples

- Research on regular and special education instructional strategies
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption Category S2

- Research that only involves **educational tests, surveys, interviews, or observations of public behavior** that meets at least one of the following criteria:
  a. Information obtained is recorded by investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers to subjects;
  b. Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, educational advancement or reputation; or
  c. Information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily be ascertained, directly or through identifiers linked to the subjects and there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

Example

- Interview consisting of audio-recording but does not record any identifying information about the information. (This example meets criteria a. above.)

Exemption Category S3

- Research involving **benign behavioural interventions** which are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. **Research involving benign behavioral interventions in conjunction with the collection of information** from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
  a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
  b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing.

Examples

- Research required participants to play online game, solve puzzle under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Exemption Category S4

- Secondary research using identifiable biospecimens or private information, if
  a. It uses publicly available identifiable biospecimens or private information; or
  b. The information will be recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

  Note: Secondary research is re-using information and/ or biospecimens that are collected for some other “primary” or “initial” study. This exemption is not applicable for Human Biomedical Research regulated under the HBRA

Examples

- A researcher who examine an existing publicly-available database.

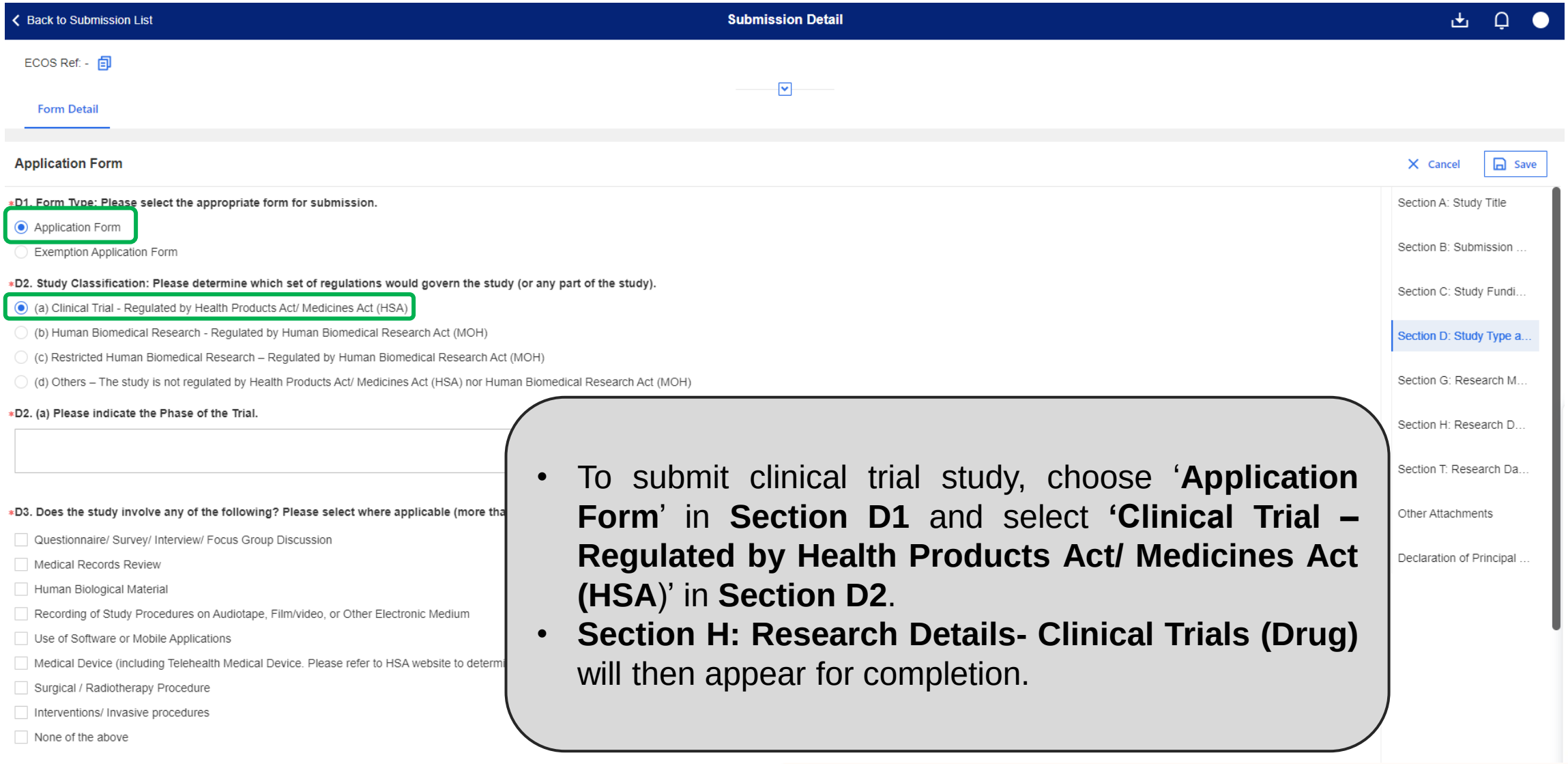
Exemption Category S5

- **Taste and food quality evaluation** and **consumer acceptance studies**:
  a. If wholesome foods without additives are consumed, or
  b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

Examples

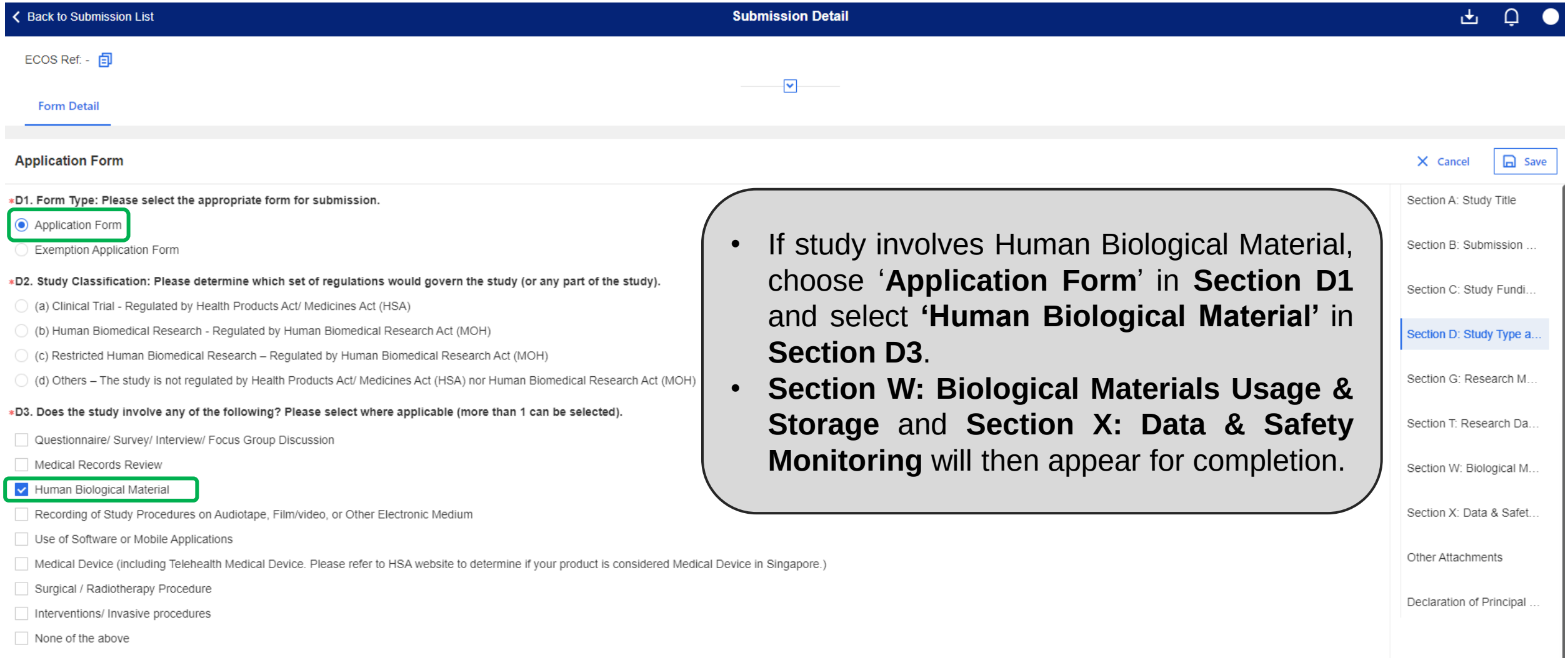
- Participants were asked to taste a set of novel snacks to determine consumers' preferences. The set of novel snacks contain food ingredients found to be safe.

Clinical Trial



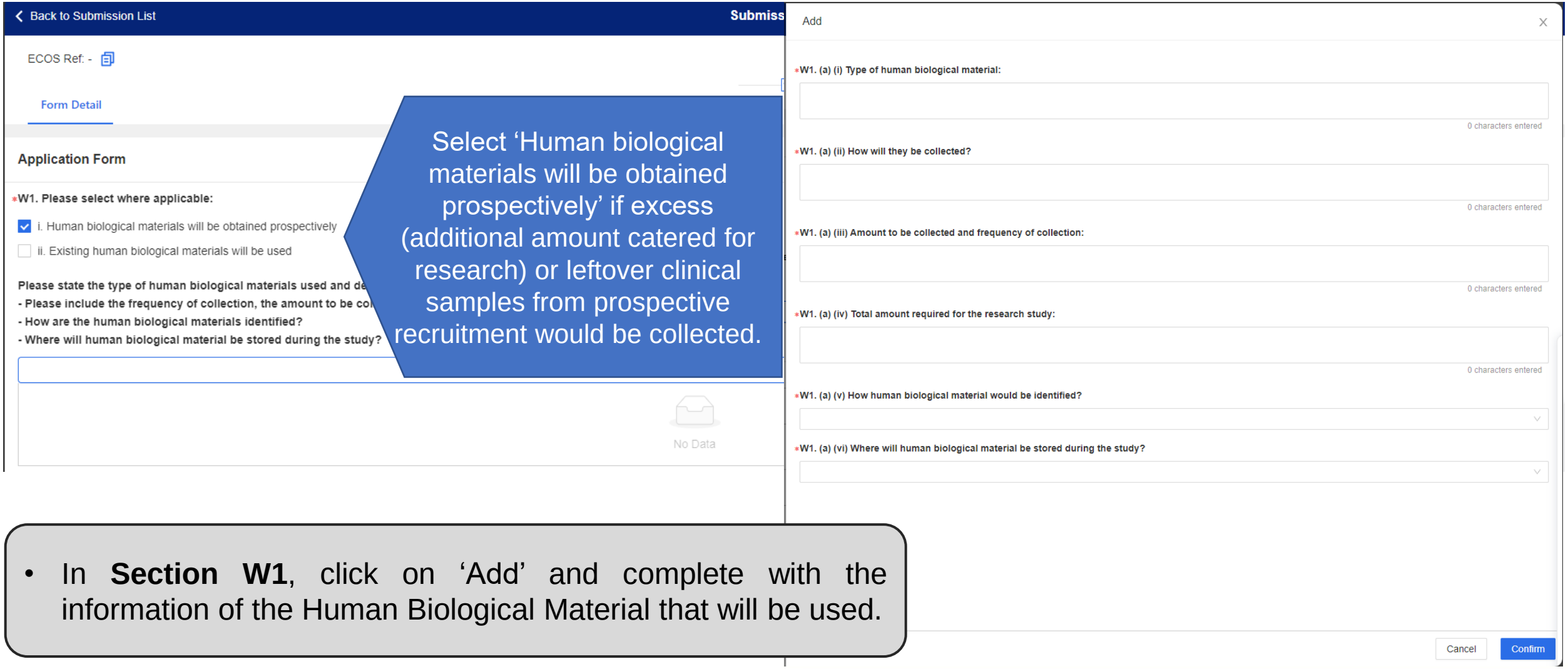
- To submit clinical trial study, choose '**Application Form**' in **Section D1** and select **'Clinical Trial – Regulated by Health Products Act/ Medicines Act (HSA)**' in **Section D2**.
- **Section H: Research Details- Clinical Trials (Drug)** will then appear for completion.

Study involving Human Biological Material



- If study involves Human Biological Material, choose '**Application Form**' in **Section D1** and select **'Human Biological Material'** in **Section D3**.
- **Section W: Biological Materials Usage & Storage** and **Section X: Data & Safety Monitoring** will then appear for completion.

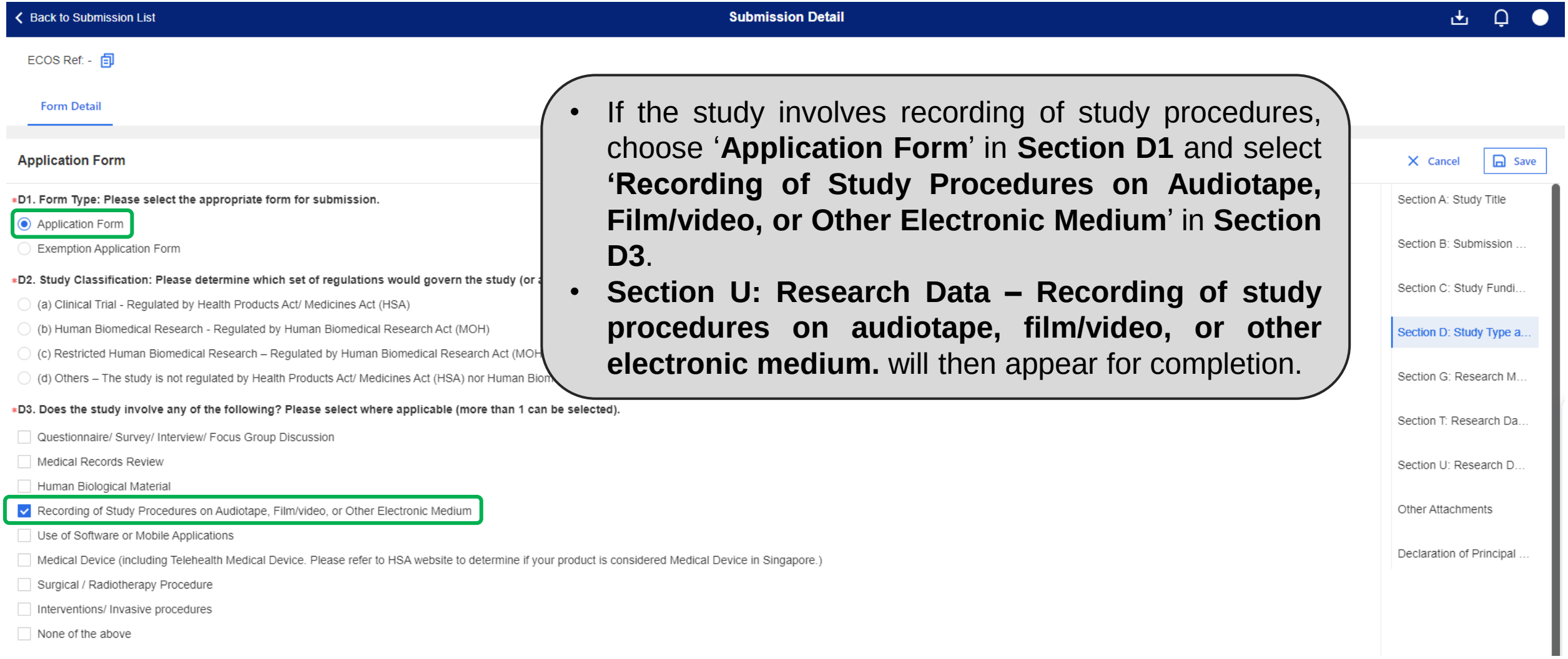
Study involving Human Biological Material



Select 'Human biological materials will be obtained prospectively' if excess (additional amount catered for research) or leftover clinical samples from prospective recruitment would be collected.

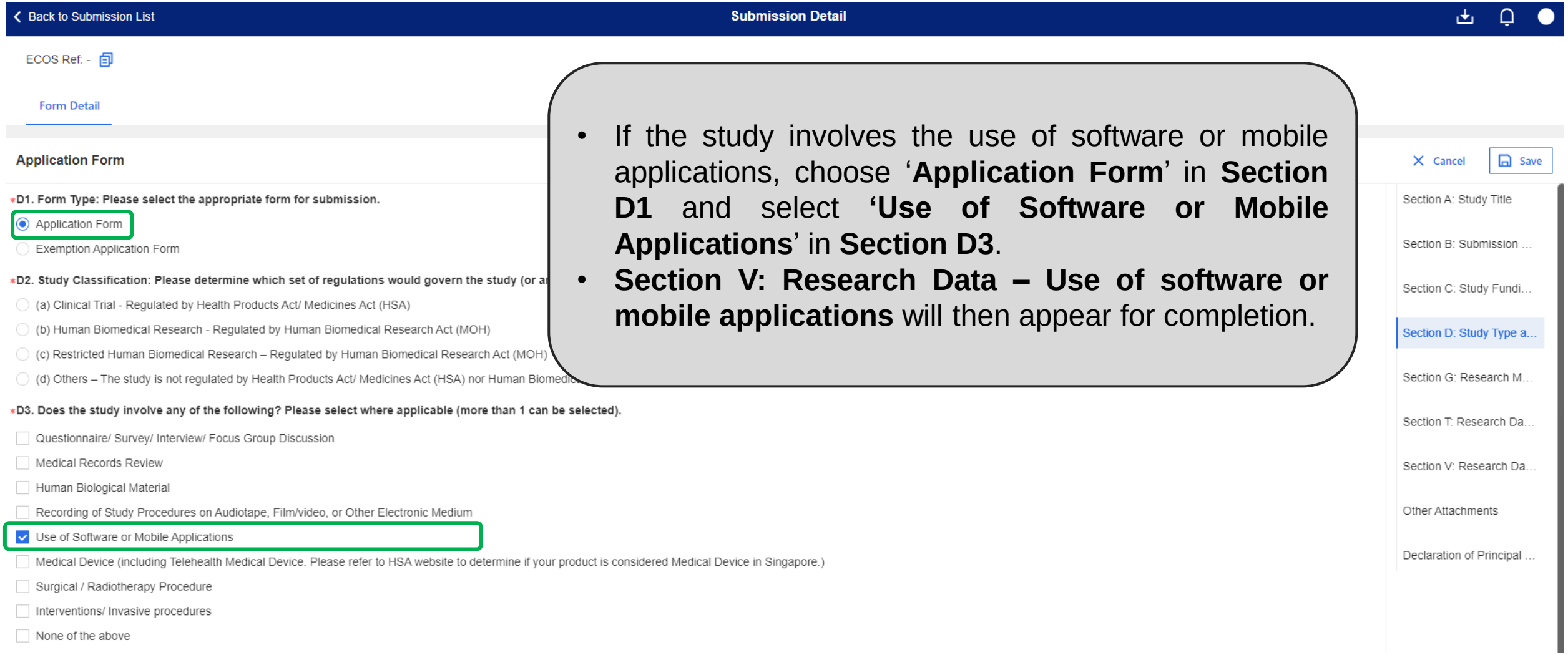
- In **Section W1**, click on 'Add' and complete with the information of the Human Biological Material that will be used.

