ECOS

The New IRB Application Form and Minimum Training Requirement

SingHealth
Defining Tomorrow's Medicine

Version dated 26 Mar 2024

Overview of ECOS

- ECOS is a web-based platform accessible by both internal and external users, jointly developed by SingHealth and NHG. It is a one stop solution to support the research lifecycle from Study Initiation to Completion, providing a more efficient management of research portfolios and ethics applications. The system consists of the following modules:

Minimum Training

Institutional Review Board

Clinical Research Management System

Compliance – Study Deviation and Non-Compliance / Serious Adverse Event

Compliance – PI Self-Assessment Form

Quality – Monitoring & Audit

Financial Conflict Of Interest
(For NHG DSRB review studies only)

Standing Database
(For NHG only)

User Account Migration from iSHaRe to ECOS

Only account of users with ongoing IRB approved studies **and** with study roles of PI, Site-PI and Co-I will be migrated.

For those who have an iSHaRe account but do not meet the migration criteria, do not worry, no action is required now.

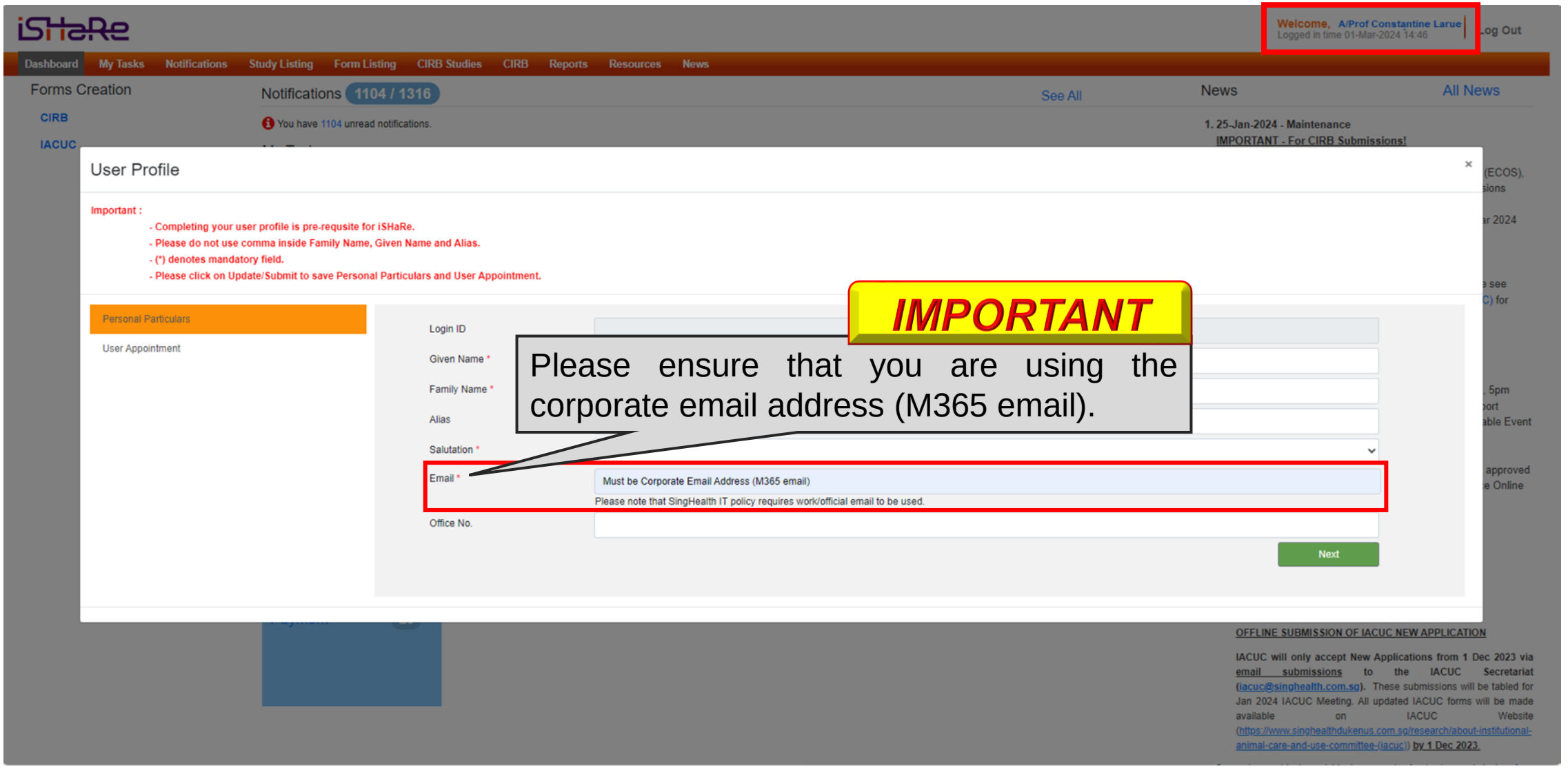
You will just need to register for an ECOS account when the system is launched.

User Account Migration from iSHaRe to ECOS

For Public Healthcare Institute (PHIs) users, ECOS login will be via corporate email address (M365 email).
Your corporate email address should have been updated in iSHaRe profile page as of **29 Feb 2024**.

For non-PHI users, the ECOS login will be based on the email address in the iSHaRe profile page as of **29 Feb 2024**.

iSHaRe Profile Page



Management of Existing Studies in iSHaRe

Please download and save a copy of study related documents before iSHaRe shuts down on **28 Mar 2024, 5pm**.

Do save it earlier to avoid heavy traffic (slowness) closer to the system shut down.

Only ongoing studies in iSHaRe with study status as ‘Approved’ as of 28 Mar 2024 would be migrated.

Minimum Training Requirement

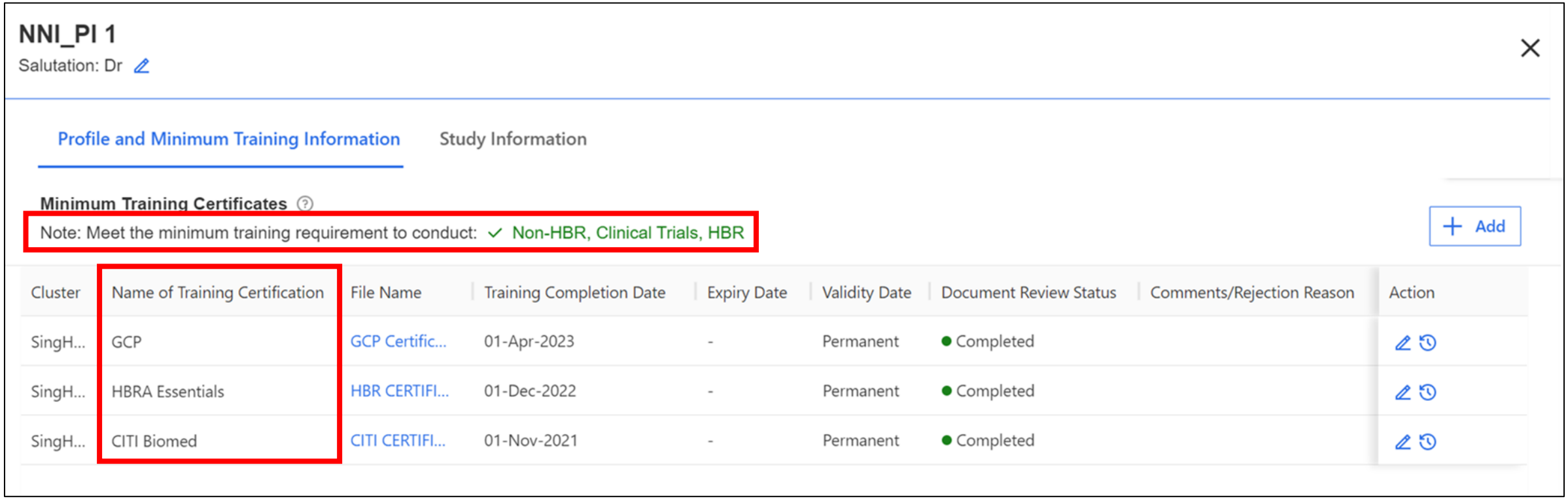
Minimum Training Requirement

		Training Certification		
		Collaborative Institutional Training Initiative (CITI) Biomedical Research Investigators and Key Personnel	Human Biomedical Research Act (HBRA) Essential	Good Clinical Practice (GCP) Certification
Type of Studies That You can Conduct	Non-HBR	✓		
	HBR	✓	✓	
	Clinical Trials	✓		✓