Study Involving Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium



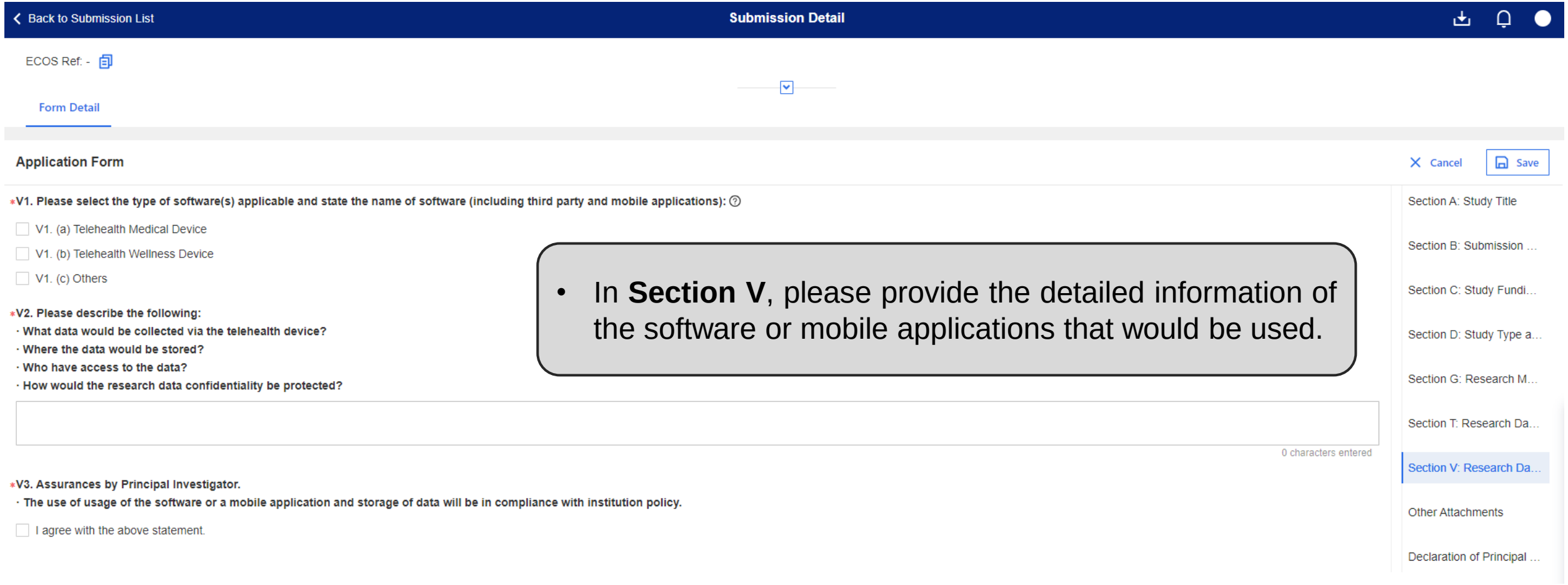
- If the study involves recording of study procedures, choose '**Application Form**' in **Section D1** and select '**Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium**' in **Section D3**.
- **Section U: Research Data – Recording of study procedures on audiotape, film/video, or other electronic medium.** will then appear for completion.

Study Involving the Use of Software or Mobile Applications



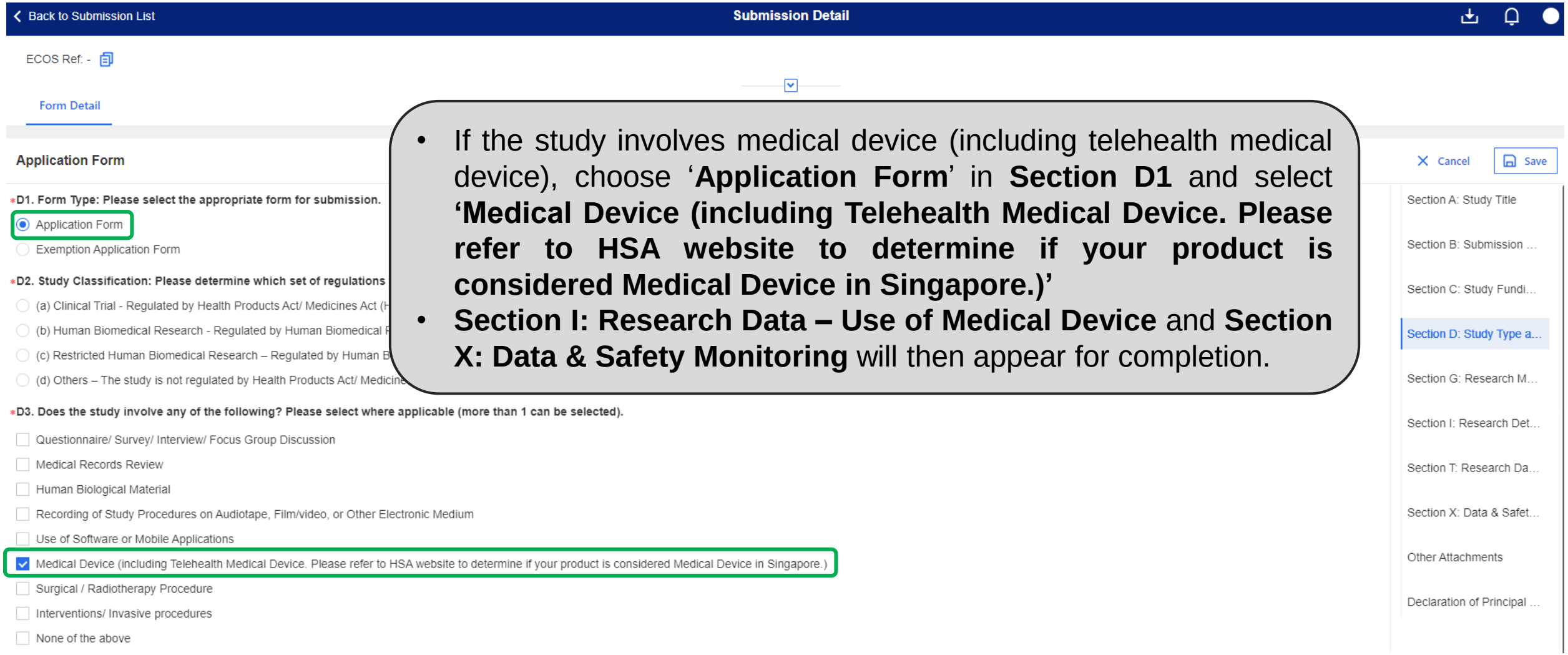
- If the study involves the use of software or mobile applications, choose '**Application Form**' in **Section D1** and select **'Use of Software or Mobile Applications**' in **Section D3**.
- **Section V: Research Data – Use of software or mobile applications** will then appear for completion.

Study Involving the Use of Software or Mobile Applications



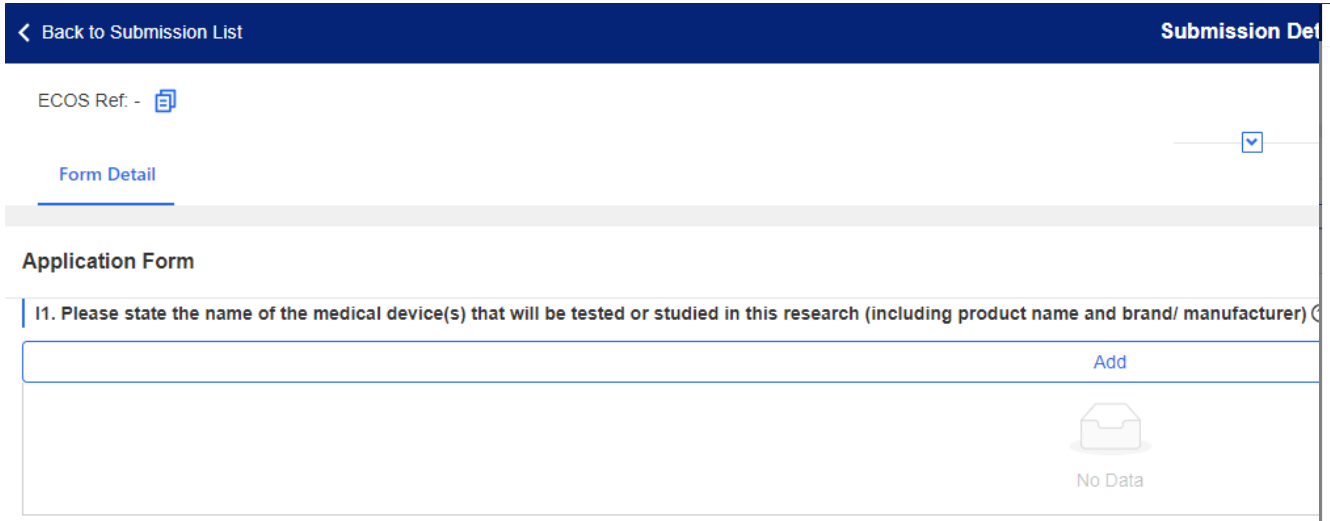
- In **Section V**, please provide the detailed information of the software or mobile applications that would be used.

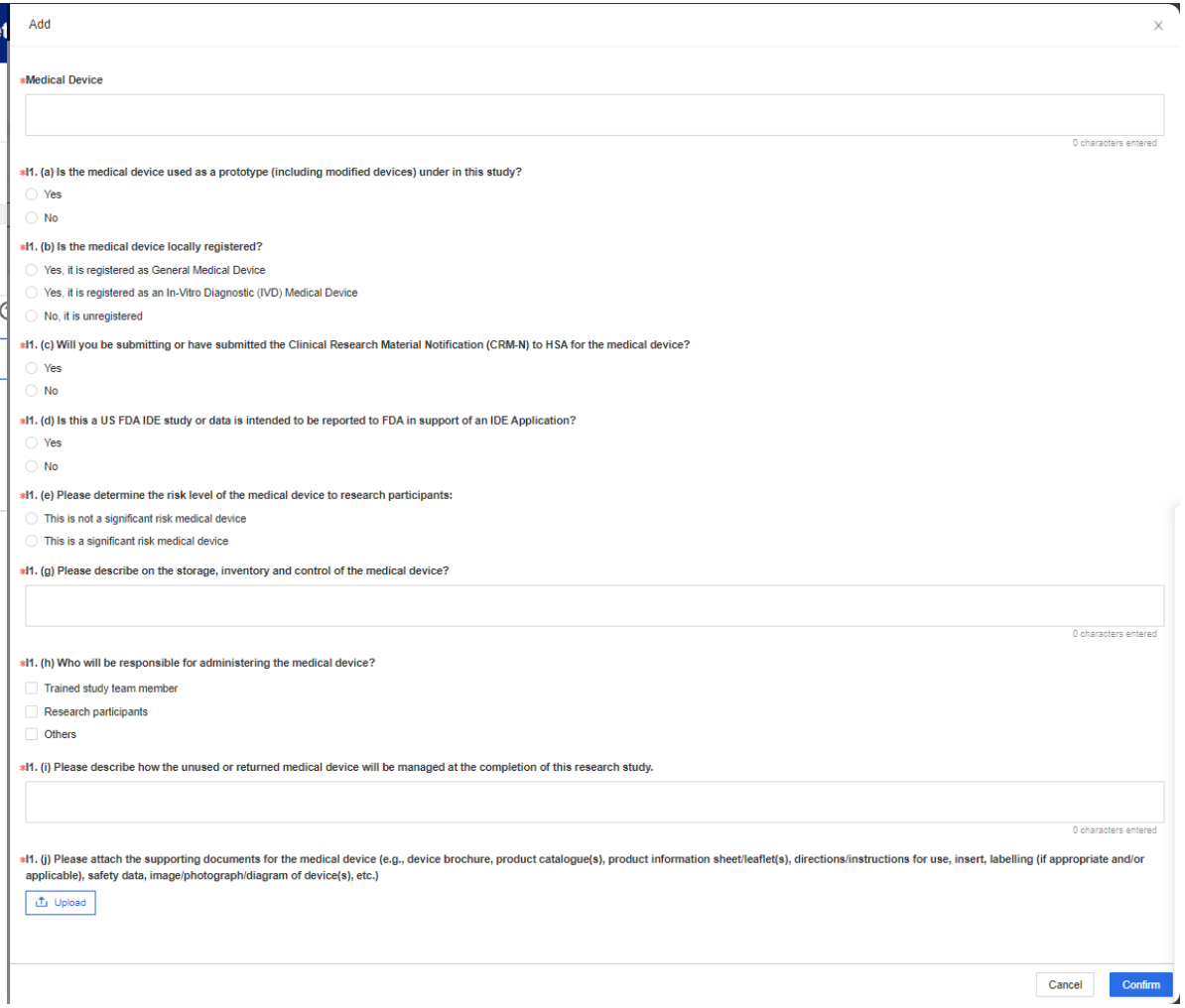
Study Involving Medical Device (including Telehealth Medical Device)



- If the study involves medical device (including telehealth medical device), choose '**Application Form**' in **Section D1** and select **'Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)'**
- **Section I: Research Data – Use of Medical Device** and **Section X: Data & Safety Monitoring** will then appear for completion.

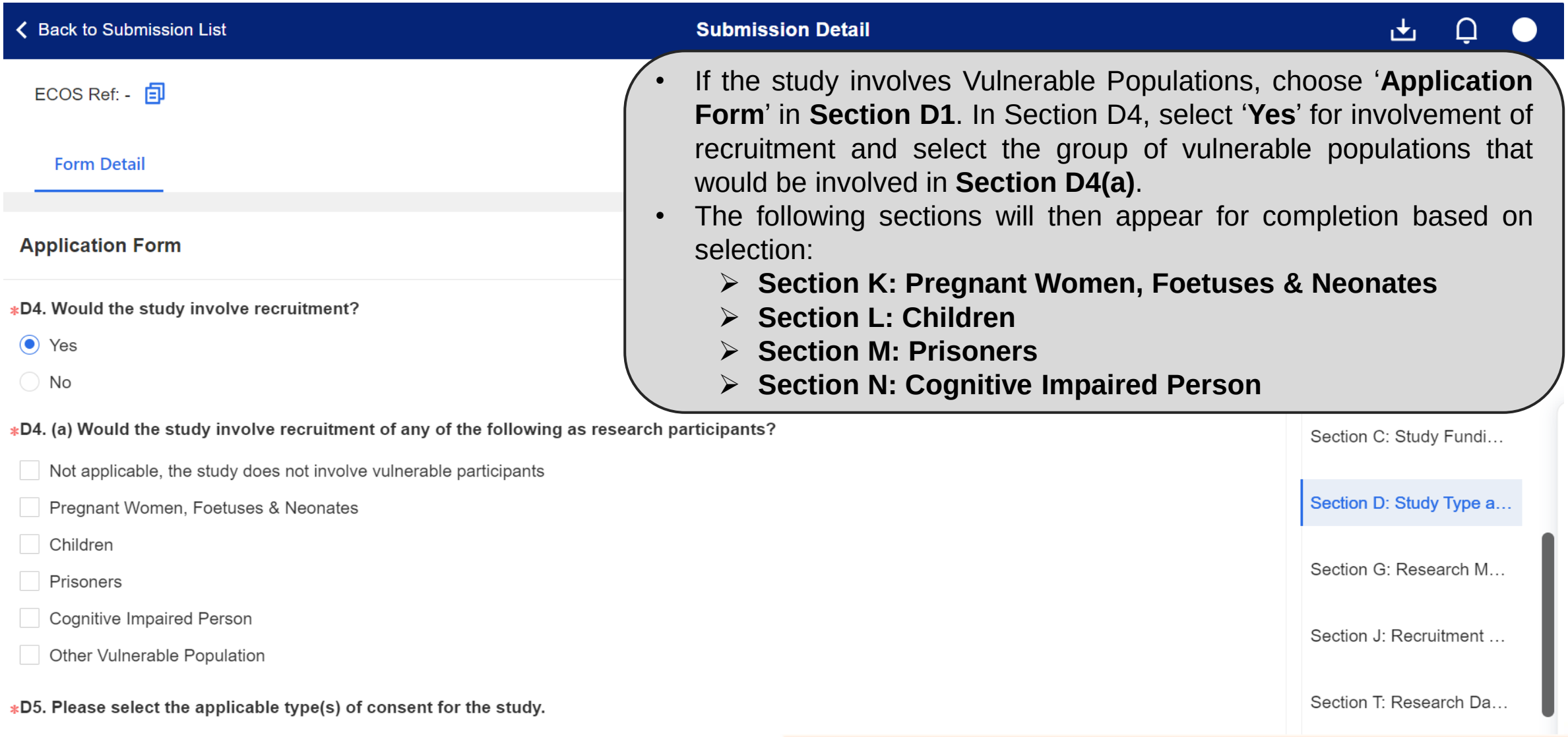
Study Involving Medical Device (including Telehealth Medical Device)





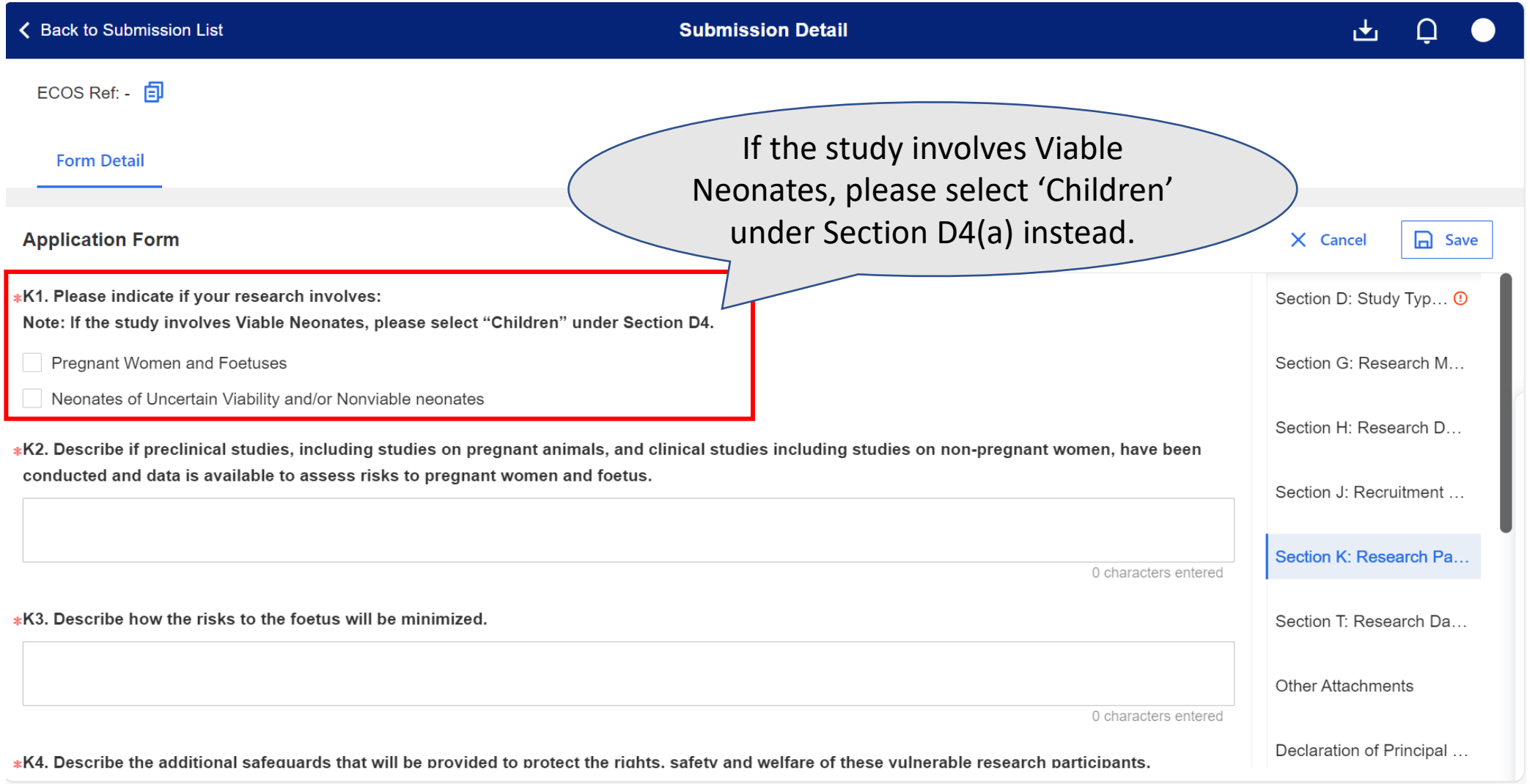
- In **Section I1**, click on ‘Add’ and complete with the information of the Medical Device that will be used.