This requirement is for **all new applications** and **existing studies if amendment** will be submitted.

SHS-RSH-CIRB-233 Minimum Training and Minimum Requirements for Investigators and Study Team Members [Intranet Access only]

Minimum Training Certificates



- In order to conduct the various type of studies, the study team must meet the minimum training requirements.

https://www.singhealthdukenus.com.sg/research/rice/Pages/Training-Requirements.aspx

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Home > Research > Research Integrity, Compliance & Ethics (RICE) Homepage > Training Requirements

Training Requirements

All SingHealth PI/Site-PI, Co-I, and study team members are required to complete the minimum research ethics and compliance trainings to help them understand and apply the principles underlying the day-to-day practice of research. This helps to ensure safety, integrity, and quality of research, in compliance with local laws, regulations and international standards. The training requirements are as follows:

Minimum Training Requirements [Mandatory for IRB submission]

From 1 April 2024, all researchers (i.e., PI/Site-PI, Co-I, and study team members) who are directly involved in the conduct of research must meet the following training requirements:

Types of Research	Training Requirements
Human Biomedical Research and all other human subject's research	○ CITI Program - Biomedical Research Investigators and Key Personnel Module and ○ SingHealth eHBRA training or equivalent
Clinical Trials regulated under Health Products Act or Medicines Act	○ CITI Program - Biomedical Research Investigators and Key Personnel Module and ○ ICH-GCP course

All researchers are encouraged to complete the above courses, if not already done so. This is because researchers are required to submit their training certificates in the ECOS [Ethics and Compliance Online System] Minimum Training Module, prior to being able to submit new IRB applications via ECOS. Details on submission of the certificates will be shared later.

- **Collaborative Institutional Training Initiative (CITI) Program** – Click here to access.
  - ***Biomedical Research Investigators and Key Personnel module***

Link: https://www.singhealthdukenus.com.sg/research/rice/Pages/Training-Requirements.aspx

Revision to the New IRB Application Form

https://www.singhealthdukenus.com.sg/research/rice/Pages/Forms%20and%20Resources.aspx

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Home > Research > Research Integrity, Compliance & Ethics (RICE) Homepage > Forms & Resources

Forms & Resources

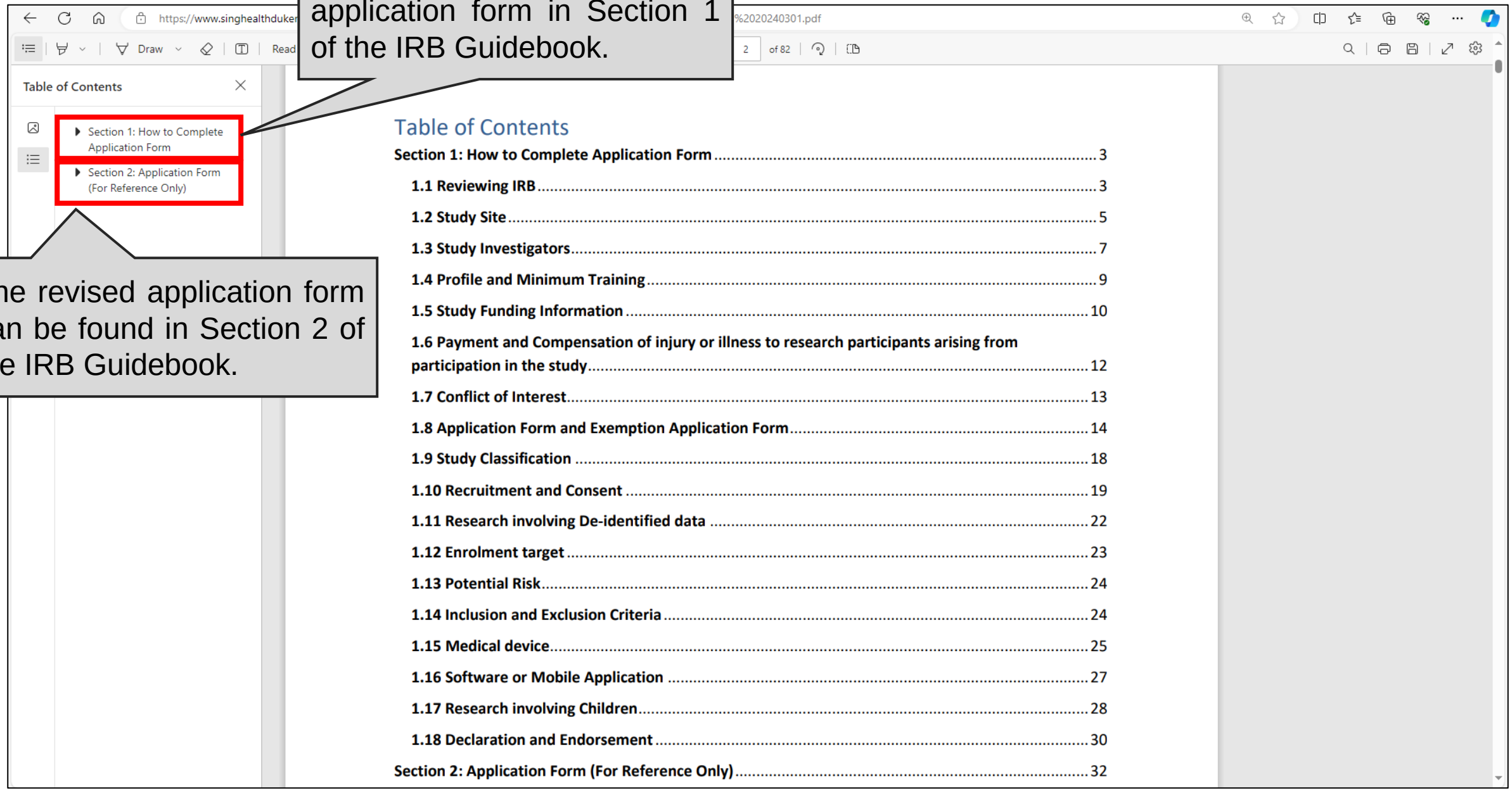
In preparation for the migration to the new online system (ECOS), please click here for more information.