Study Involving Vulnerable Populations

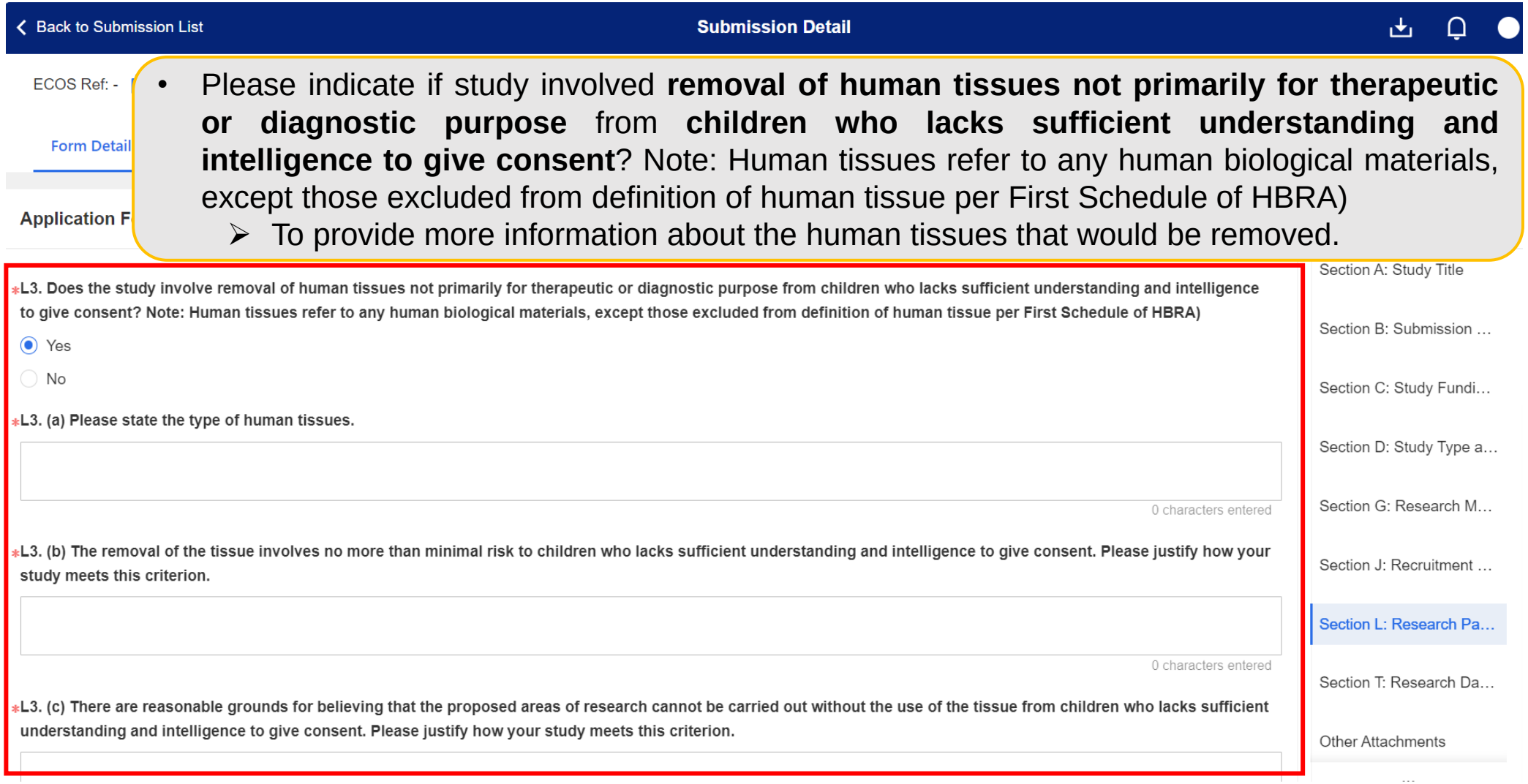


- If the study involves Vulnerable Populations, choose '**Application Form**' in **Section D1**. In Section D4, select '**Yes**' for involvement of recruitment and select the group of vulnerable populations that would be involved in **Section D4(a)**.
- The following sections will then appear for completion based on selection:
  - **Section K: Pregnant Women, Foetuses & Neonates**
  - **Section L: Children**
  - **Section M: Prisoners**
  - **Section N: Cognitive Impaired Person**

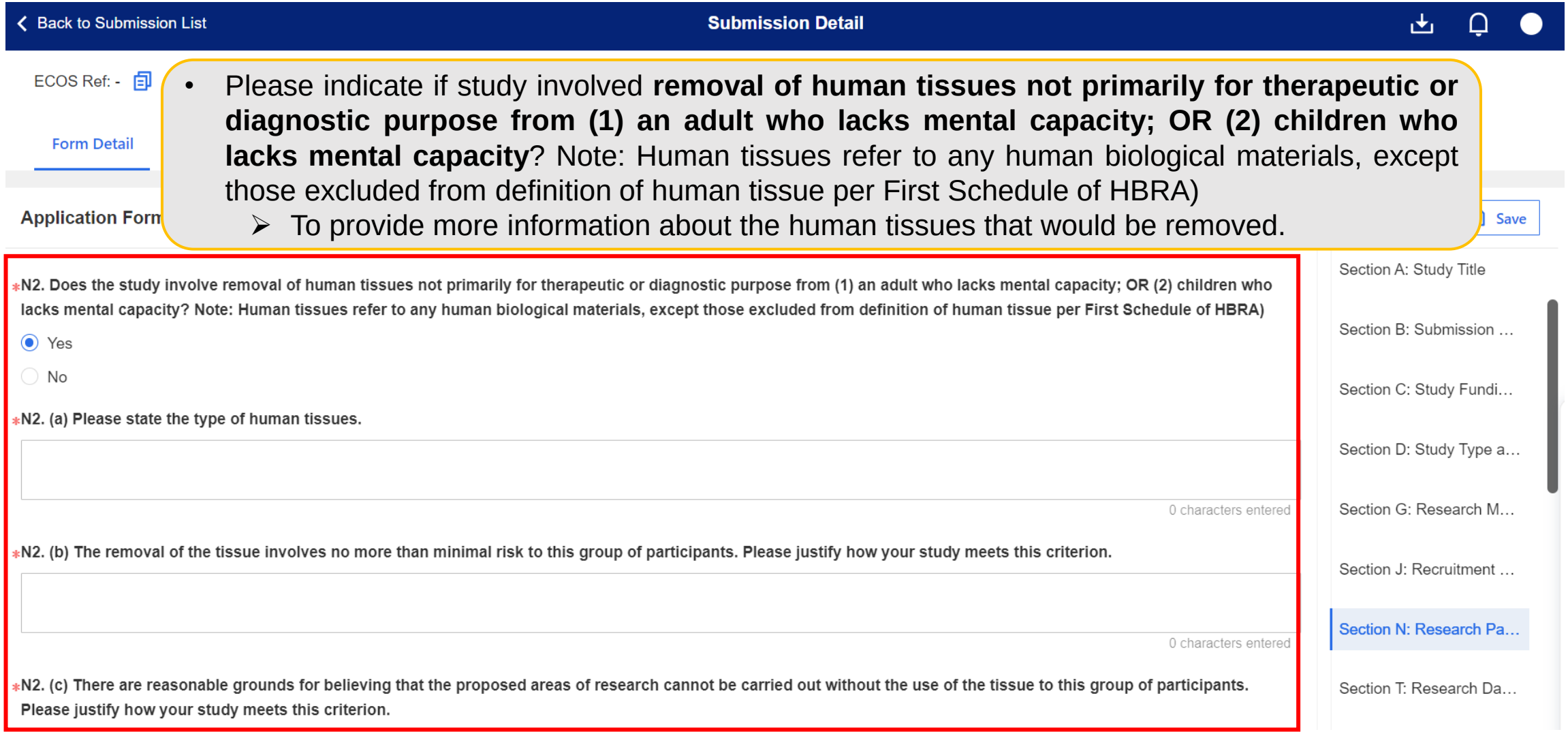
Study Involving Vulnerable Populations – Pregnant Women, Foetuses & Neonates



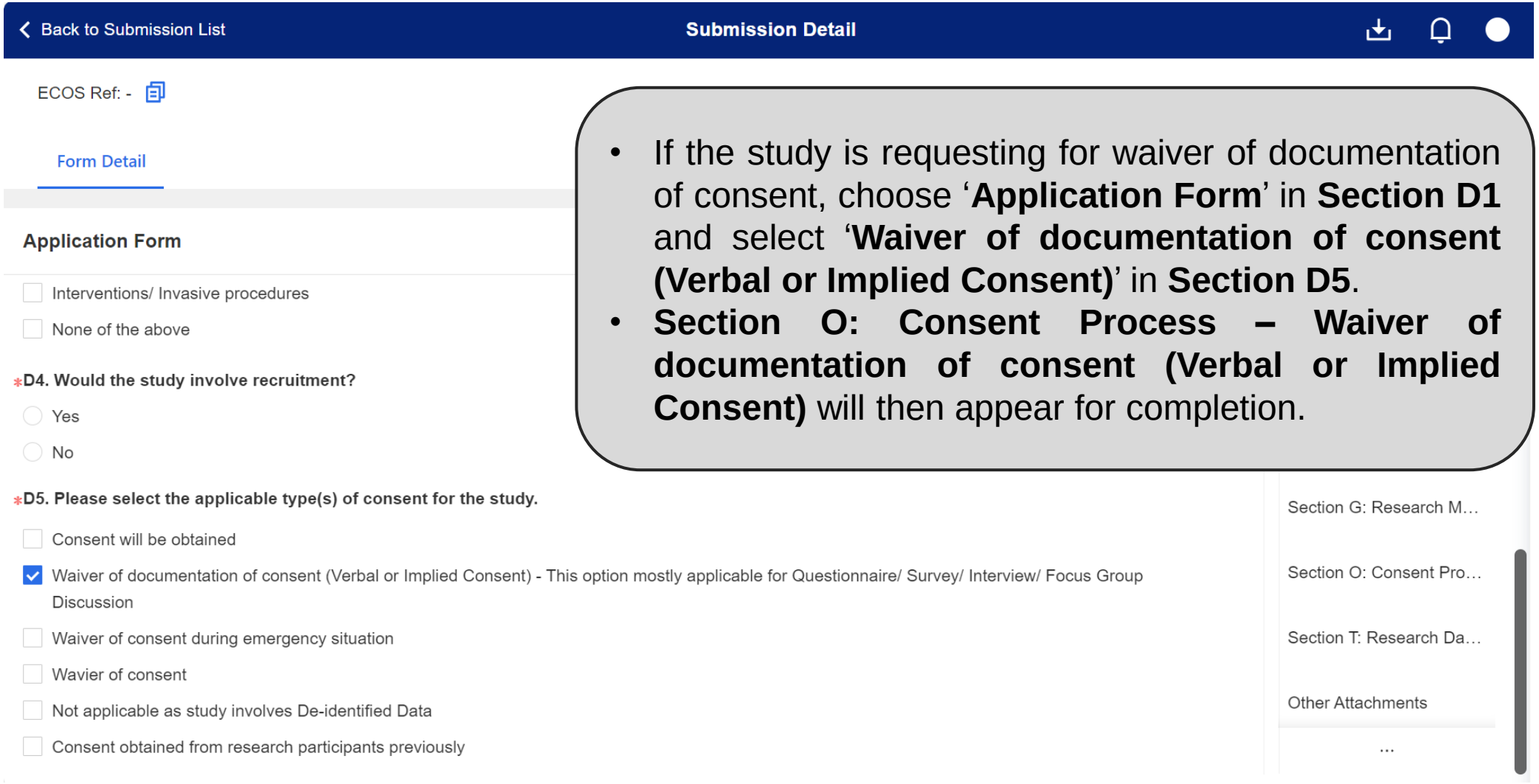
Study Involving Vulnerable Populations – Children



Study Involving Vulnerable Populations – Cognitive Impaired Person

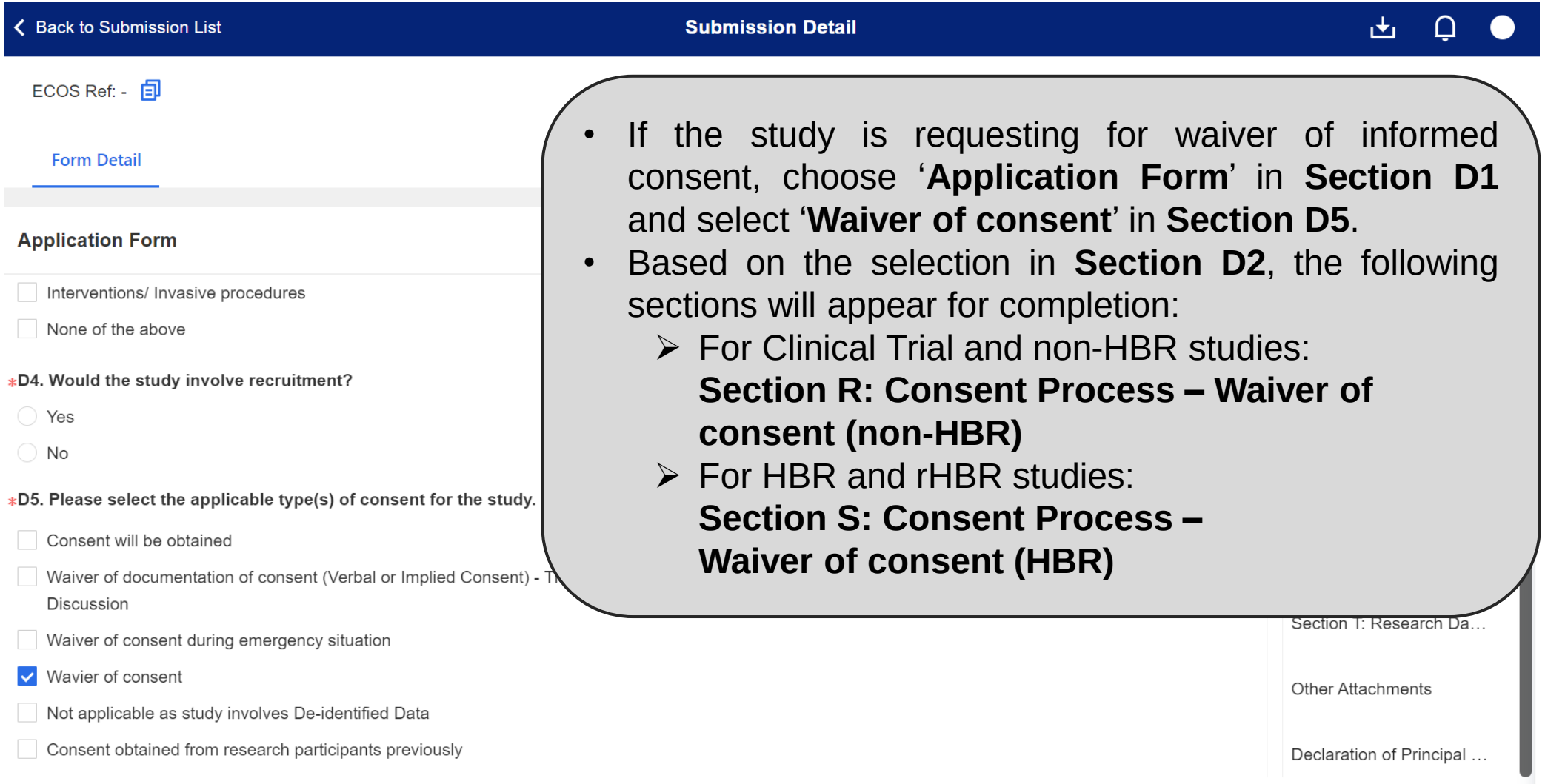


Waiver of Documentation of Informed Consent



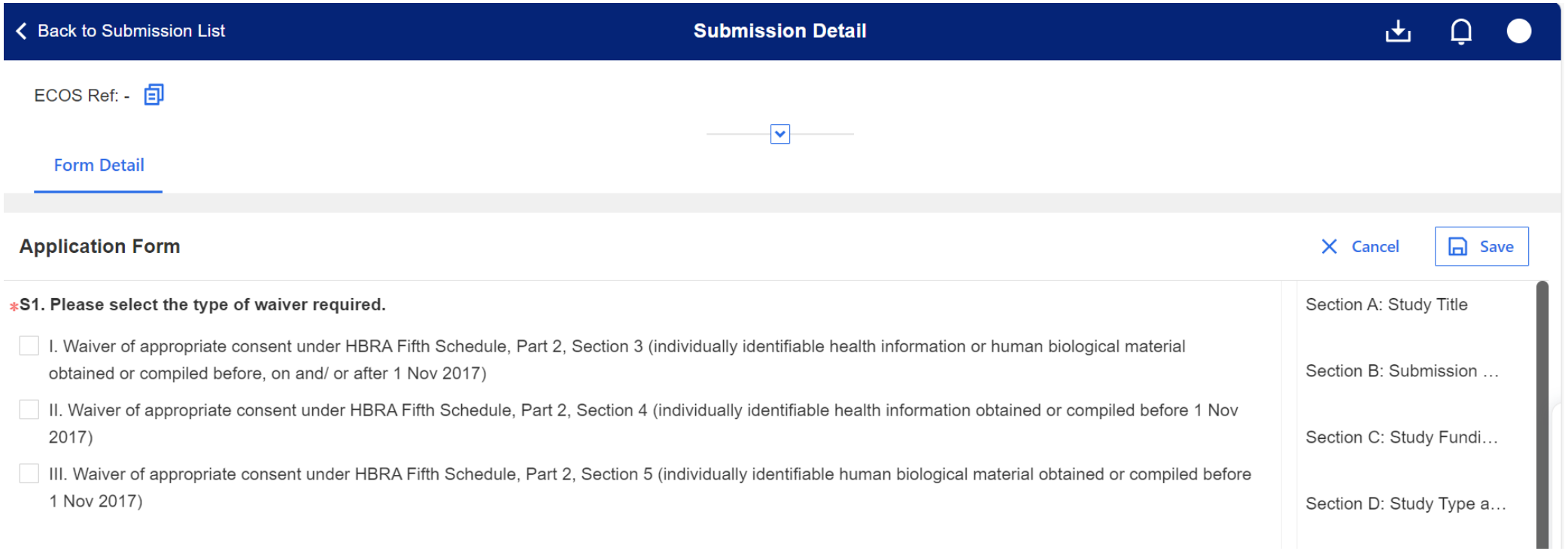
- If the study is requesting for waiver of documentation of consent, choose '**Application Form**' in **Section D1** and select '**Waiver of documentation of consent (Verbal or Implied Consent)**' in **Section D5**.
- **Section O: Consent Process – Waiver of documentation of consent (Verbal or Implied Consent)** will then appear for completion.