Forms

Document Name	Version Number & Date	Link
IRB Guidebook: Application Form	V1, 1 Mar 2024	Download
SAE Reporting Form	V1, 8 Feb 2024	Download
Study Deviation Non-Compliance Report Form	V1, 29 Jan 2024	Download
Restricted Human Biomedical Research Form	v1, 27 Sep 2022	Download
Non-Local SAE Reporting Form	v0, 24 Jun 2020	Download

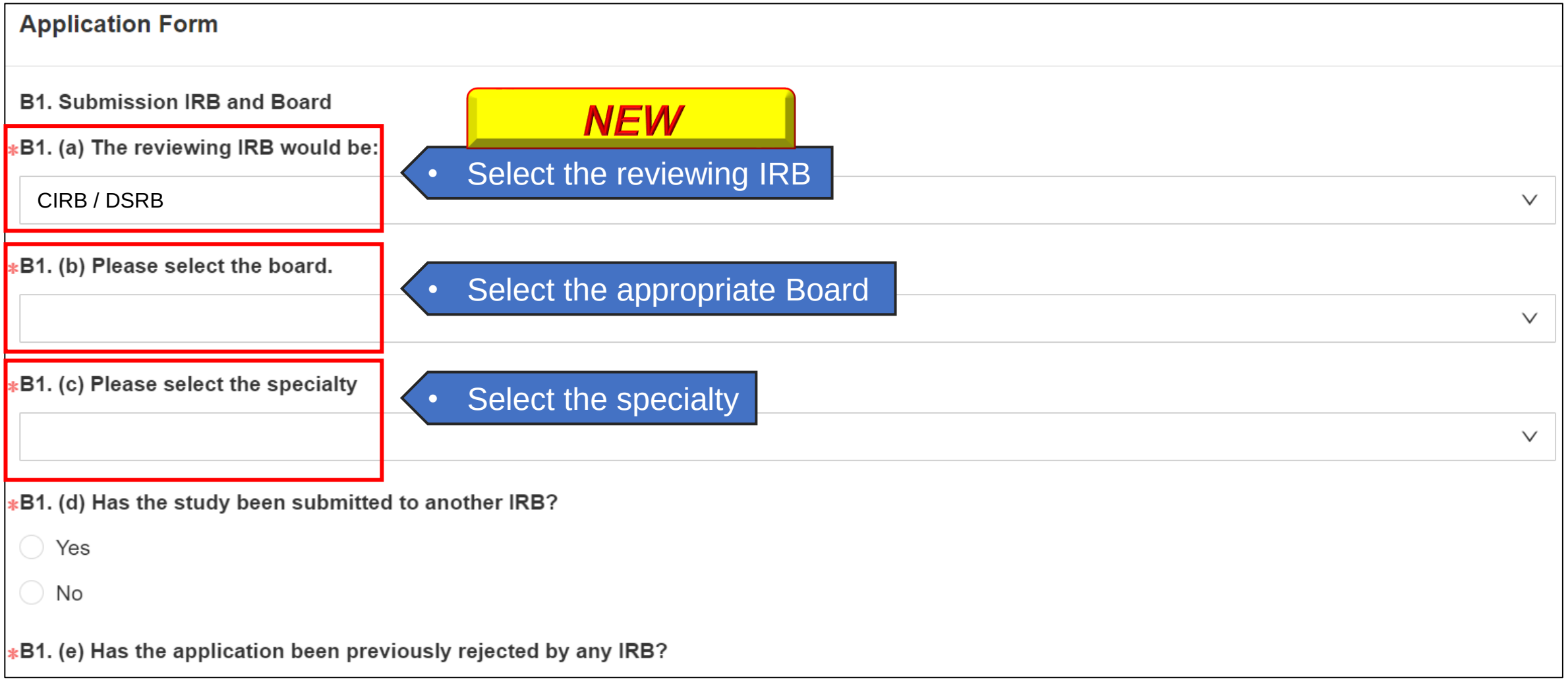
Link: https://www.singhealthdukenus.com.sg/research/rice/Pages/Forms%20and%20Resources.aspx

Guide on how to complete the application form in Section 1 of the IRB Guidebook.



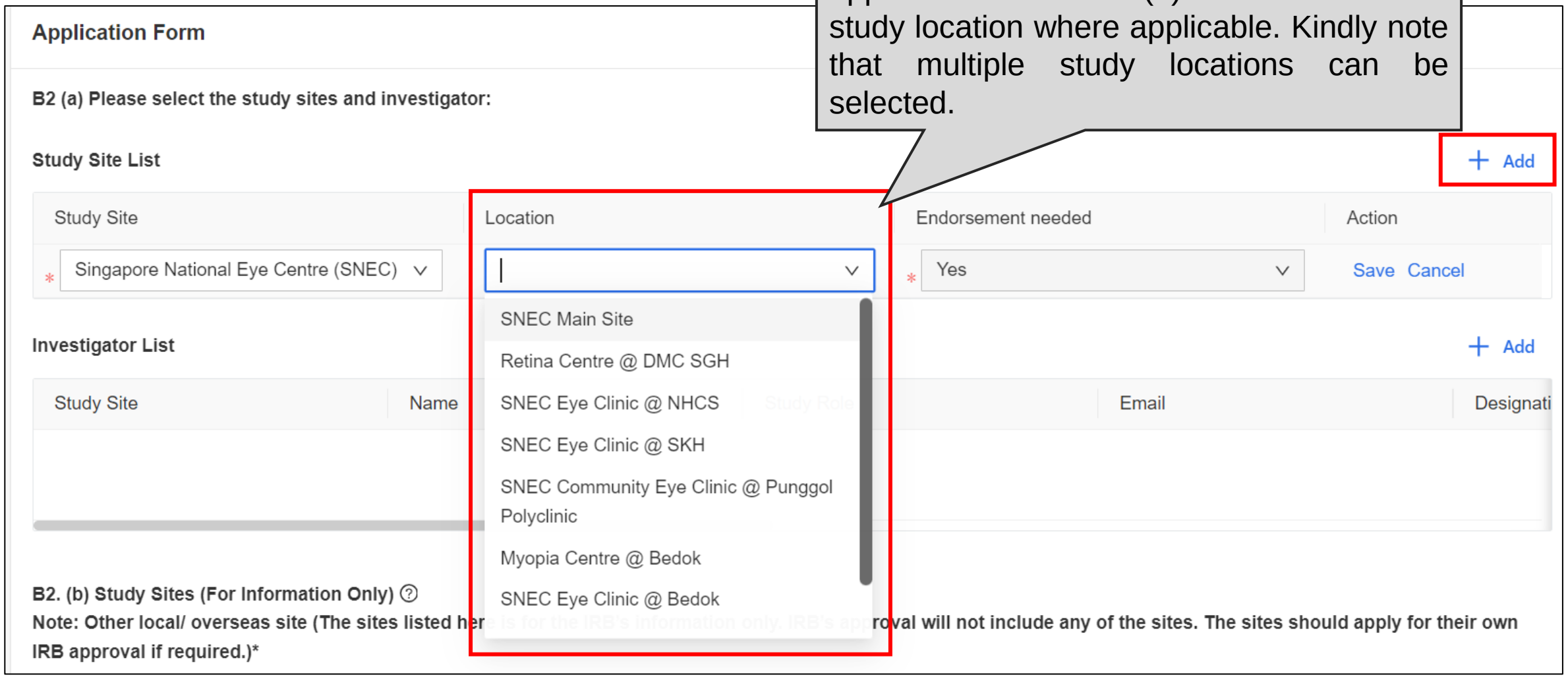
The revised application form can be found in Section 2 of the IRB Guidebook.

Section B1: Submission IRB and Board



Section B2: Study Site

After choosing a study site, if the study site has multiple locations, available options will appear in Section B2 (a). Please select the study location where applicable. Kindly note that multiple study locations can be selected.



Section B2: Study Site

Application Form

Study Site List + Add

Study Site	Location	Endorsement needed	Action
* Singapore National Eye Centre (SNEC)	SNEC Main Site	* Yes	Edit Delete

Investigator List + Add

Study Site	Name	Study Role	Email	Designati

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

B2. (b) Study Sites (For Information Only) ⓘ

Note: Other local/ overseas site (The sites listed here is for the IRB's information only. IRB's approval will not include any of the sites. The sites should apply for their own IRB approval if required.)*

0 characters entered

Section B2: Study Investigator

IMPORTANT

Only **PI, Site-PI and Co-I** would need to be added in the application form.

Ensure that the **correct appointment** is added to the application form for users with multiple appointments.

Other roles such as **Study Team Member, Study Administrator and Study Sponsor** will be managed in Clinical Research Management System (CRMS).

Adding Study Investigator

Application Form

Study Site List + Add

Study Site	Location	Endorsement needed	Action
* Singapore National Eye Centre (SNEC)	SNEC Main Site	* Yes	Edit Delete

Investigator List + Add

Study Site	Name	Study Role	Email	Designati

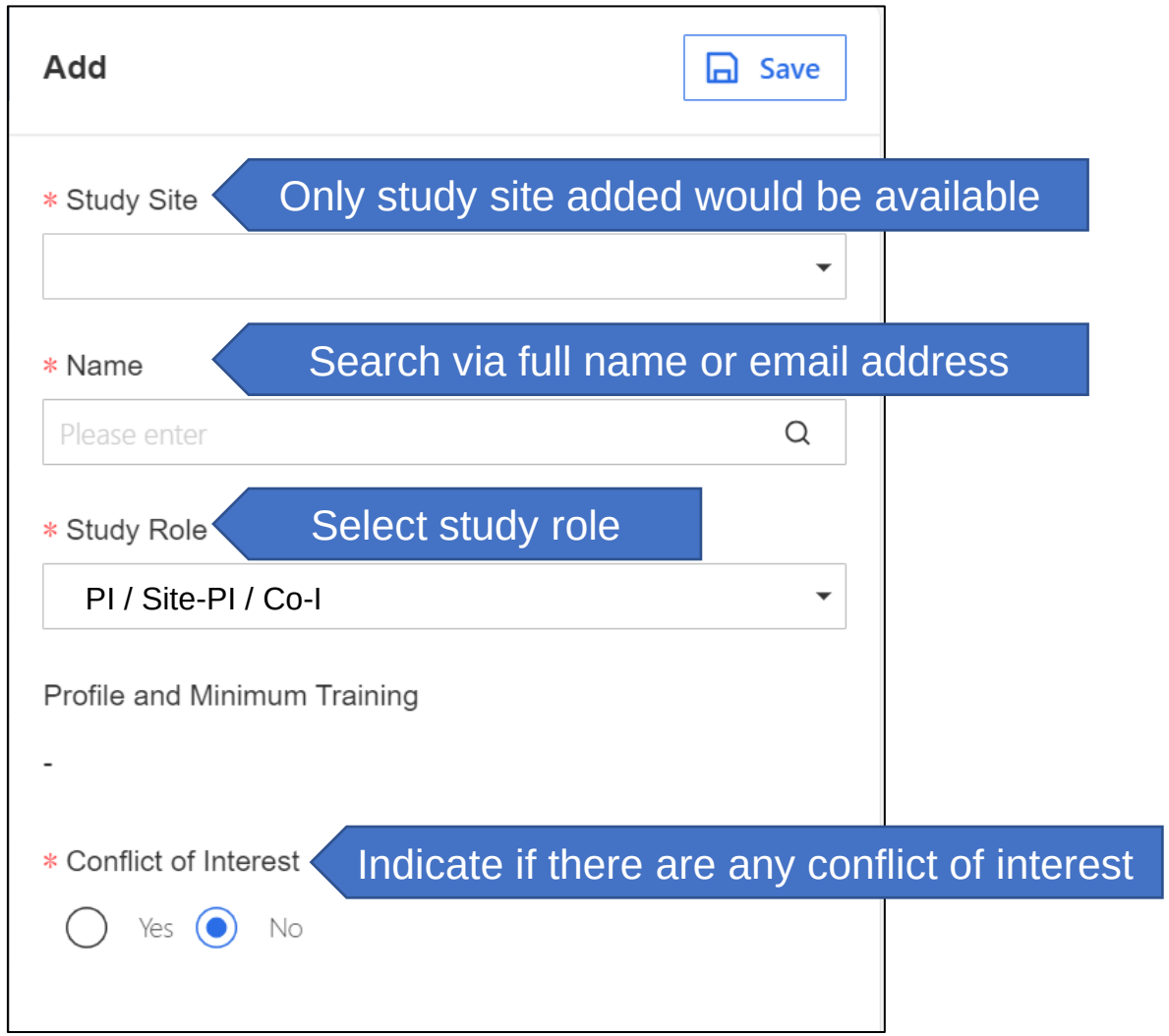
B2. (b) Study Sites (For Information Only) ⓘ

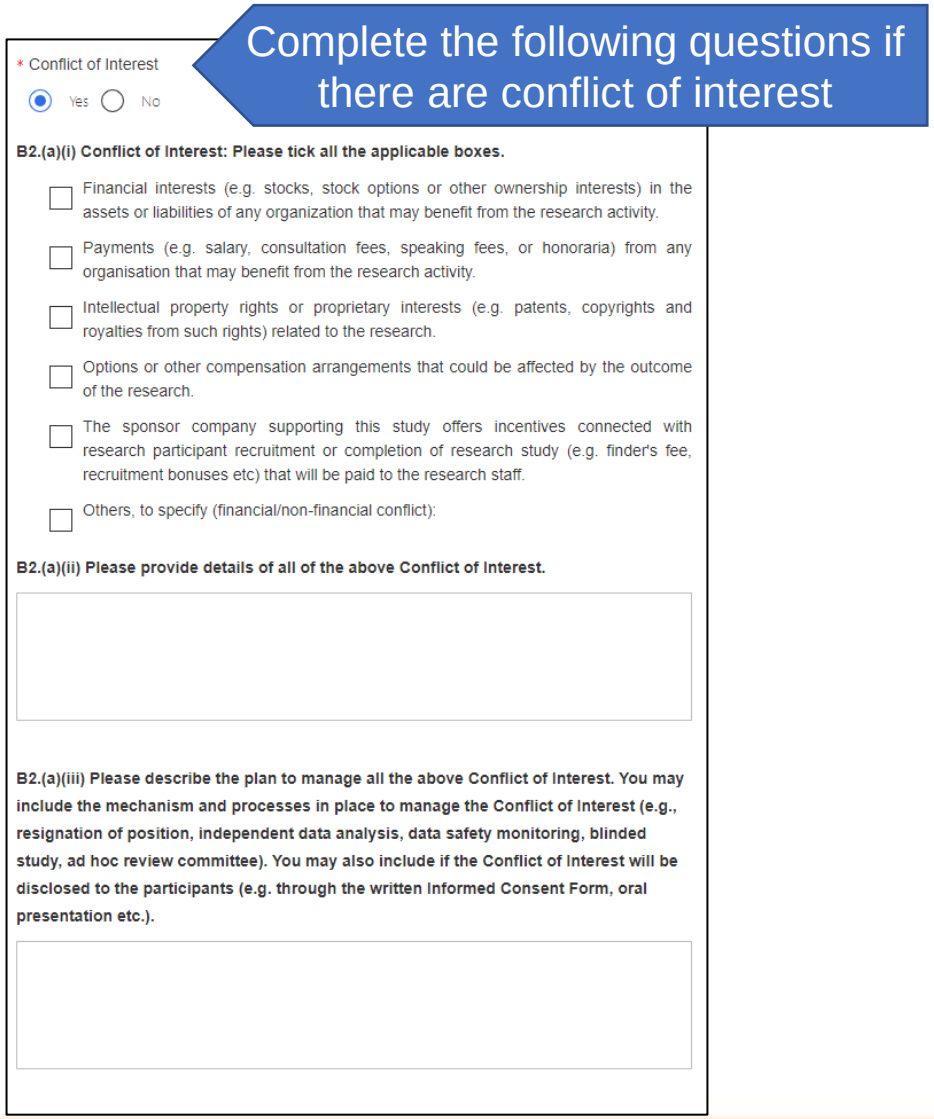
Note: Other local/ overseas site (The sites listed here is for the IRB's information only. IRB's approval will not include any of the sites. The sites should apply for their own IRB approval if required.)*