Waiver of Informed Consent



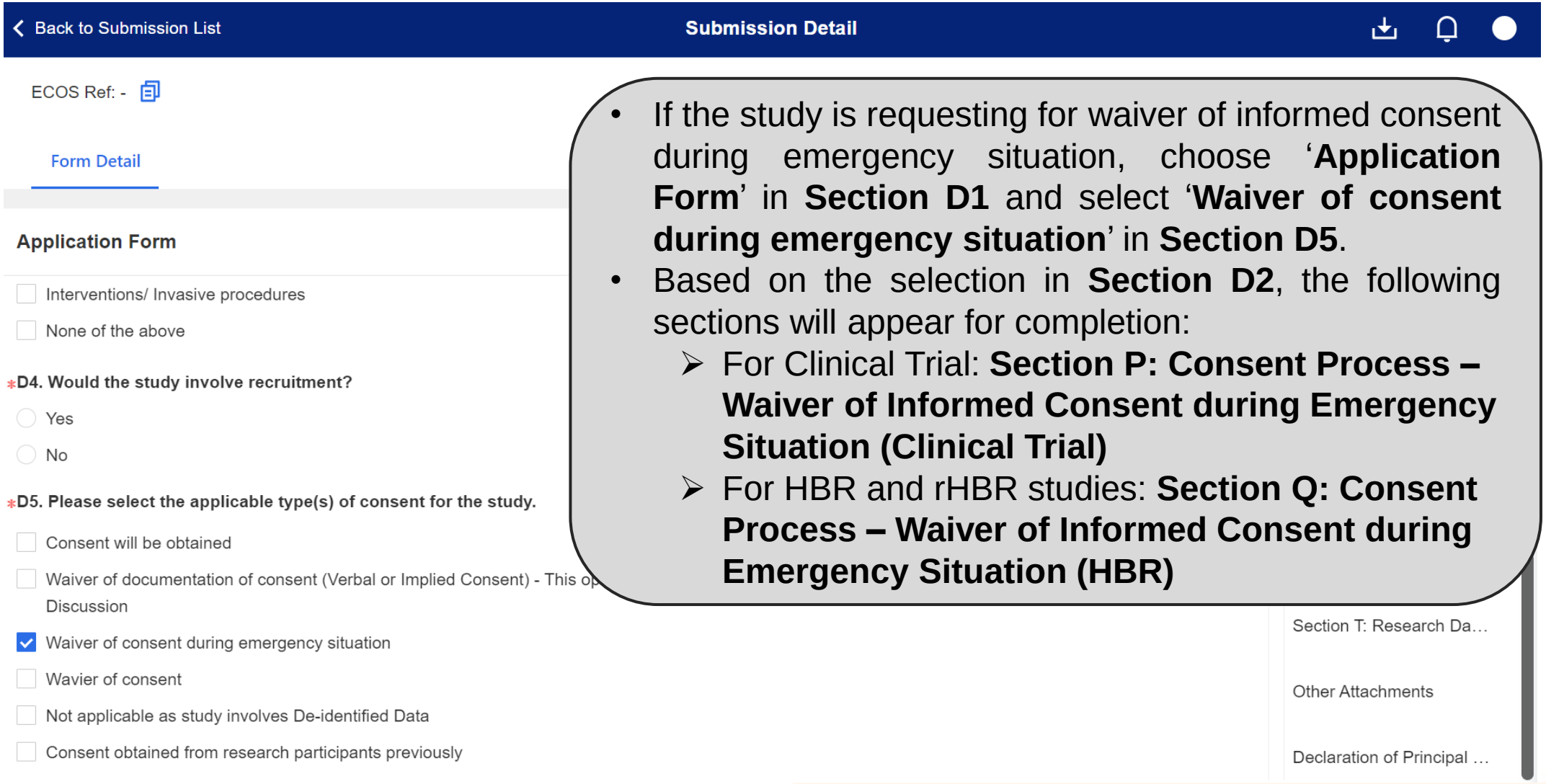
- If the study is requesting for waiver of informed consent, choose '**Application Form**' in **Section D1** and select '**Waiver of consent**' in **Section D5**.
- Based on the selection in **Section D2**, the following sections will appear for completion:
  - For Clinical Trial and non-HBR studies: **Section R: Consent Process – Waiver of consent (non-HBR)**
  - For HBR and rHBR studies: **Section S: Consent Process – Waiver of consent (HBR)**

Waiver of Informed Consent (HBR)



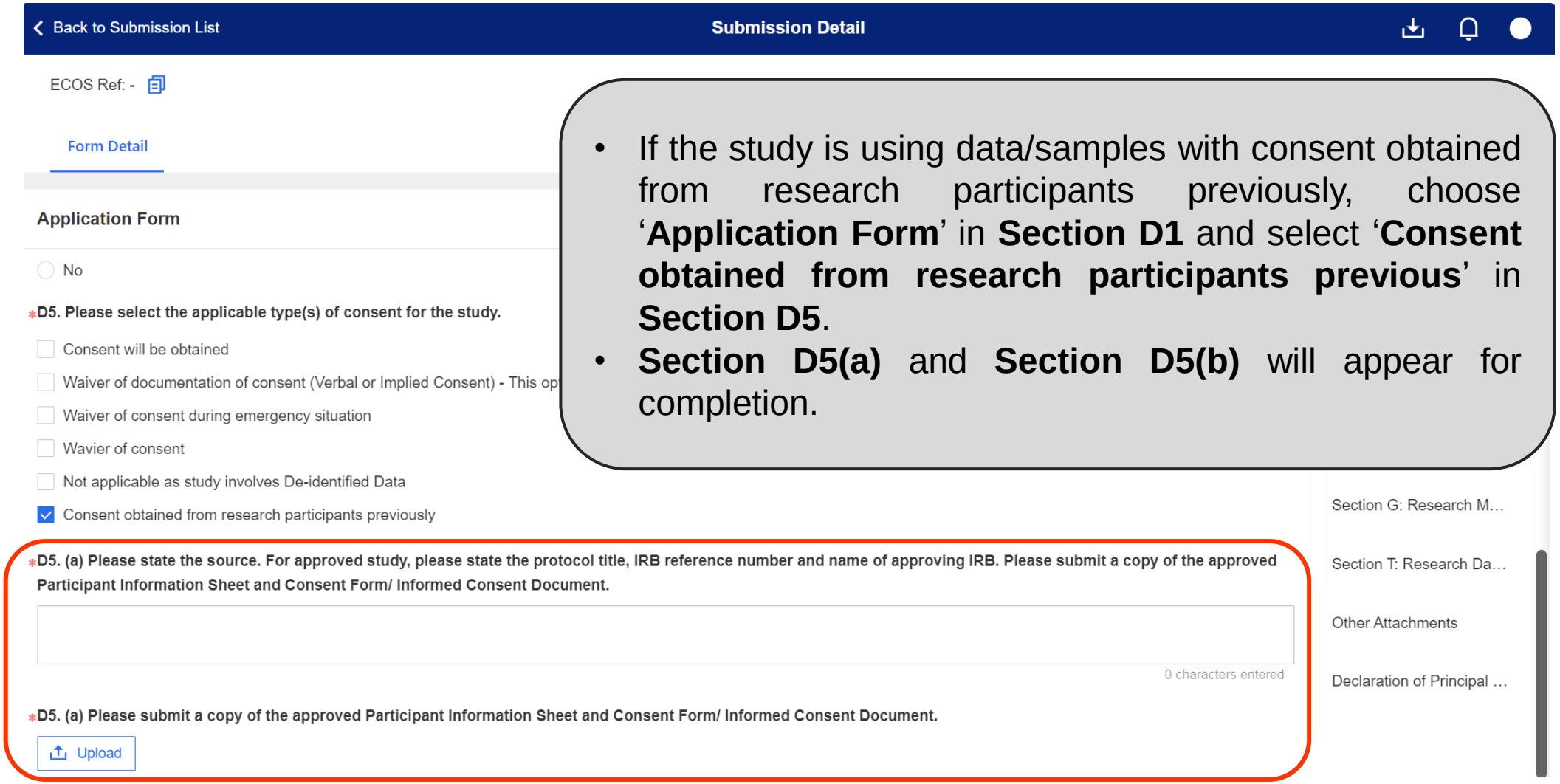
- It is not required to submit PDPA Practicability Calculator.
- Please ensure that the study meets the ‘Greater Public Good’ criteria.

Waiver of Consent during Emergency Situation



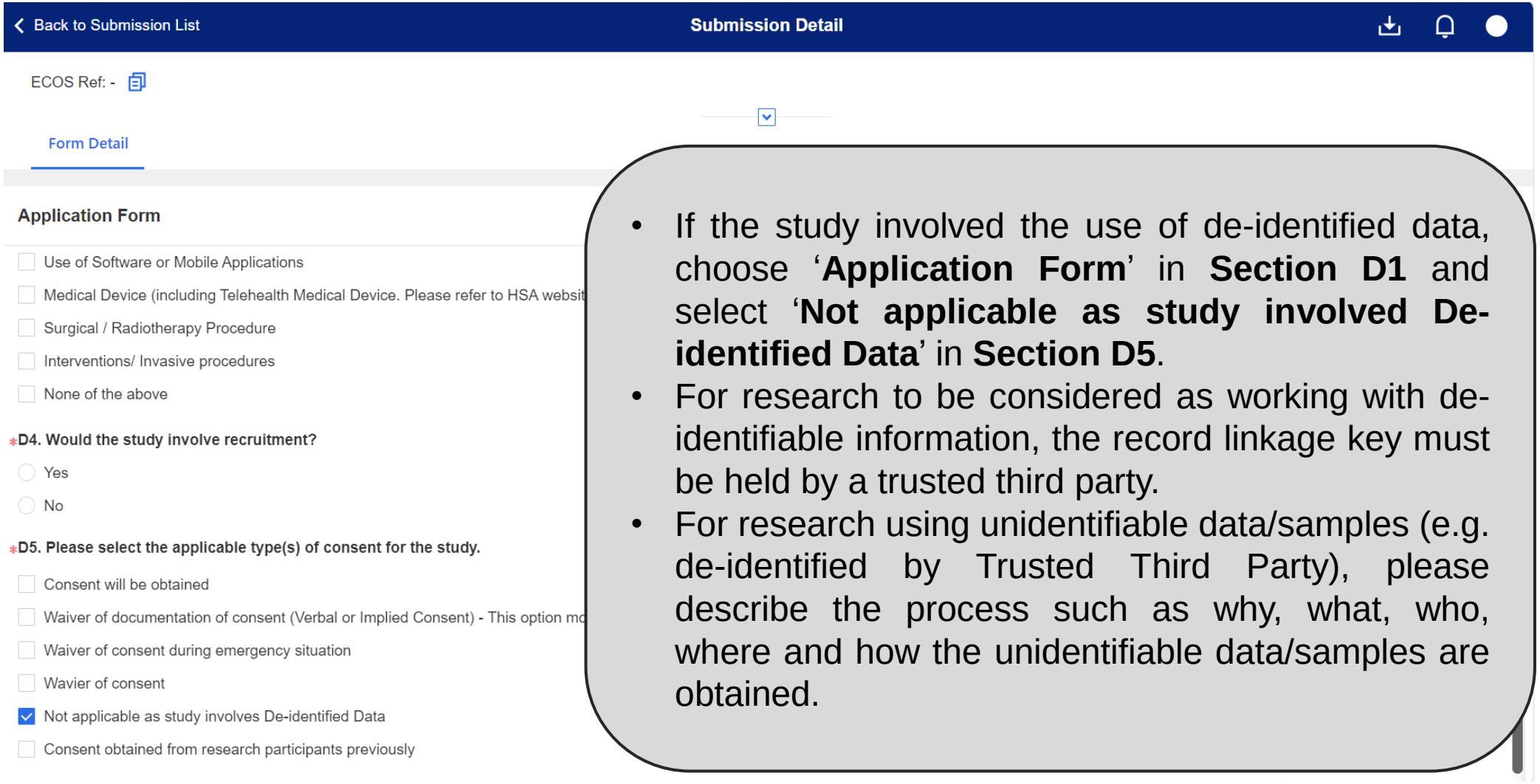
- If the study is requesting for waiver of informed consent during emergency situation, choose '**Application Form**' in **Section D1** and select '**Waiver of consent during emergency situation**' in **Section D5**.
- Based on the selection in **Section D2**, the following sections will appear for completion:
  - For Clinical Trial: **Section P: Consent Process – Waiver of Informed Consent during Emergency Situation (Clinical Trial)**
  - For HBR and rHBR studies: **Section Q: Consent Process – Waiver of Informed Consent during Emergency Situation (HBR)**

Consent Obtained from Research Participants Previously



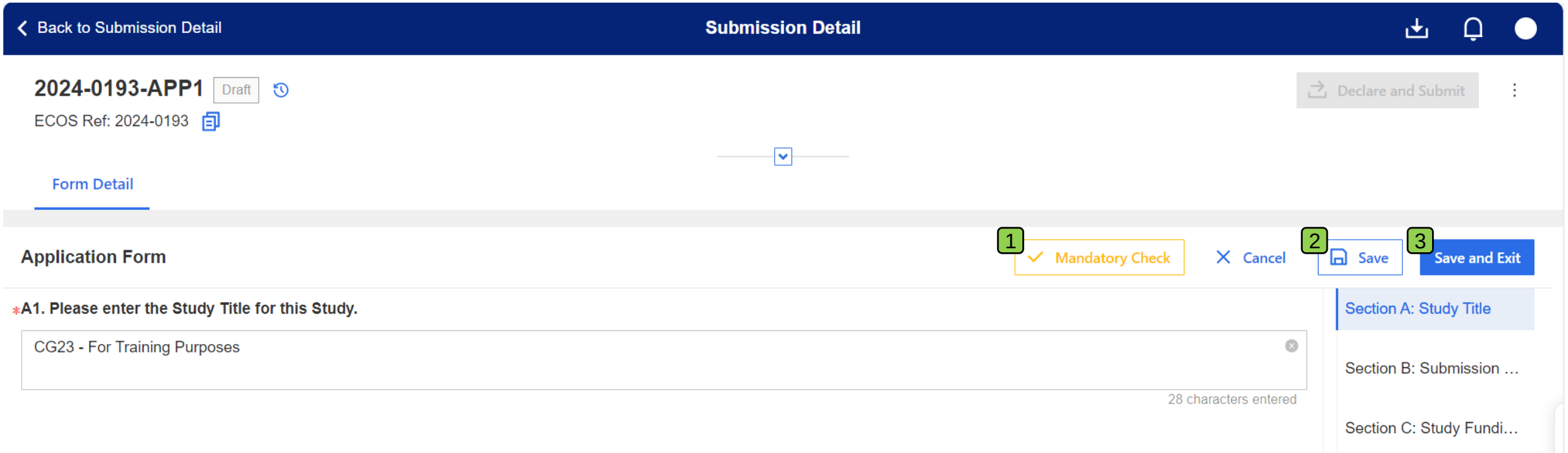
- If the study is using data/samples with consent obtained from research participants previously, choose '**Application Form**' in **Section D1** and select '**Consent obtained from research participants previous**' in **Section D5**.
- **Section D5(a)** and **Section D5(b)** will appear for completion.

Study involves De-identified Data



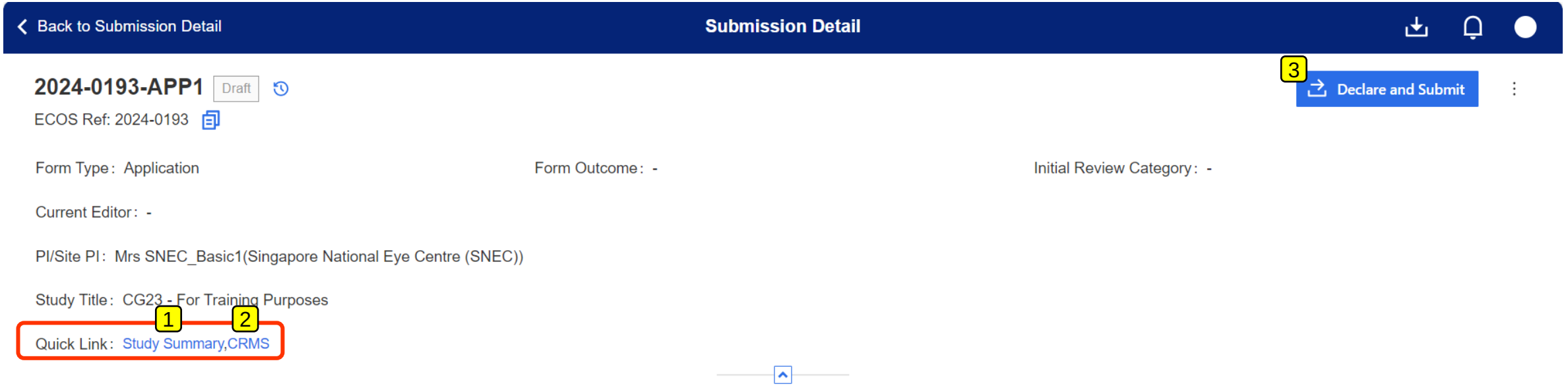
- If the study involved the use of de-identified data, choose '**Application Form**' in **Section D1** and select '**Not applicable as study involved De-identified Data**' in **Section D5**.
- For research to be considered as working with de-identifiable information, the record linkage key must be held by a trusted third party.
- For research using unidentifiable data/samples (e.g. de-identified by Trusted Third Party), please describe the process such as why, what, who, where and how the unidentifiable data/samples are obtained.

Features of Application Form



1. Click ‘Mandatory Check’ to ensure that all form fields are filled.
2. Use ‘Save’ frequently to ensure that all information are saved.
3. Use ‘Save and Exit’ to save and exit editing mode.

Features of Application Form

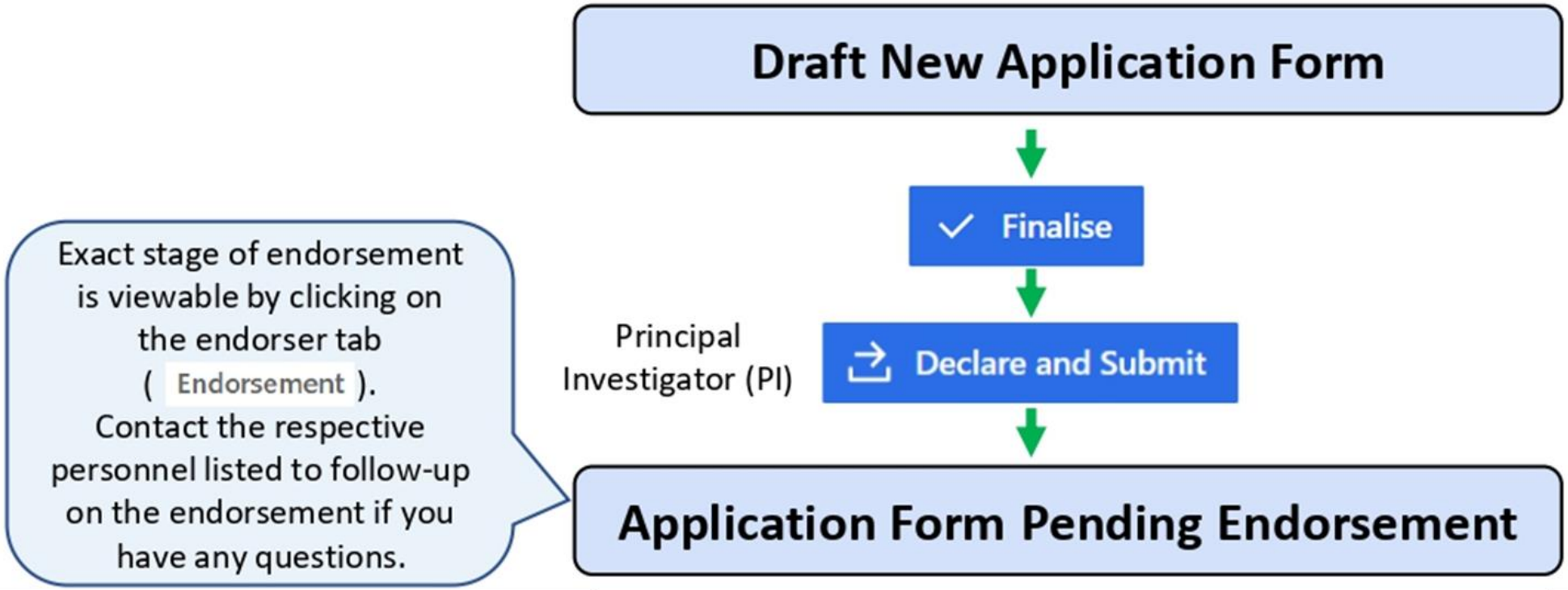


1 View the 'Study Summary' such as Forms, Forms Attachments and Study Letter submitted for the study.

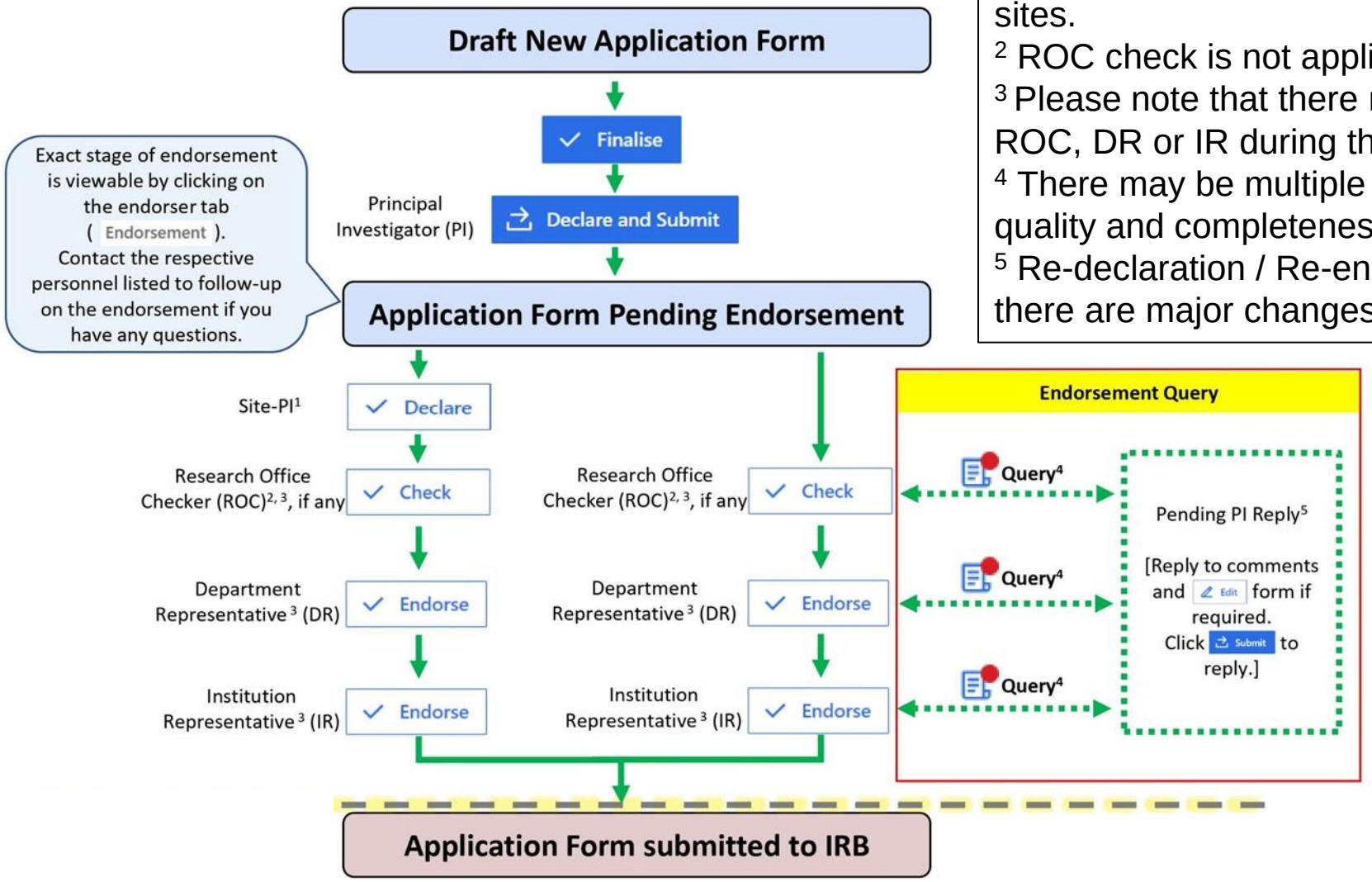
2 Refer to the training for CRMS module for more information.