0 characters entered

Adding Study Investigator

NEW





Adding Study Investigator

Application Form

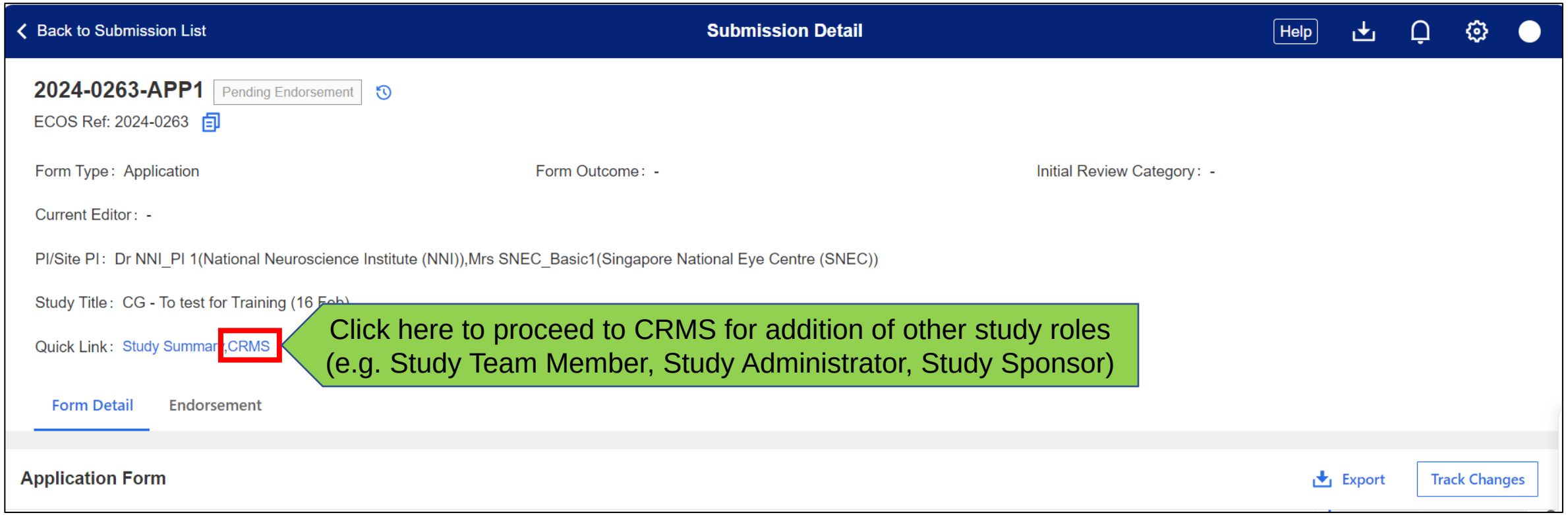
Export

Investigator List

Study Site	Name	Study Role	Email	Designati
Singapore National Eye Centre (SNEC)	SNEC_Basic2	PI		Basic Us
Singapore National Eye Centre (SNEC)	SNEC_Basic1	Co-I		Basic Us
National Neuroscience Institute (NNI)	NNI_PI 1	Site PI		Senior C
National Neuroscience Institute (NNI)	NNI_PI 2	Co-I		Senior C

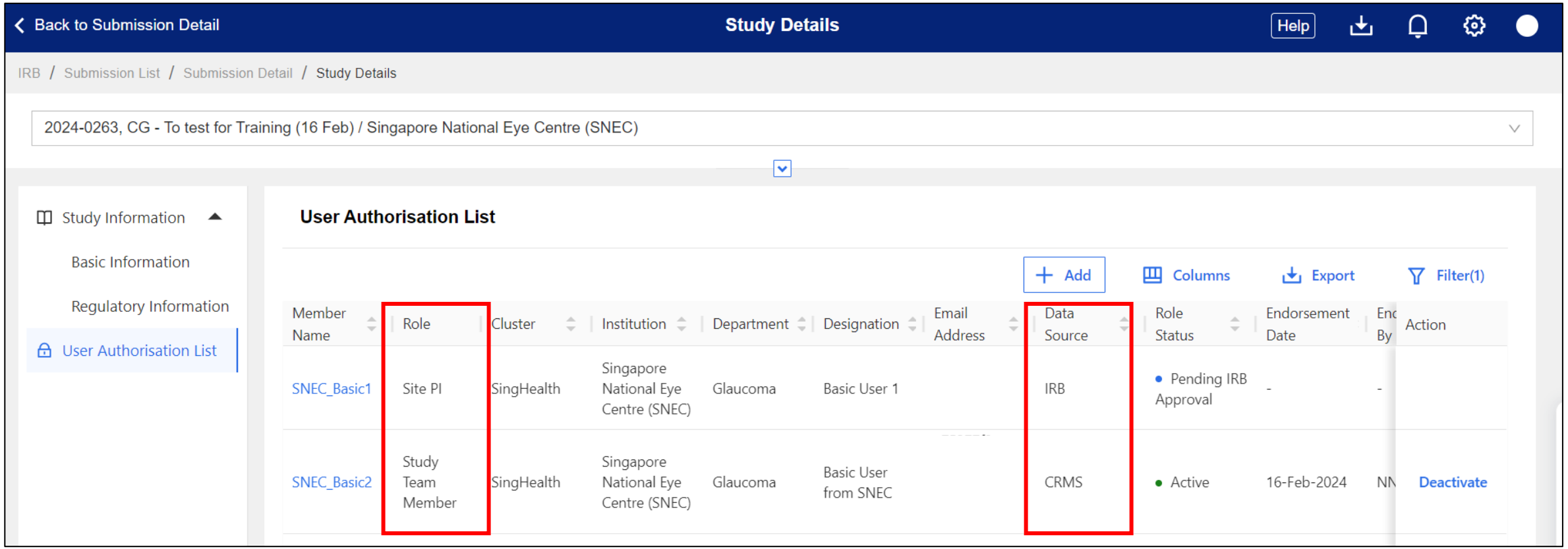
How to add other roles?

NEW



CRMS: User Authorization List

NEW



- For addition of other roles, PI would be responsible to ensure that the user added has the necessary certification to conduct the study.

Section C1: Study Funding - Grant

Application Form

*C1. (b) (i) Name of Grant Agency:

*C1. (b) (ii) Grant Holder:

Provide the name of the Grant Holder

*C1. (b) (iii) Grant Amount Applied for:

Specify Grant Amount, if amount is in other currency, please amend accordingly.

SGD-

NEW

If there are additional grant information after approval, please include it in CRMS module.

C1. (b) (iv) Has the grant been approved?

- Yes

Upload the grant approval letter if grant had been approved

- No

C1. (b) (v) Is the study's initiation dependent on grant approval?

- Yes

State the alternate funding if study initiation is not dependent on grant approval

- No

C1. (b) (vi) Grant Reference Number

Provide the Grant Reference Number

Section C1:
Study Funding - Pharmaceutical/ Industry Sponsored

Application Form

NEW

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

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

Provide the name of the Sponsor Company

*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?

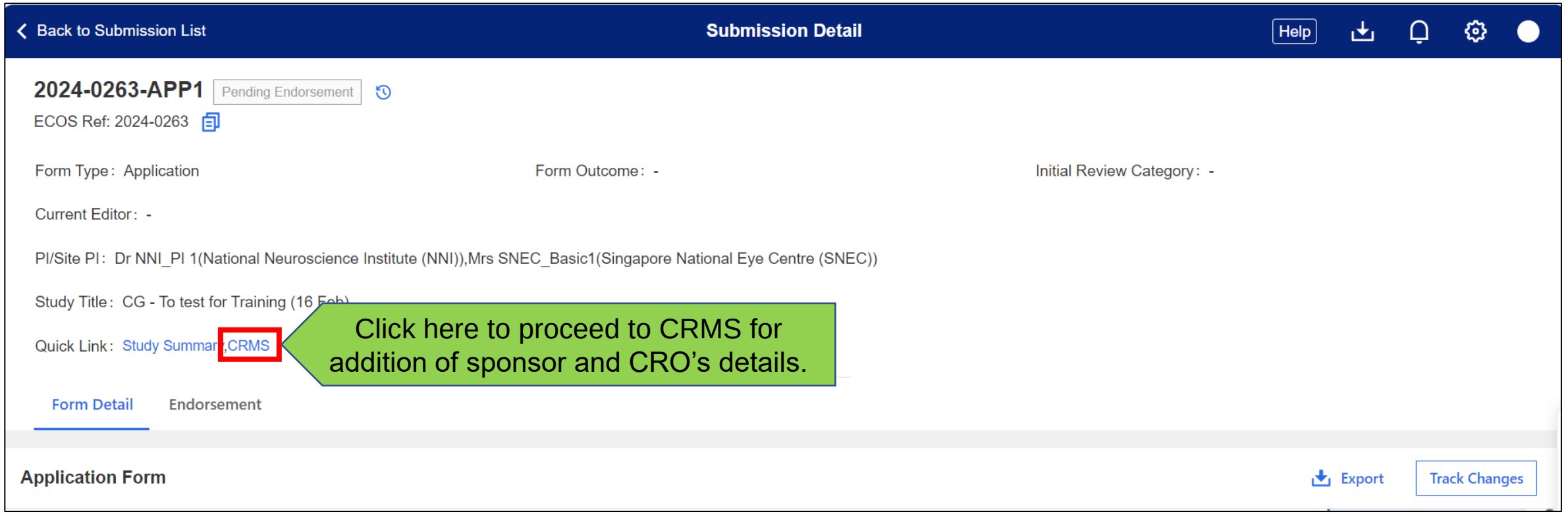
- Yes
- No

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

- Yes

How to add details of Sponsor and CRO?

NEW



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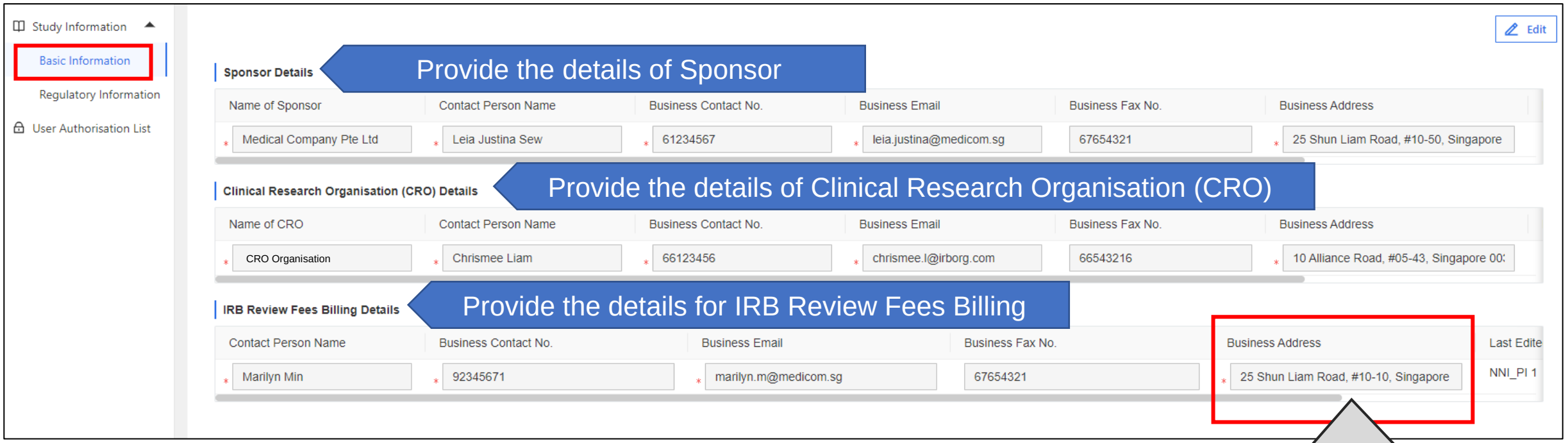
CRMS: Study Information – Basic Information



For the issuing of invoice, this address will be used. Please ensure correct address is provided.

Study Classification

Section D2: Study Classification

Application Form

***D1. Form Type: Please select the appropriate form for submission.**

- ○ Application Form
- ○ Exemption Application Form

***D2. Study Classification: Please determine which set of regulations would govern the study (or any part of the study).**

- ○ (a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)
- ○ (b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)
- ○ (c) Restricted Human Biomedical Research – Regulated by Human Biomedical Research Act (MOH)
- ○ (d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)

After selection of the **Form Type**, please determine which set of regulations would govern the study (or any part of the study).

Section D2 (b): Human Biomedical Research

D2. (b) (i) Any research that involves (if applicable):

- [ ] a. human gametes or human embryos.
- [ ] b. cytoplasmic hybrid embryos.
- [ ] c. the introduction of any human-animal combination embryo into an animal or human.
- [ ] d. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo).
- [ ] e. any entity created as a result of any process referred to in (c) or (d).

***D2. (b) (ii) My human biomedical research is intended to study:**

- [ ] a. the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body.
- [ ] b. the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques.
- [ ] c. the performance or endurance of human individuals.

***D2. (b) (iii) Where the research involves:**

- [ ] a. subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual.
- [ ] b. the use of any individually-identifiable human biological material.
- [ ] c. the use of any individually-identifiable health information.

Note:
(1) When options from D2. (b) (i) is selected, selections from D2. (b) (ii) and D2. (b) (iii) are NOT required unless applicable.
(2) When options from D2. (b) (i) is not selected, selections from D2. (b) (ii) and D2. (b) (iii) are mandatory.

Study Involving …

NEW

Section D3: Study Involving …

*D1. Form Type: Please select the appropriate form for submission.