3 For PI, the ' Declare and Submit ' button will be displayed, and form will be 'Pending Endorsement' upon submission.
For all other roles, the ' Finalise ' button will be displayed, and form will be 'Pending PI Declaration' upon submission.

Submission Workflow

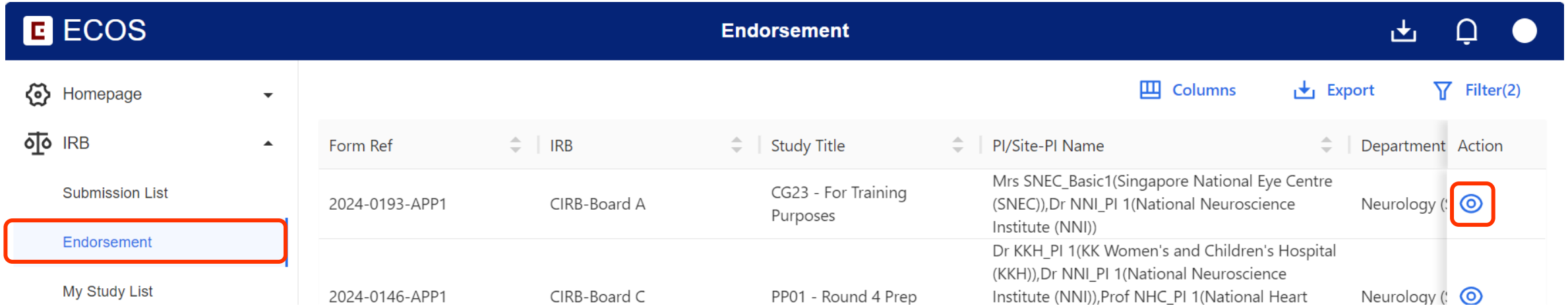


Submission Workflow

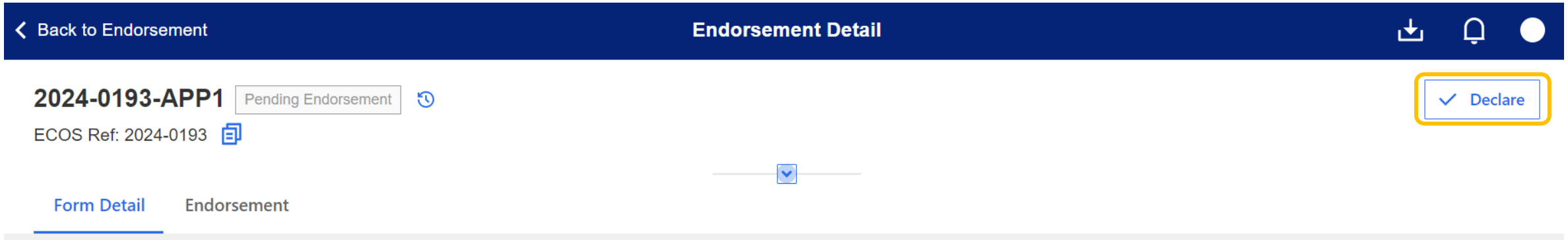


Note:
[1] This is only applicable for study involving multi-sites.
[2] ROC check is not applicable for all institutions
[3] Please note that there may be queries from ROC, DR or IR during the endorsement process.
[4] There may be multiple returns depending on the quality and completeness of reply
[5] Re-declaration / Re-endorsement is required if there are major changes to the application form.

Site-PI Declaration

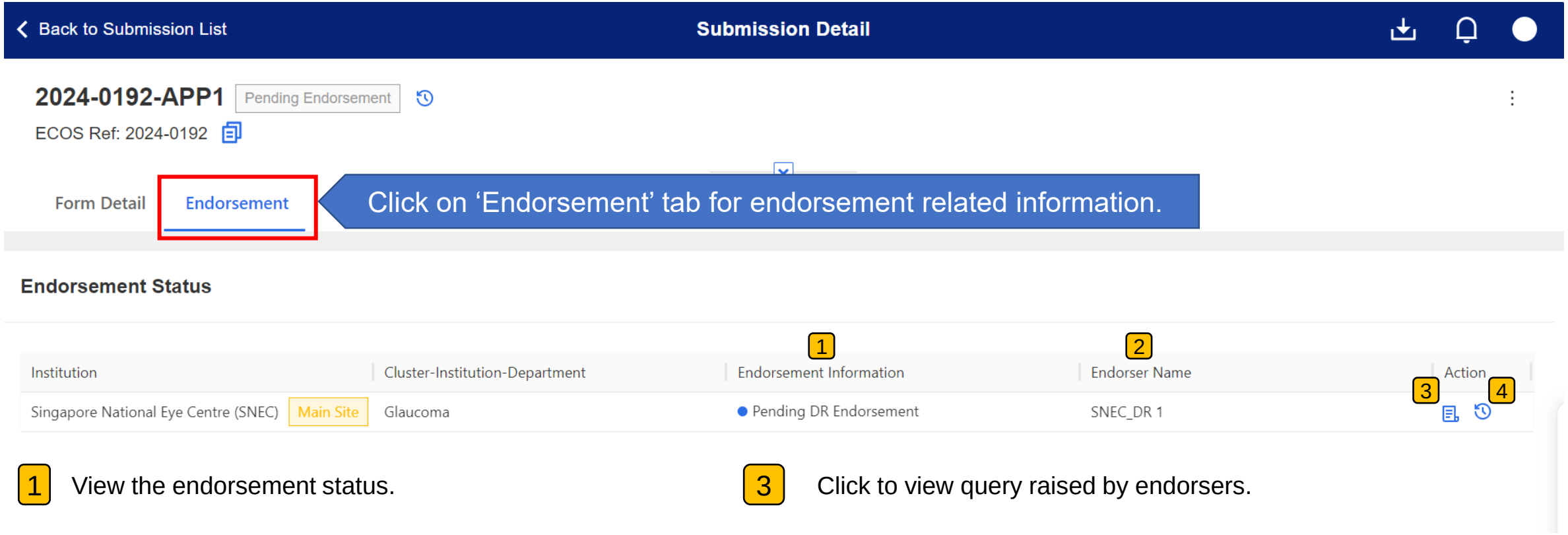


- For studies involving multi-sites, site-PI will click on the [Endorsement] tab, followed by the ‘ 👁 ’ icon to view the study.



- Site-PI will click on ‘ ✓ Declare ’ to perform site-PI declaration.

Endorsement Status



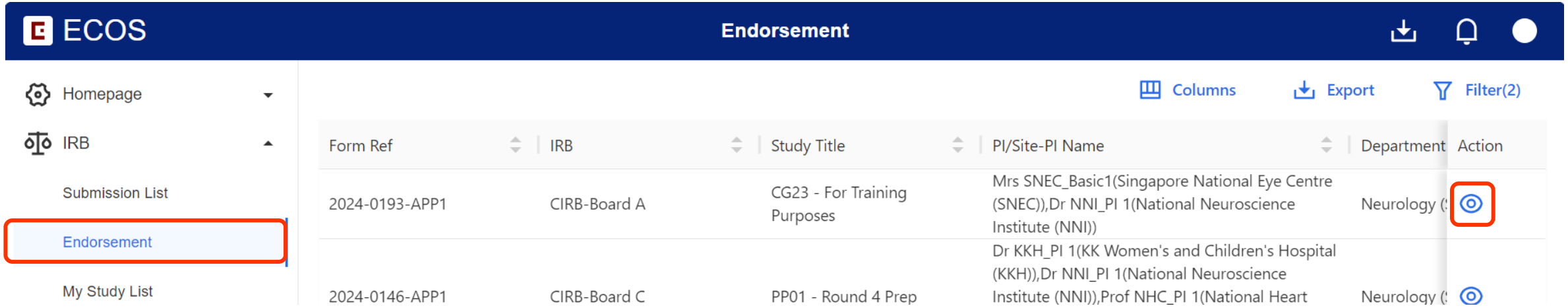
1 View the endorsement status.

2 View the name of endorser to complete the pending task.

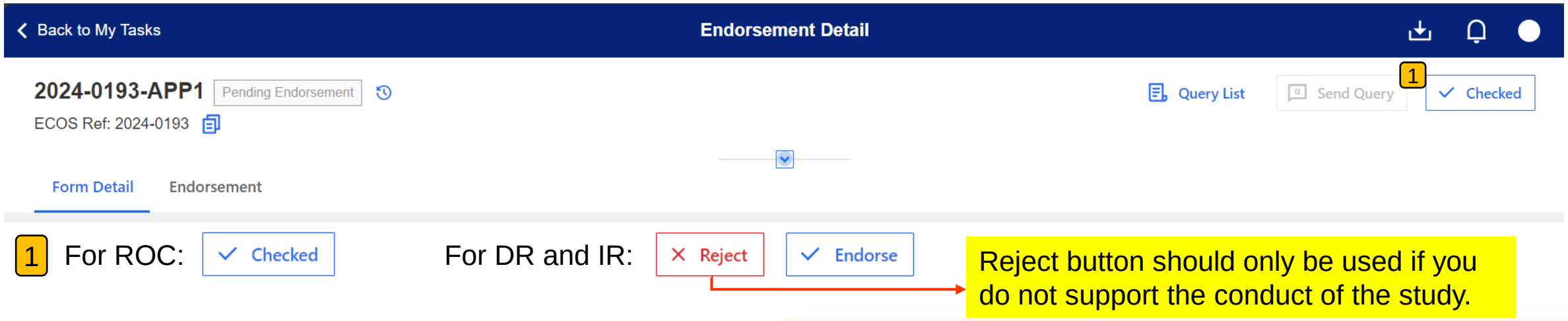
3 Click to view query raised by endorsers.

4 View the endorsement history.

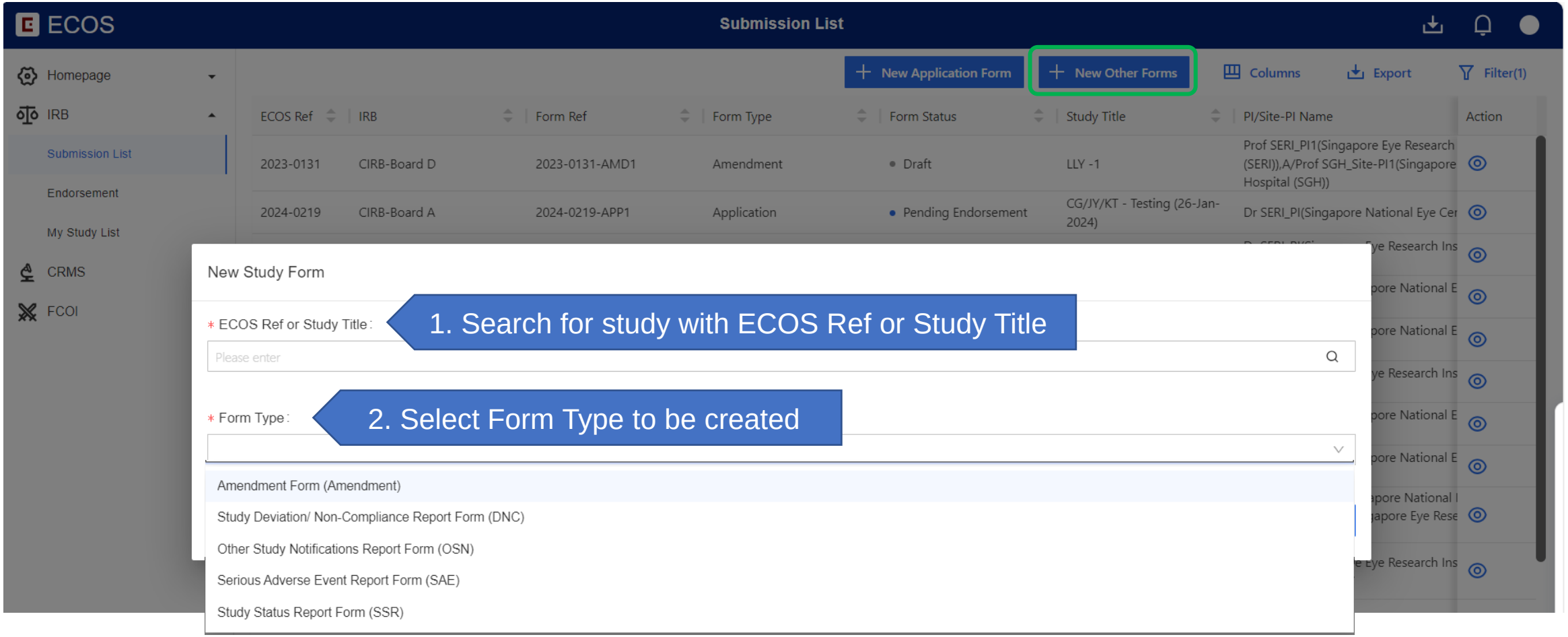
How to endorse? (For ROC, DR and IR)



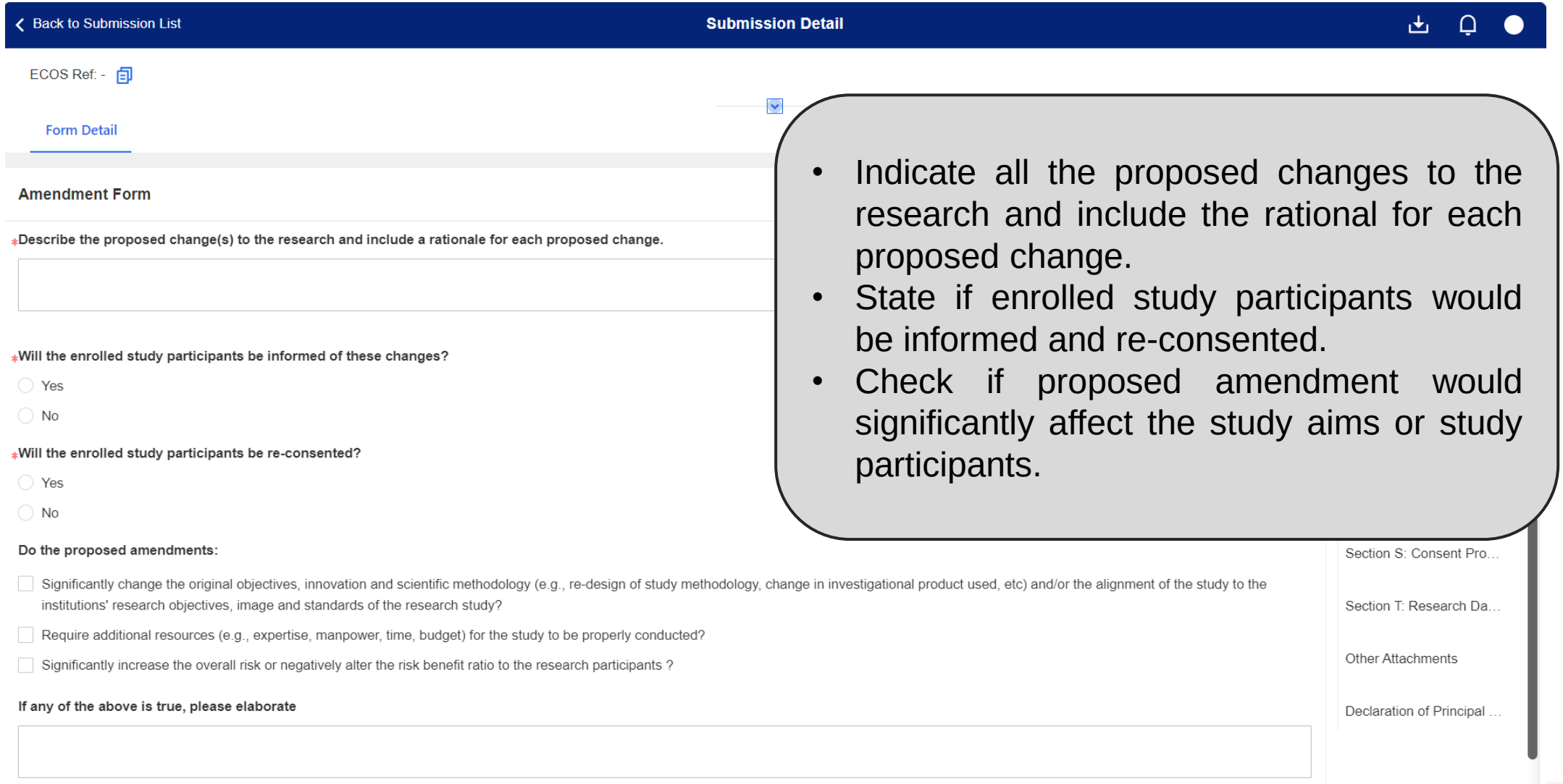
- For all endorser, click on the [Endorsement] tab, followed by the ‘ 👁 ’ icon to view the study.



Creation of Other Forms

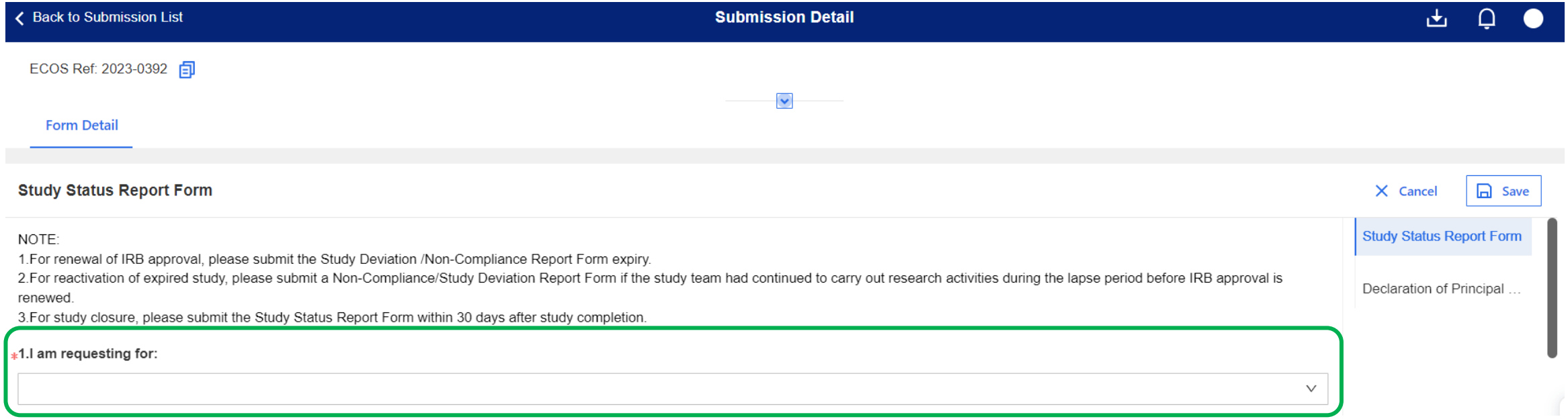


Amendment Form (AMD)



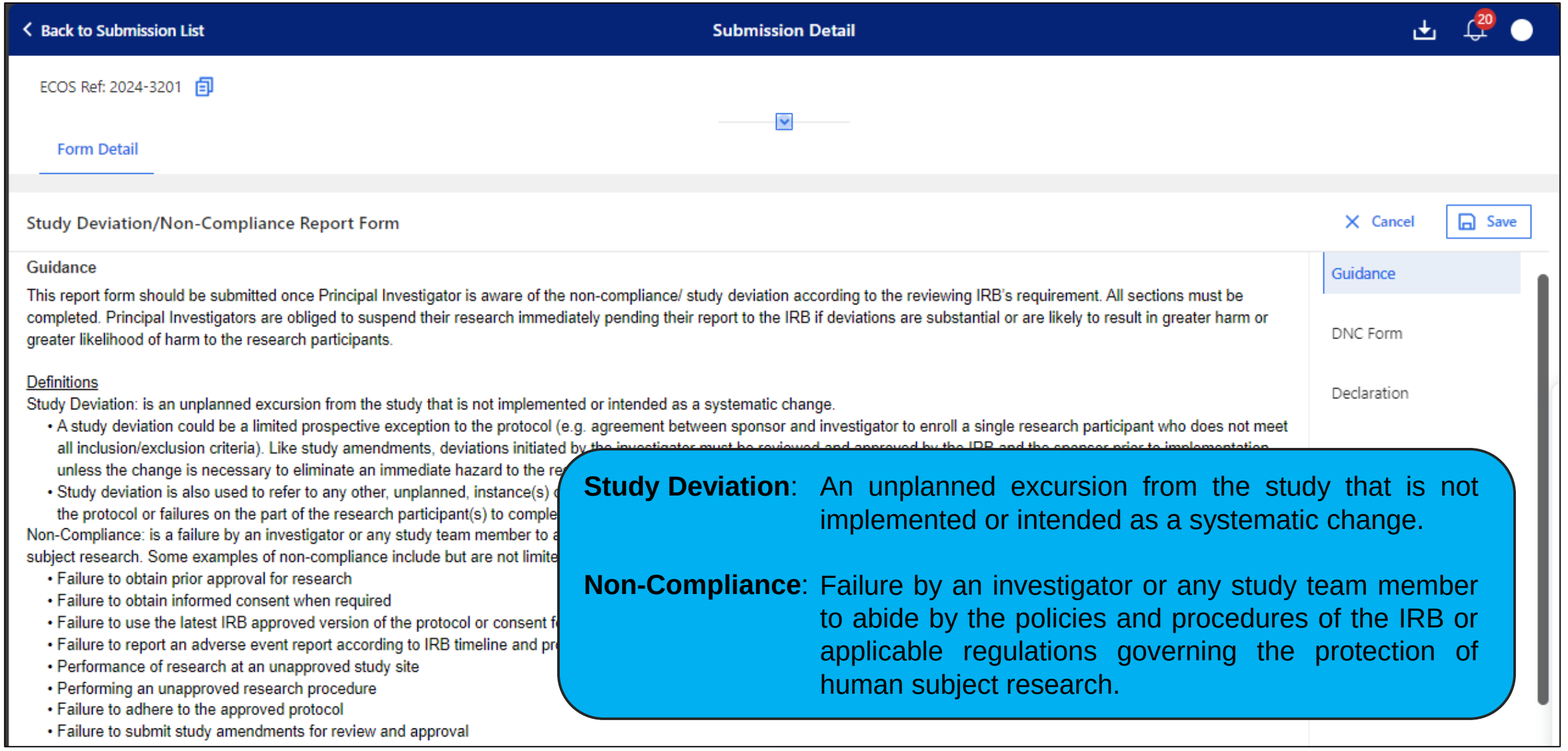
- Indicate all the proposed changes to the research and include the rational for each proposed change.
- State if enrolled study participants would be informed and re-consented.
- Check if proposed amendment would significantly affect the study aims or study participants.

Study Status Report Form (SSR)



- Select the reason for submission of SSR as follows:
  - ➢Study Renewal
  - ➢Study Reactivation
  - ➢Study Closure

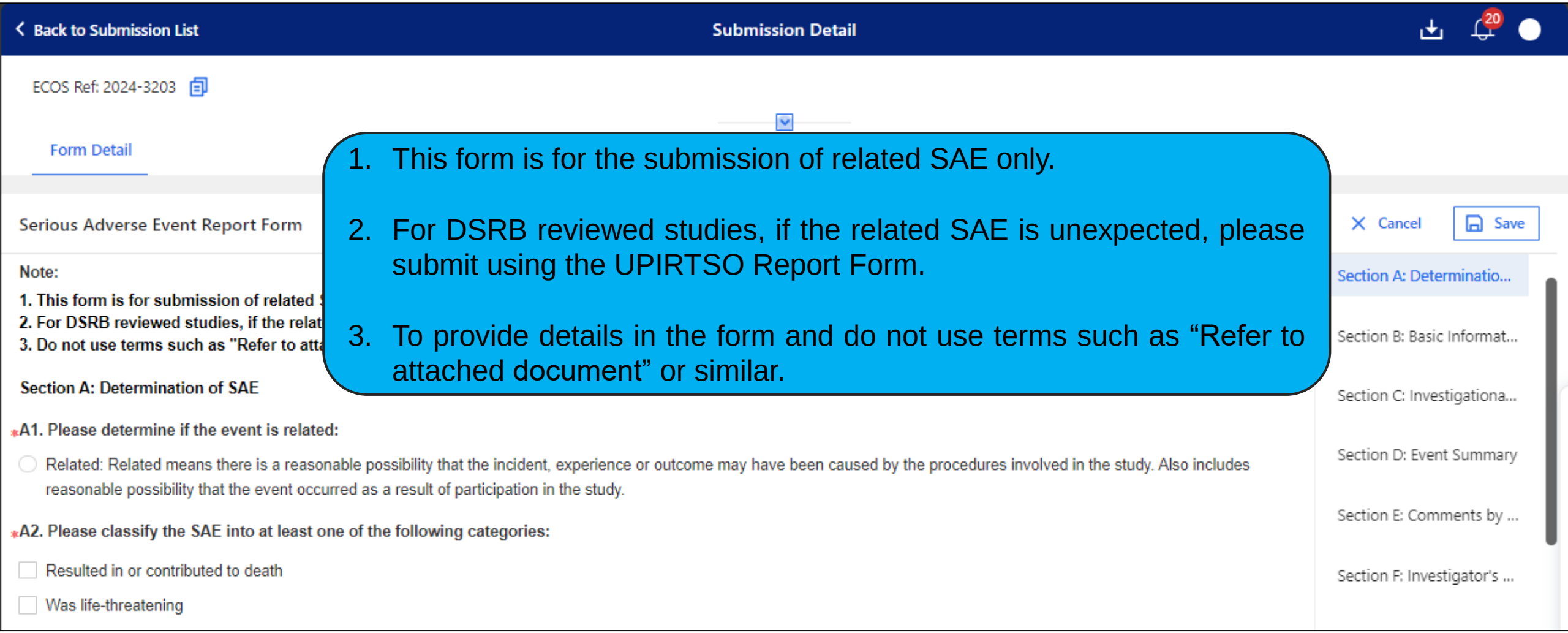
Study Deviation/ Non-Compliance Report Form (DNC)



Study Deviation: An unplanned excursion from the study that is not implemented or intended as a systematic change.

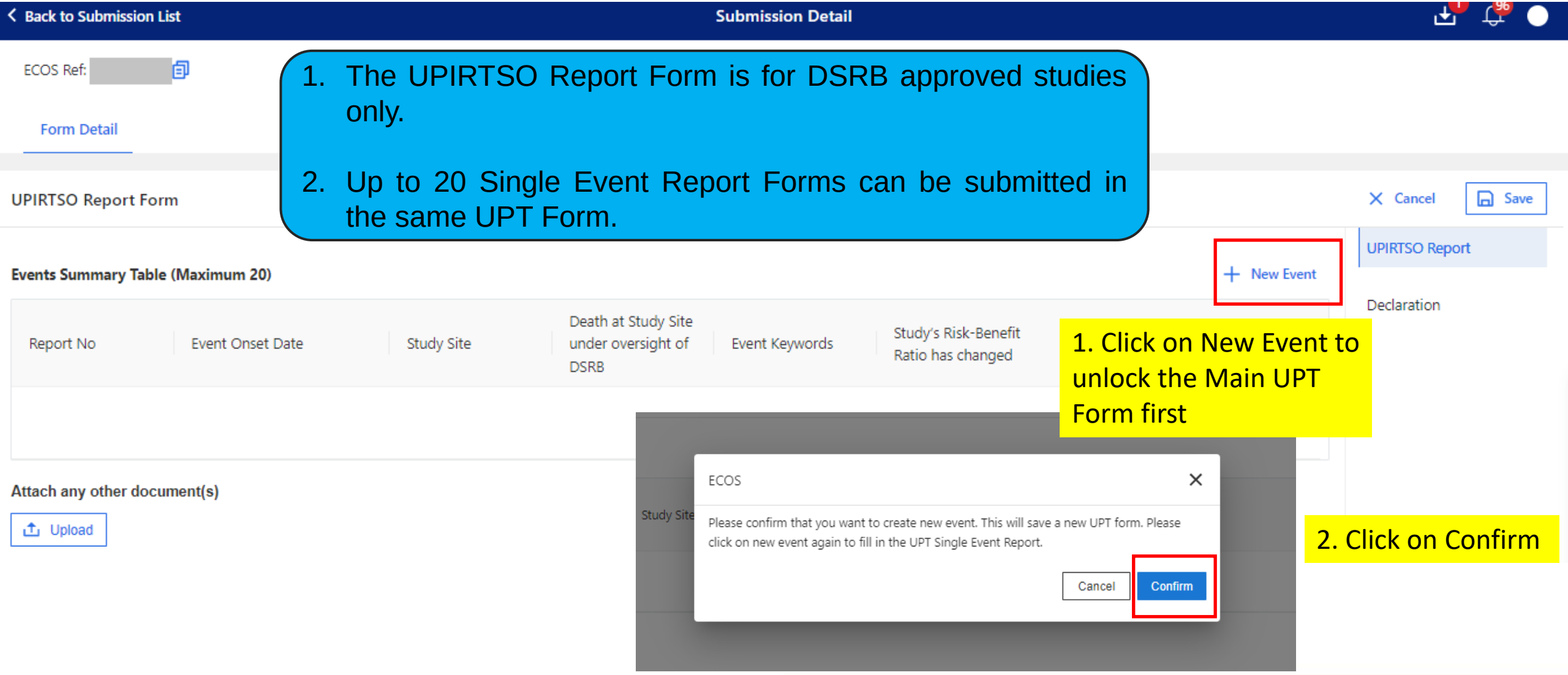
Non-Compliance: Failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research.

Serious Adverse Event Report Form (SAE)

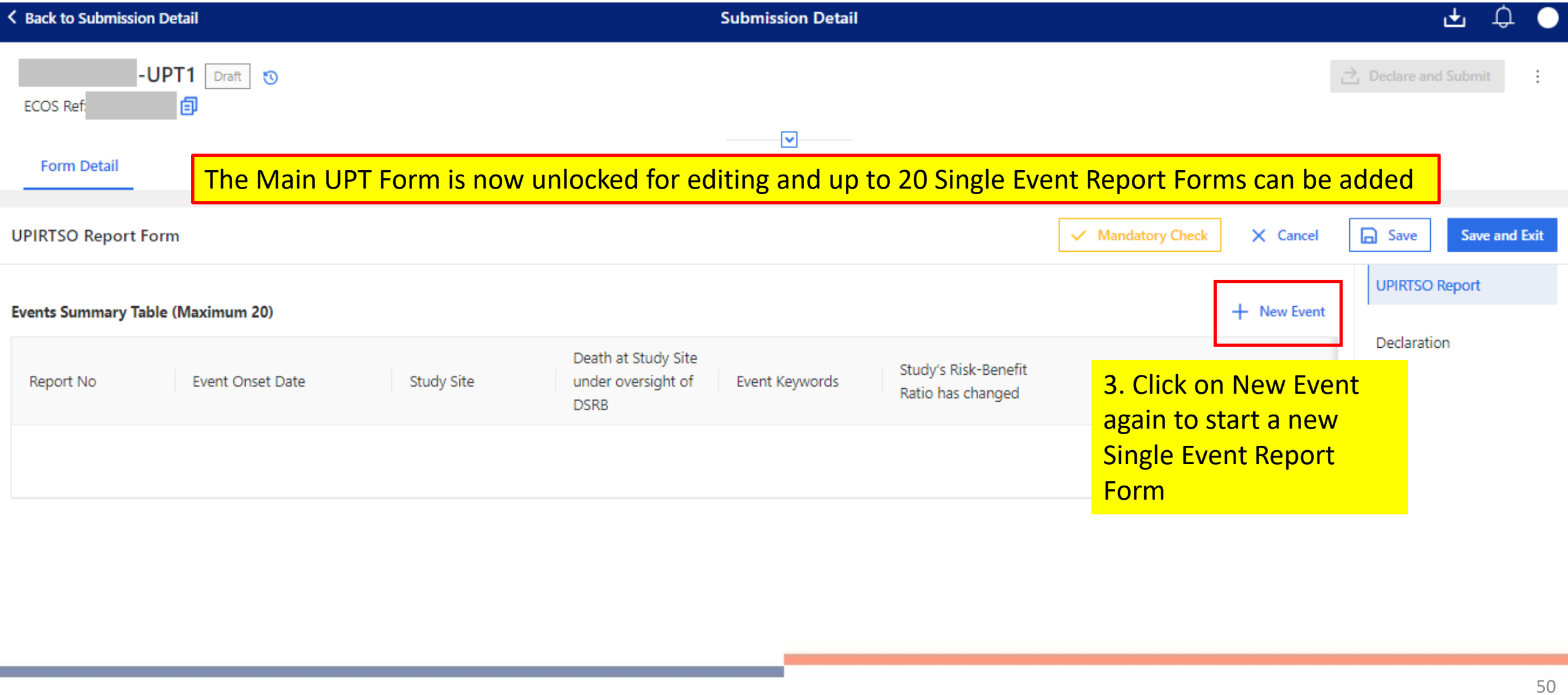


1. This form is for the submission of related SAE only.
2. For DSRB reviewed studies, if the related SAE is unexpected, please submit using the UPIRTSO Report Form.
3. To provide details in the form and do not use terms such as “Refer to attached document” or similar.

UPIRTSO Report Form (UPT)

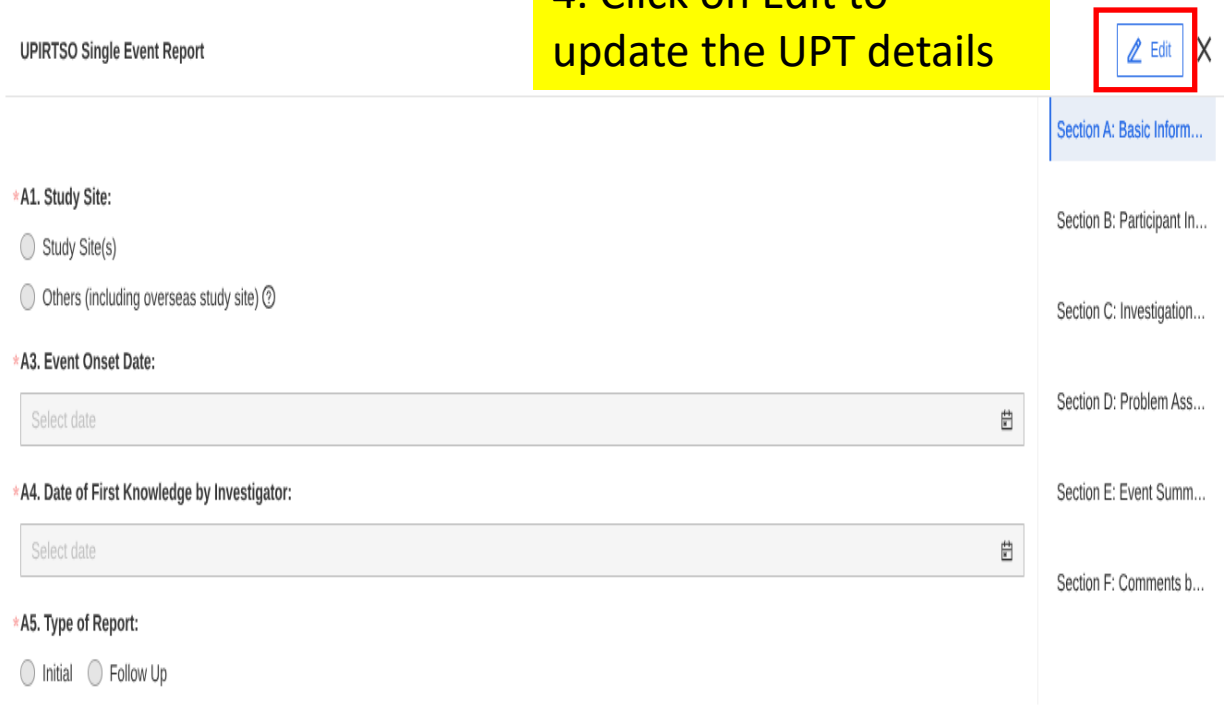


UPIRTSO Report Form (UPT)

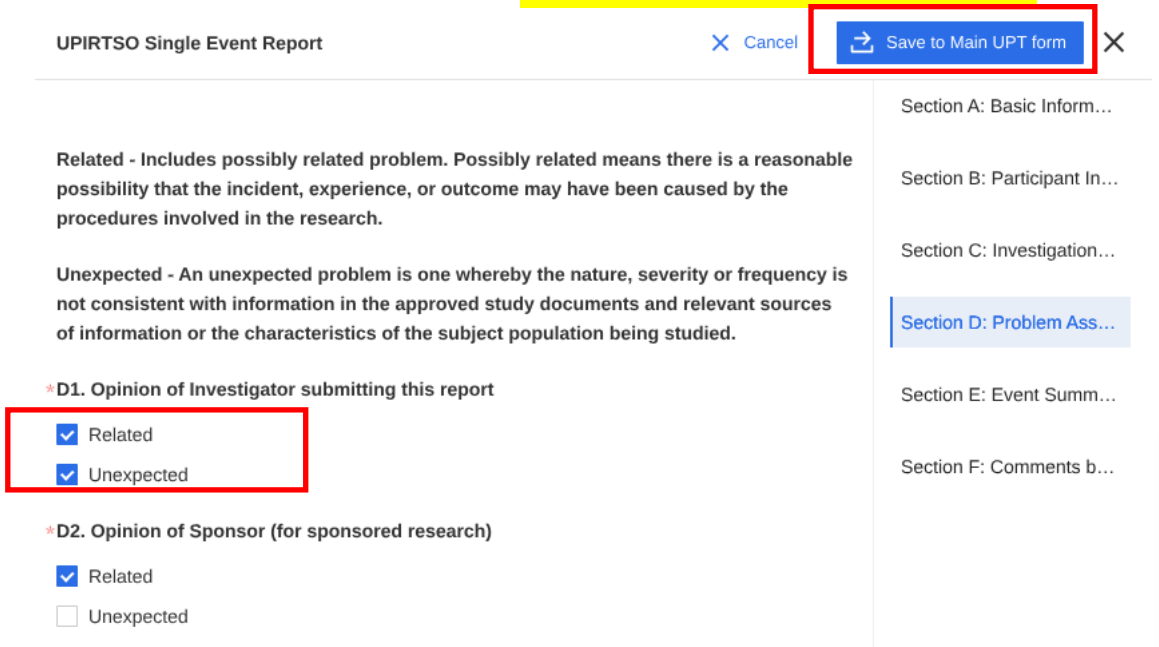


UPIRTSO Report Form (UPT)

4. Click on Edit to update the UPT details



5. Click on Save to Main UPT Form

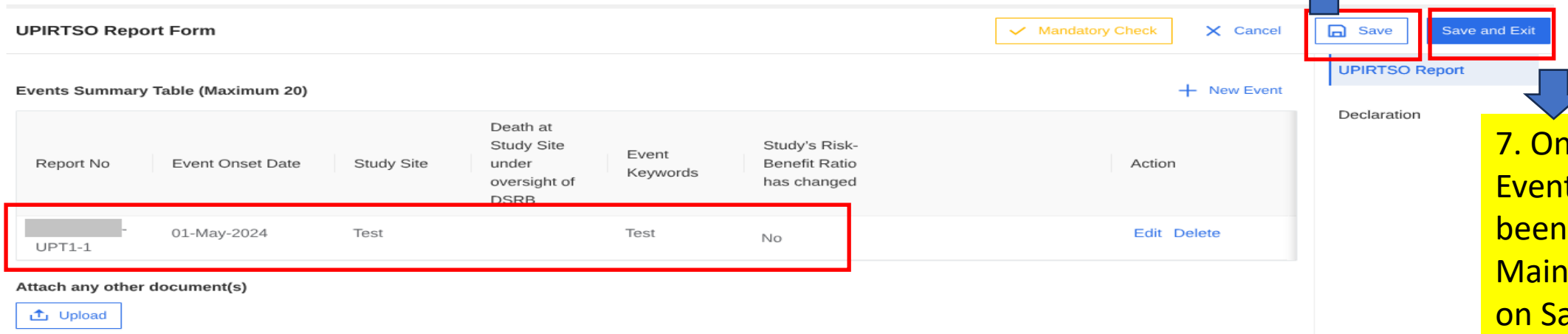


Reminder for **Section D1**:
If the event is not a local death that occurred at local Study Site, then the PI must assess the event to be **both Related and Unexpected** to fulfill the UPT reporting criteria.