- (•) Application Form
- ( ) Exemption Application Form

*D2. Study Classification: Please determine which set of regulations would govern the study (or any part of the study).

- ( ) (a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)
- ( ) (b) Human Biomedical Research - Regulated by Human Biomedical Resear
- ( ) (c) Restricted Human Biomedical Research – Regulated by Human Biomedi
- ( ) (d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Research Act (MOH)

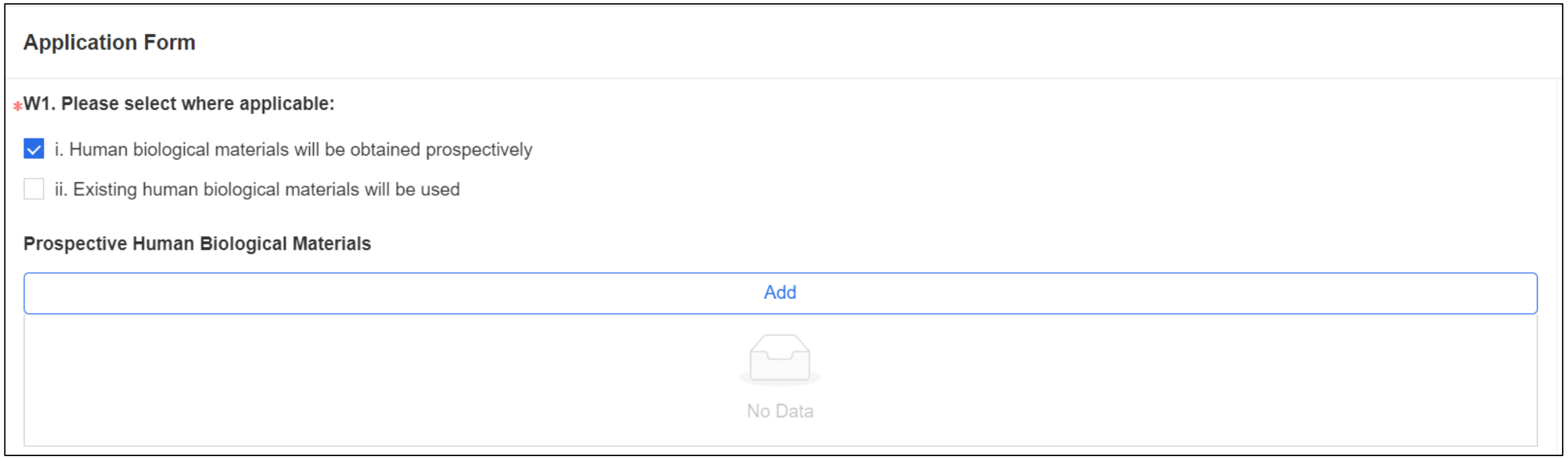
After **Application Form** had been selected as the **Form Type**, select what does the study procedures involved.

*D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).

- [ ] Questionnaire/ Survey/ Interview/ Focus Group Discussion
- [ ] Medical Records Review
- [ ] Human Biological Material — Section W will appear
- [ ] Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium — Section U will appear
- [ ] Use of Software or Mobile Applications — Section V will appear
- [ ] Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)
- [ ] Surgical / Radiotherapy Procedure — Section I will appear
- [ ] Interventions/ Invasive procedures
- [ ] None of the above

NEW

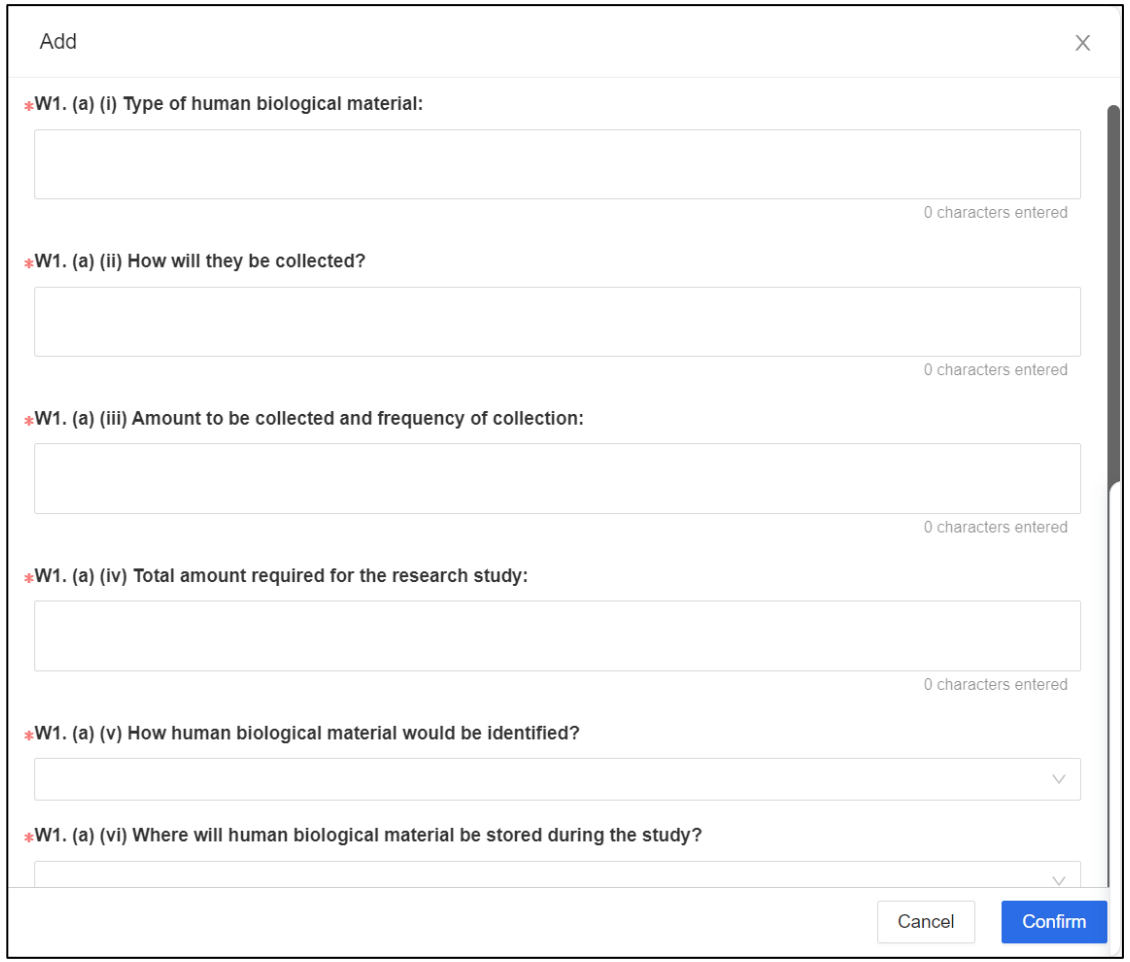
Section W: Human Biological Material (HBM)