UPIRTSO Report Form (UPT)

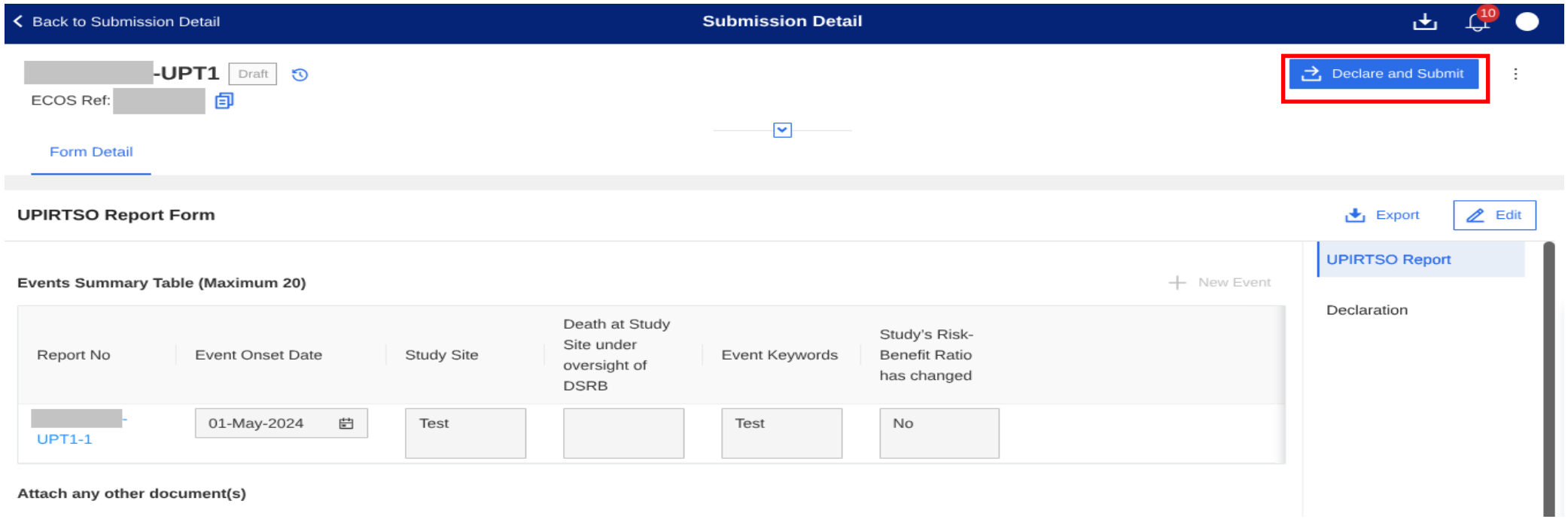
6. The key details will be displayed in the Main UPT Form. Click on Save to save the Single Event Report Form in the Main UPT Form

Remember to save each time a new Single Event Report Form is added



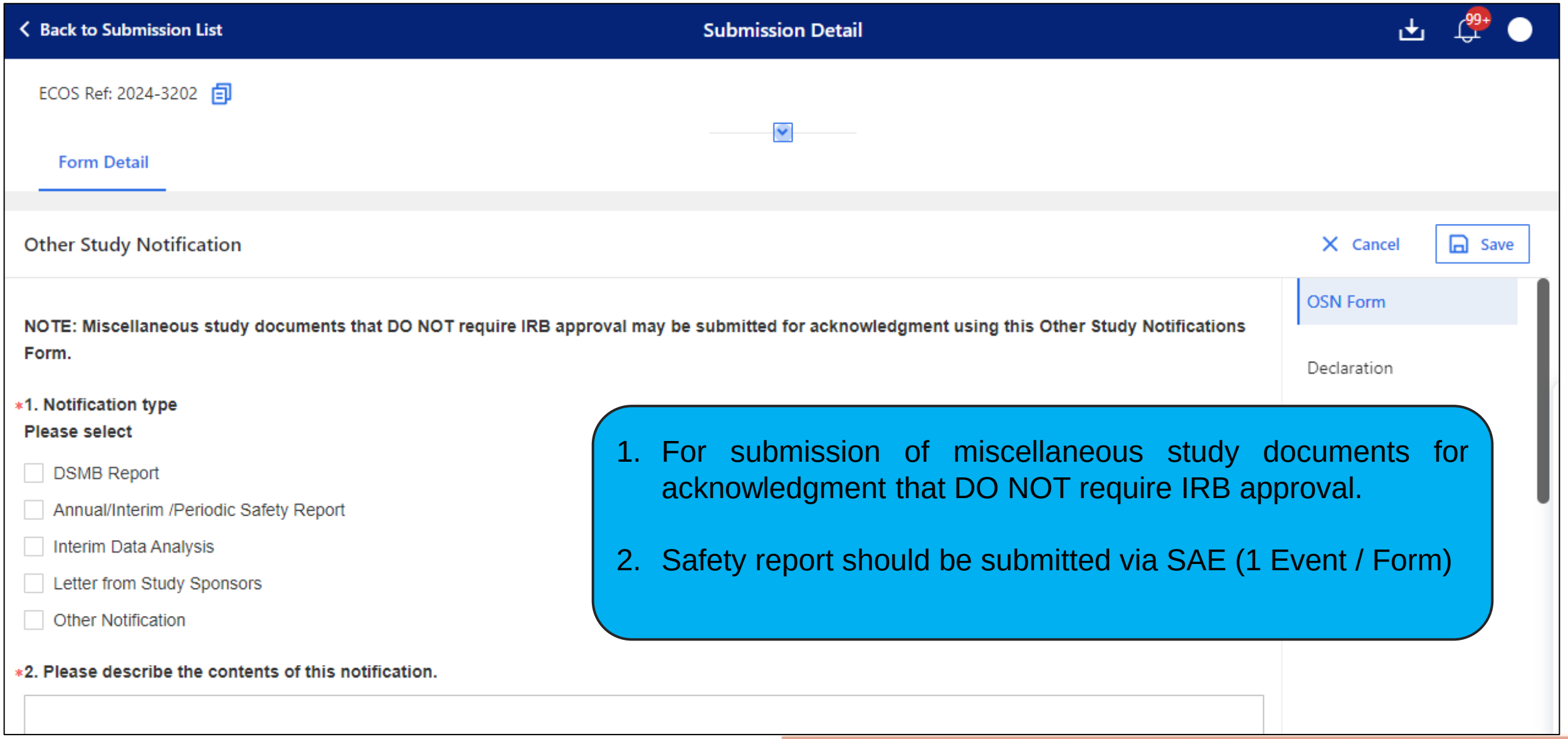
7. Once all the Single Event Reports have been saved in the Main UPT Form, click on Save and Exit

UPIRTSO Report Form (UPT)



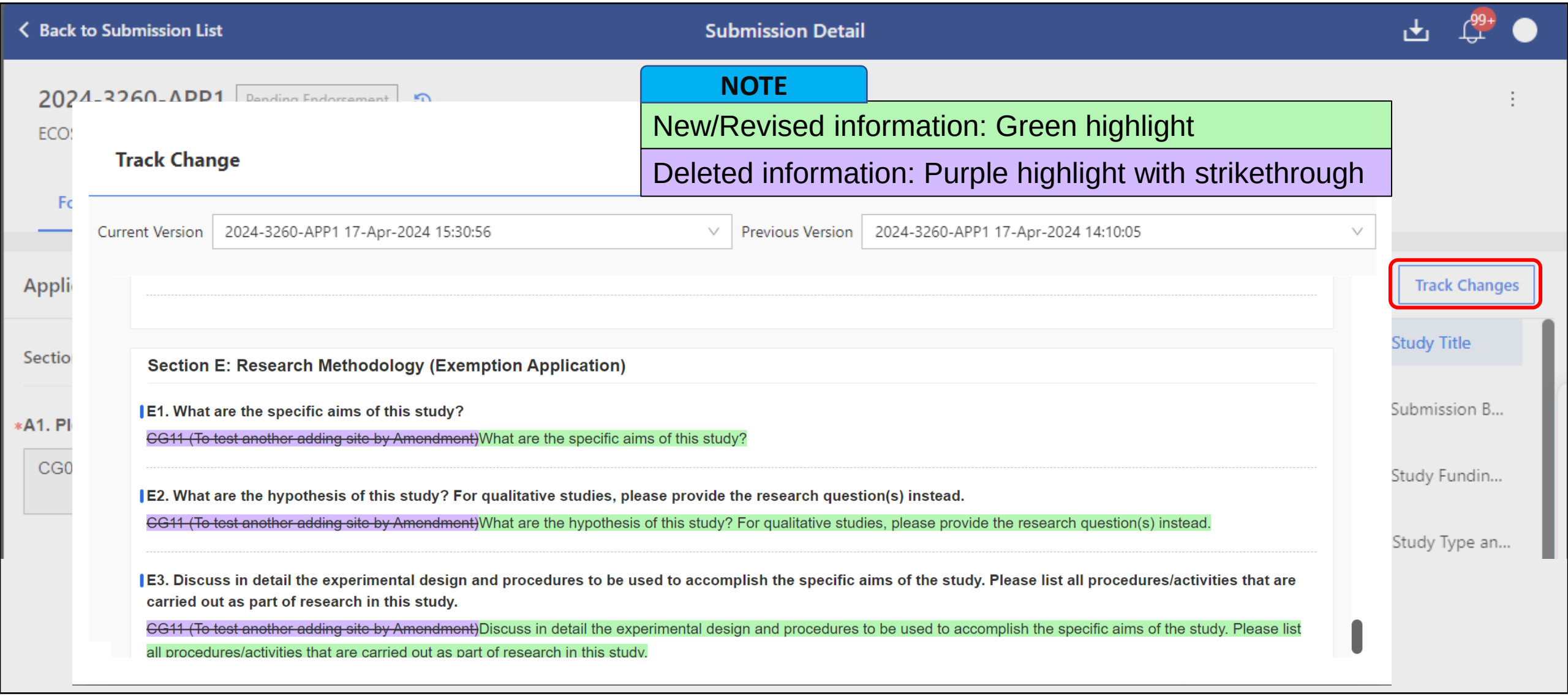
8. Click Declare and Submit to submit the UPT Form

Other Study Notification Form (OSN)

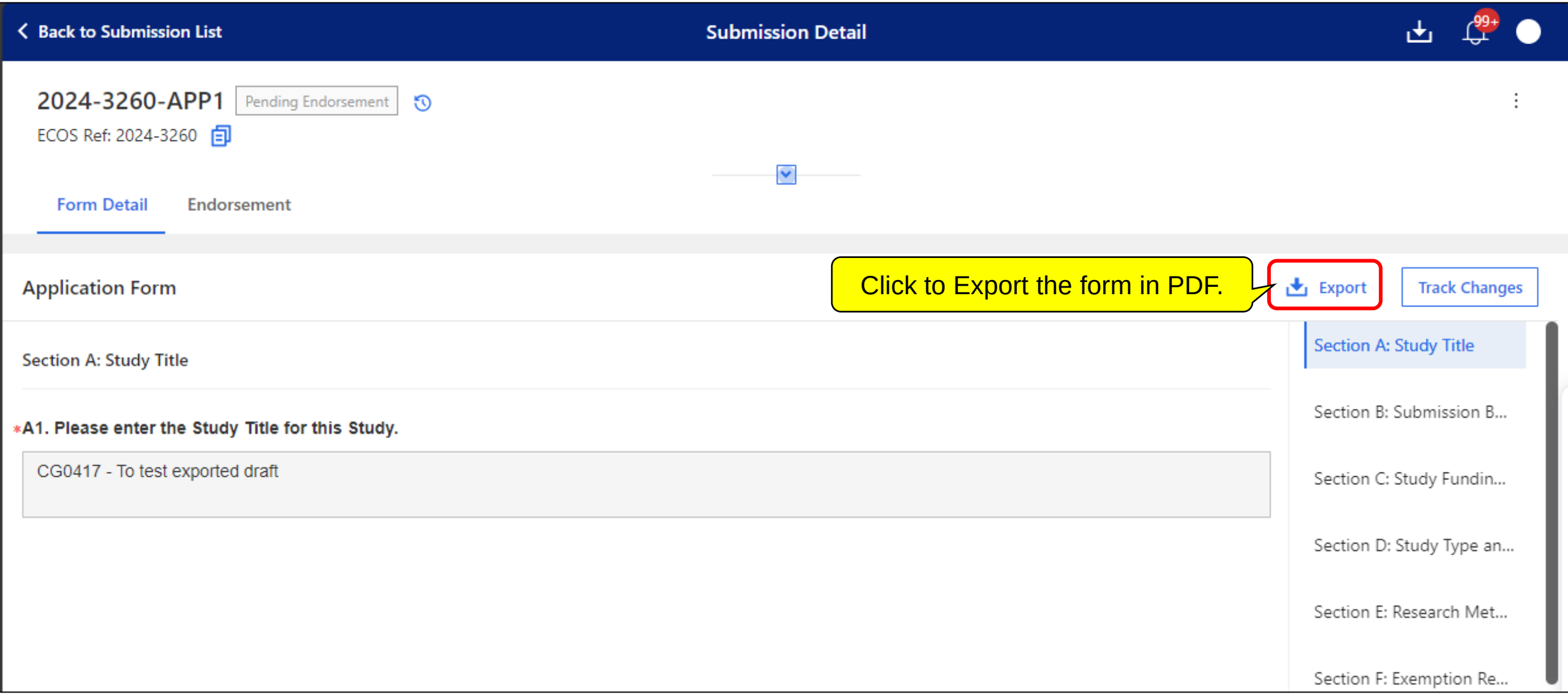


1. For submission of miscellaneous study documents for acknowledgment that DO NOT require IRB approval.
2. Safety report should be submitted via SAE (1 Event / Form)

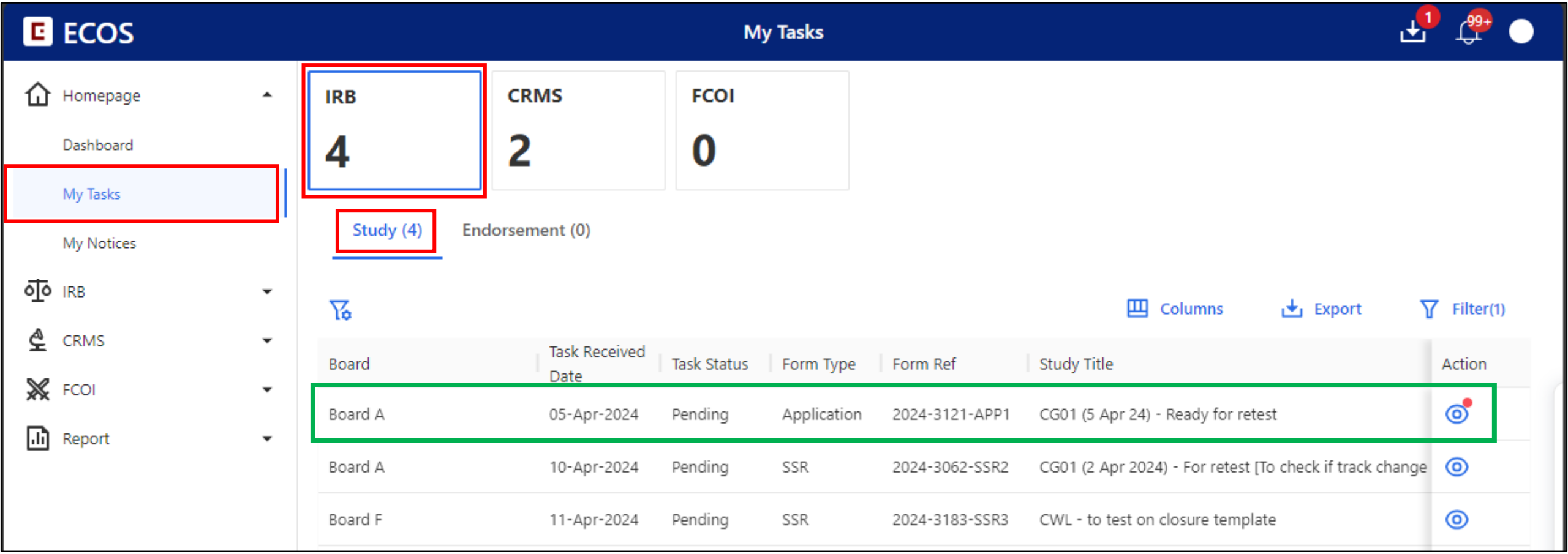
Track Changes



Export

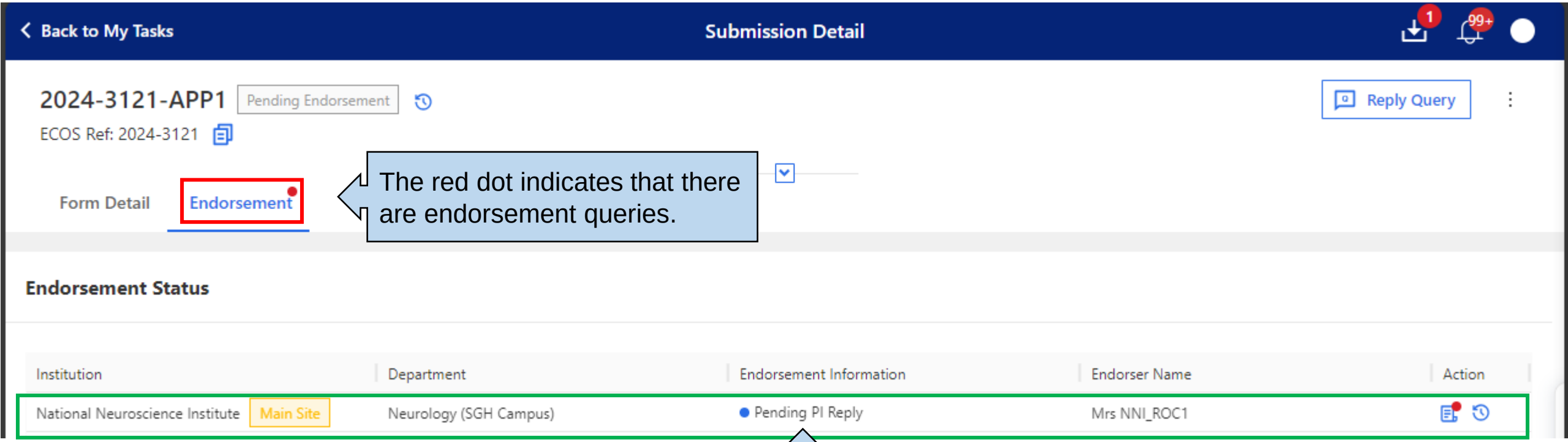

Back to Submission List
Submission Detail
99+
2024-3260-APP1
Pending Endorsement
ECOS Ref: 2024-3260
Form Detail
Endorsement
Application Form
Click to Export the form in PDF.
Export
Track Changes
Section A: Study Title
*A1. Please enter the Study Title for this Study.
CG0417 - To test exported draft
Section A: Study Title
Section B: Submission B...
Section C: Study Fundin...
Section D: Study Type an...
Section E: Research Met...
Section F: Exemption Re...

Query - Pending PI Reply



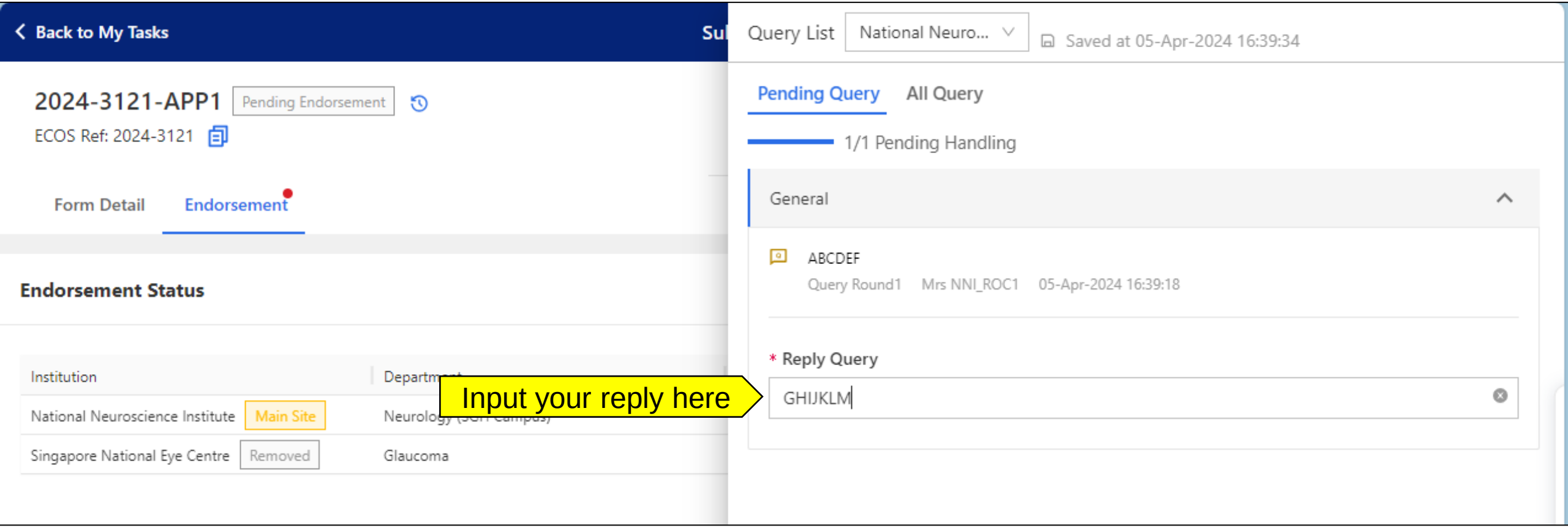
For PI, when there are endorsement or IRB query pending PI reply, the PI will receive a task in [My Tasks] and the action button would be with a red dot to symbolize that there are action required.

ROC/DR/IR Query that is Pending PI Reply



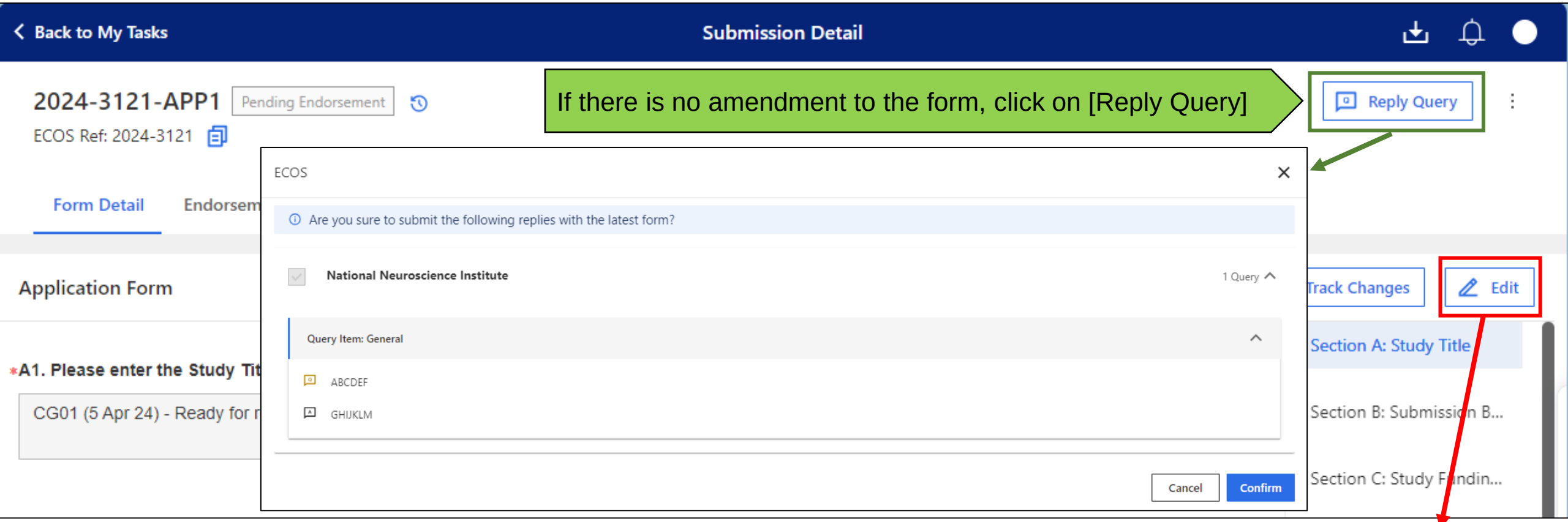
Click on the ‘ ’ icon to view and address the queries sent by ROC, DR or IR.

ROC/DR/IR Query that is Pending PI Reply



Note: Click the area outside to close the Query List.

ROC/DR/IR Query that is Pending PI Reply

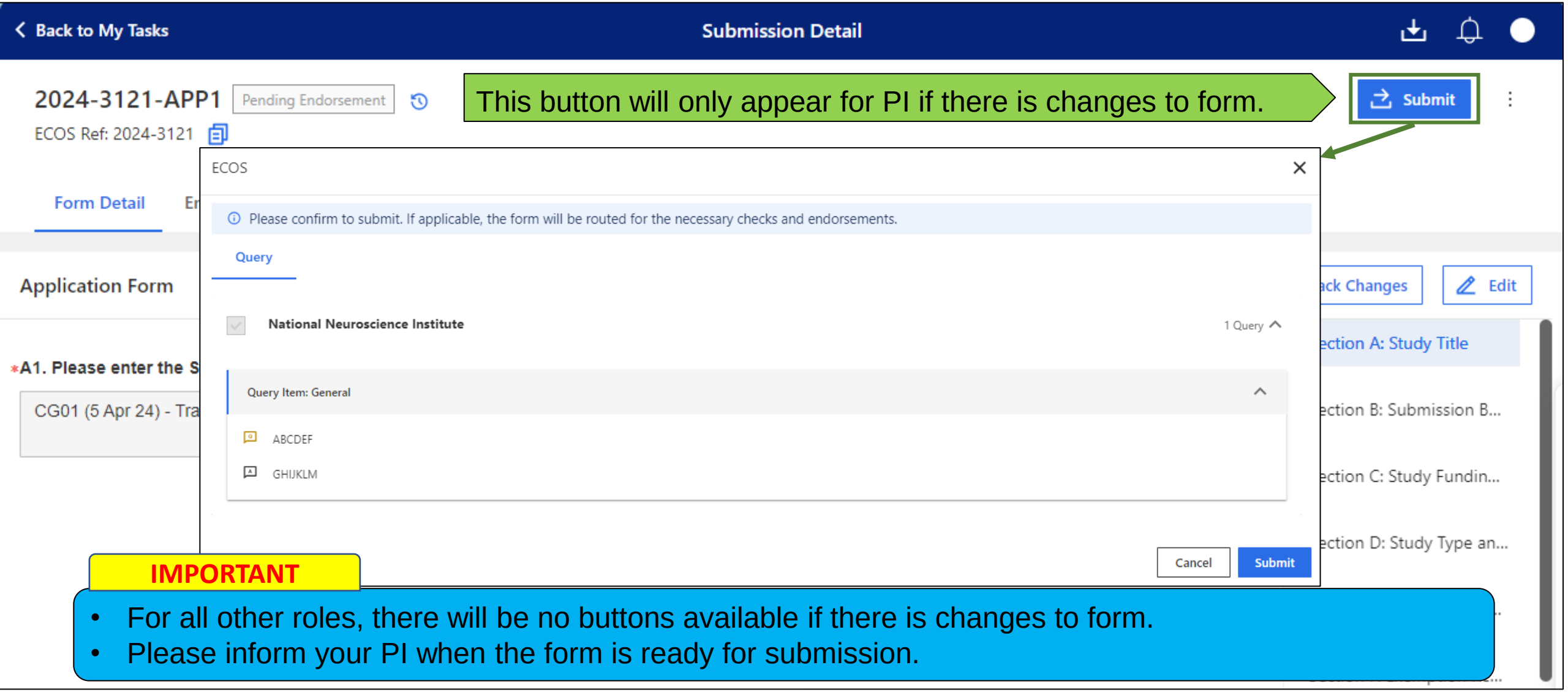


Click on [Edit] to amend the form if required.

IMPORTANT

- All roles will have the [Reply Query] button if there are no changes to the form.
- If there are changes to the form, only Overall PI will have the [Submit] button.

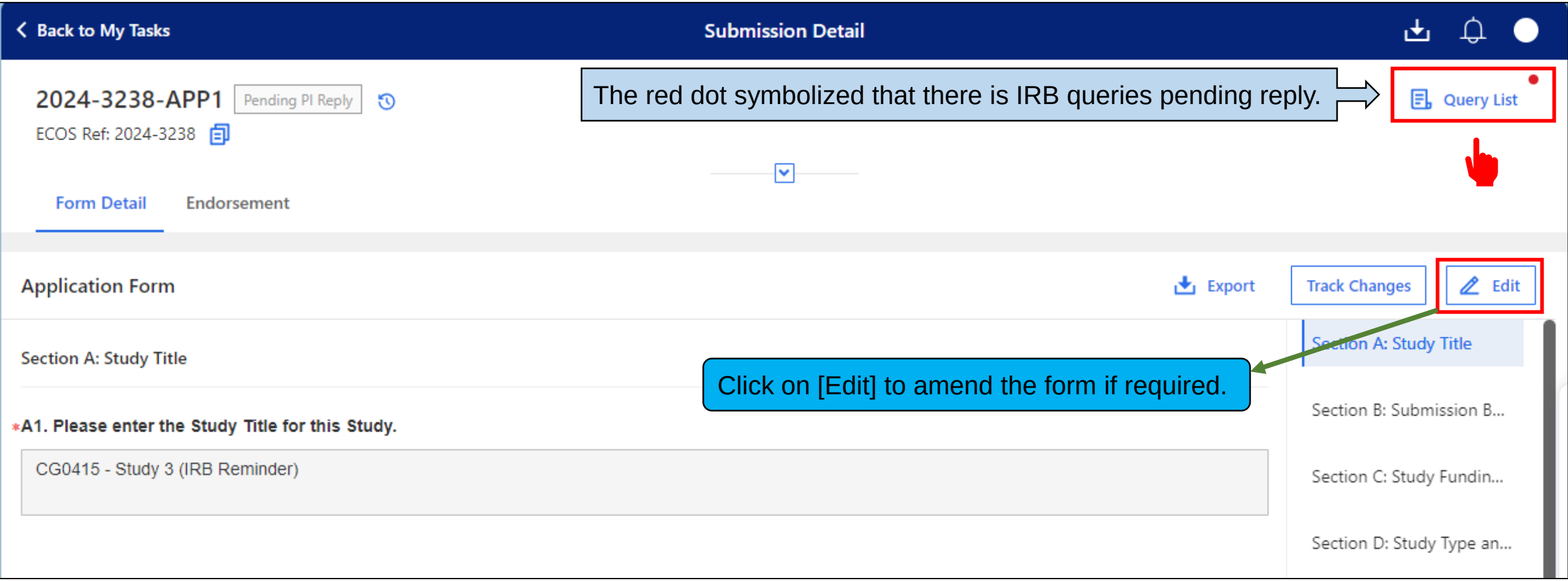
ROC/DR/IR Query that is Pending PI Reply - PI Reply with Amendment to Form



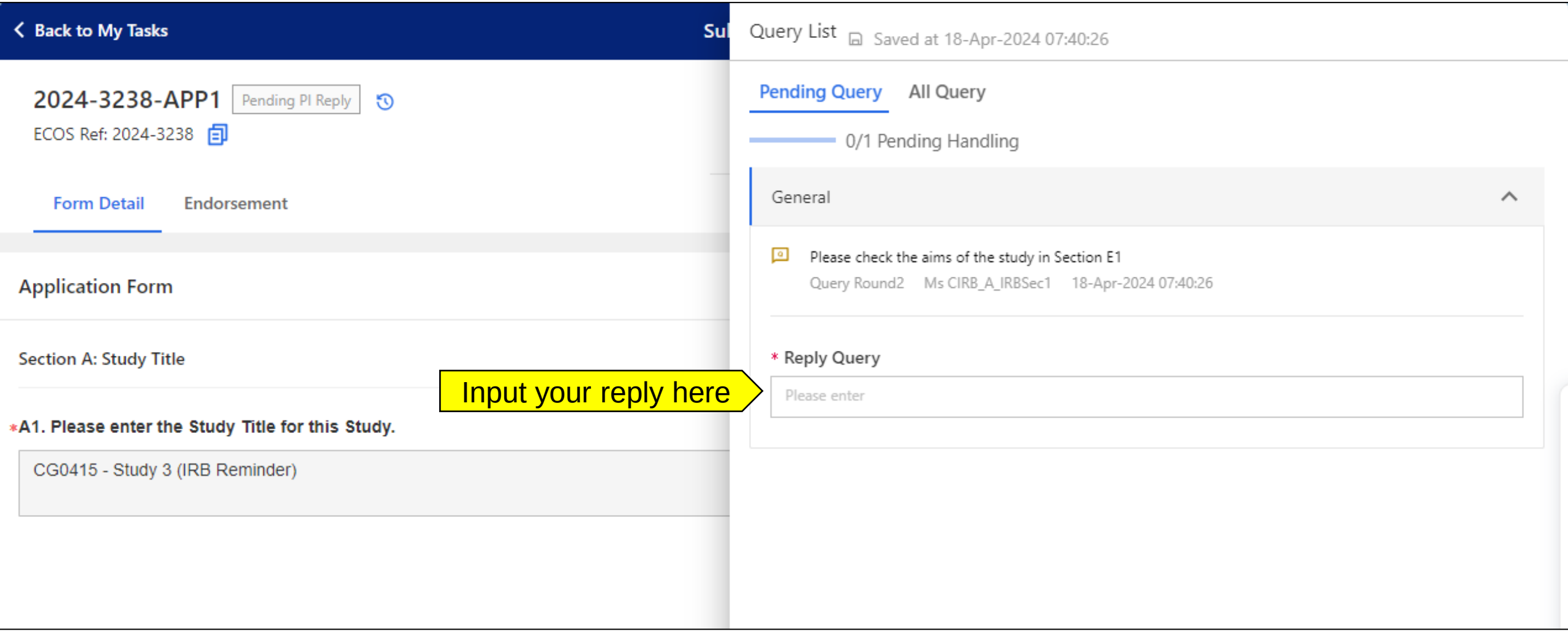
IMPORTANT

- For all other roles, there will be no buttons available if there is changes to form.
- Please inform your PI when the form is ready for submission.

IRB Query that is Pending PI Reply



IRB Query that is Pending PI Reply

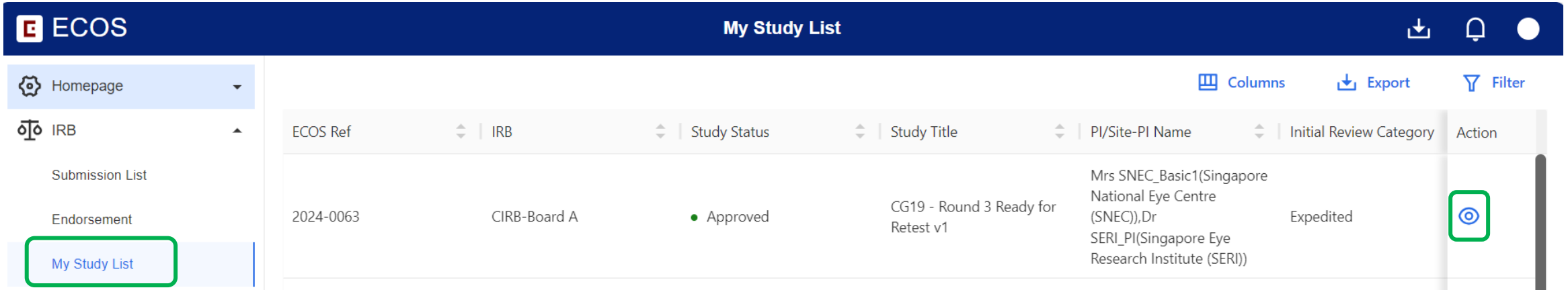


Note: Click the area outside to close the Query List.

Unlocking of Form for Re-Endorsement

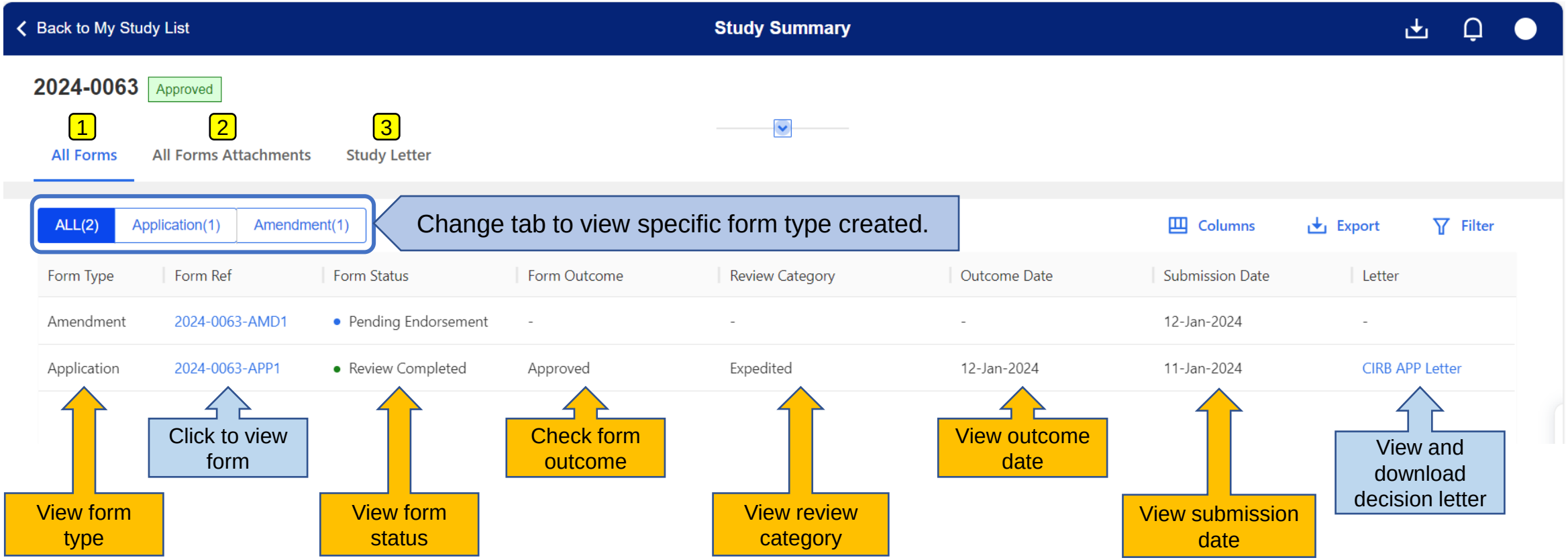
- Section B2: Addition of study sites (Endorsement for additional sites only)
- Section B2: Change/ Addition of PI/ Site-PI (Endorsement for additional sites only)
- Section D1: Change of study classification to ‘Clinical Trial’
- Section D3: Inclusion of Vulnerable Participants
- Section H4: Change to Placebo Controlled Trial
- IRB may unlock the Application Form if there are major changes made besides the scenario described above.

Study Summary



- Click on [My Study List].
- Find the study and click on ‘ ’ to view the study summary.

Study Summary



1 Display all forms that had been created for the study.

2 Display the list of attachments uploaded in all forms

3 Display the study letter issued by IRB (e.g. Suspension or Termination letter)