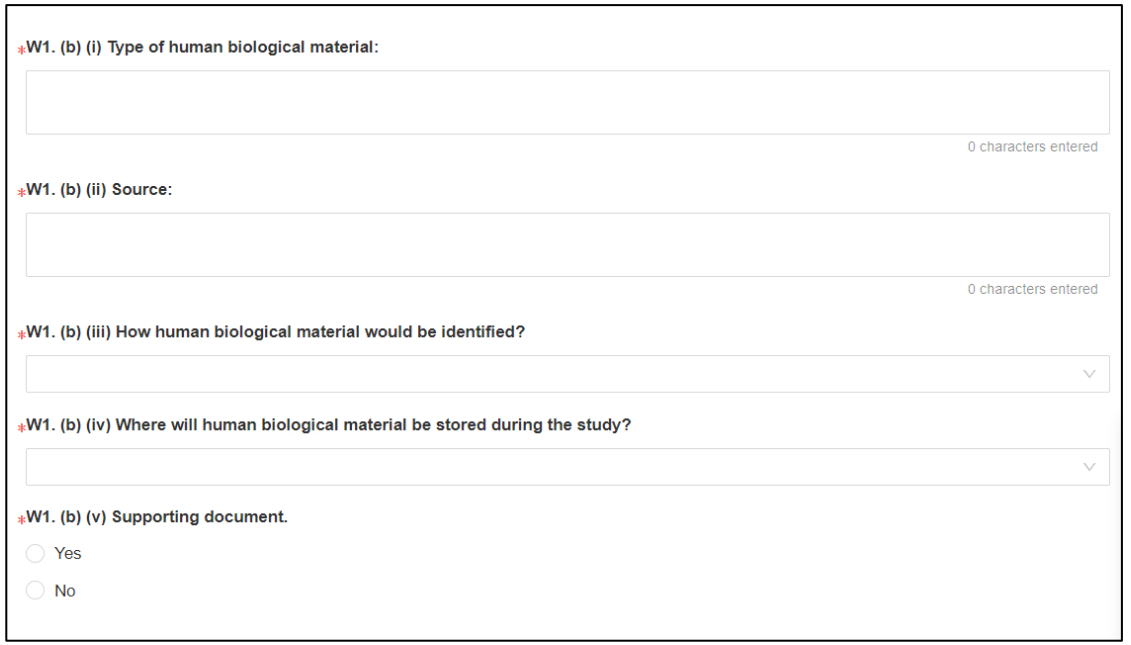
- In **Section W1**, select if HBM would be obtain prospectively or existing HBM would be used.
- Add the number of Type of HBM to be used accordingly.
- If HBM will be collected prospectively from research participant, please select ‘Human biological materials will be obtained prospectively’.

NEW

Section W: Human Biological Material (HBM)



HBM would be obtained prospectively.



Existing HBM would be used.

Section U: Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium

NEW

Application Form

*U1. Please describe the contents of the recording (e.g. audio-recoding of interview/ focus group discussion, images of facial feature, etc).

s entered

*U2. What is the medium (audio tape/ video etc) used for recording?

s entered

*U3. Explain how the recorded information will be used in the study.

aracters entered

*U4. For how long and where will the recording medium be stored? Who will have access, how will access be controlled and monitored?

0 characters entered

*U5. How will the recording medium be disposed?

The questions are similar to the questions from Section R2 of the iSHaRe Application Form but it is now in Section U on its own.

NEW

Section V: Use of Software or Mobile Applications

Application Form

*V1. Please select the type of software(s) applicable and state the name of software (including third party and mobile applications) Please also attach the supporting documents (if any): ⓘ

- ☐ V1. (a) Telehealth Medical Device
- ☐ V1. (b) Telehealth Wellness Device
- ☐ V1. (c) Others

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

*V2. Please describe the following:

· What data would be collected via the telehealth device?
· Where the data would be stored?
· Who have access to the data?
· How would the research data confidentiality be protected?

0 characters entered

*V3. Assurances by Principal Investigator.

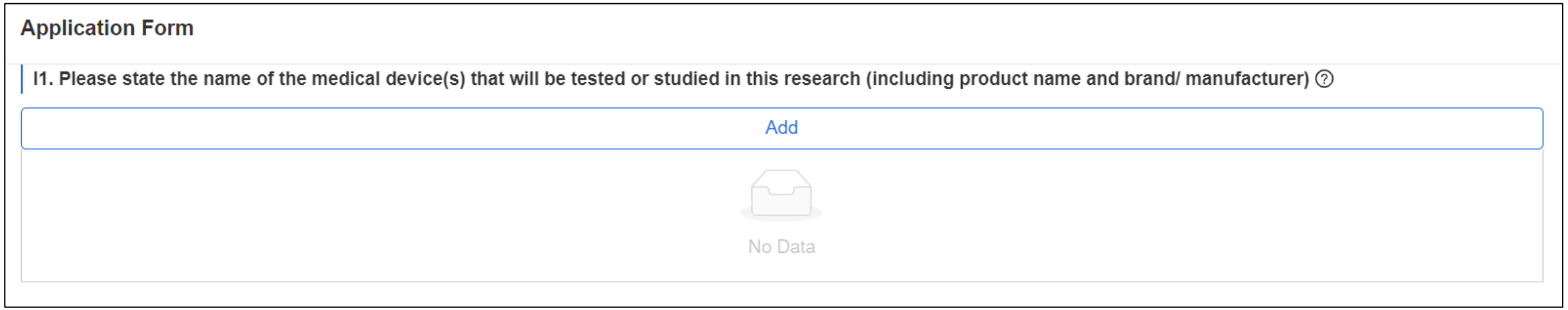
· The use of usage of the software or a mobile application and storage of data will be in compliance with institution policy.

☐ I agree with the above statement.

Click here for HSA Website for Telehealth Product

Section I:
Medical Device (including Telehealth Medical Device)

NEW



- In **Section I1**, add the number of medical devices that would be tested or studied in this research.

Click here for HSA Website for Medical Device

Section I:
Medical Device (including Telehealth Medical Device)

NEW

Add

*Medical Device

0 characters entered

*I1. (a) Is the medical device used as a prototype (including modified devices) under in this study?

- Yes
- No

*I1. (b) Is the medical device locally registered?

- Yes, it is registered as General Medical Device
- Yes, it is registered as an In-Vitro Diagnostic (IVD) Medical Device
- No, it is unregistered

*I1. (c) Will you be submitting or have submitted the Clinical Research Material Notification (CRM-N) to HSA for the medical device?

- Yes
- No

*I1. (d) Is this a US FDA IDE study or data is intended to be reported to FDA in support of an IDE Application?

- Yes
- No

Add

*I1. (e) Please determine the risk level of the medical device to research participants:

- This is not a significant risk medical device
- This is a significant risk medical device

*I1. (g) Please describe on the storage, inventory and control of the medical device?

0 characters entered

*I1. (h) Who will be responsible for administering the medical device?

- Trained study team member
- Research participants
- Others

*I1. (i) Please describe how the unused or returned medical device will be managed at the completion of this research study.

0 characters entered

*I1. (j) Please attach the supporting documents for the medical device (e.g., device brochure, product catalogue(s), product information sheet/leaflet(s), directions/instructions for use, insert, labelling (if appropriate and/or applicable), safety data, image/photograph/diagram of device(s), etc.)

Upload

Research Methodology

Section E / G of ECOS Application Form: Research Methodology

NEW

- Combination of the following sections in iSHaRe Application Form
  - Section F: Research Methodology
  - Section I: Study Sites & Recruitment Targets
  - Section K: Research Participant Characteristics

NEW

Section E5 / G12: Enrolment Target

Note:

(1)For the distribution of Males, Females and Children to be enrolled into the study, please use the Enrolment Target Minimum number to provide an approximate distribution ratio.

(2)Please note that enrolling research participants beyond the Enrolment Target Maximum without the IRB's approval would constitute a non-compliance. If you intend to recruit beyond the Enrolment Target Maximum, please submit a study amendment to increase the enrolment target for approval.

(3)Enrolment Target Min must be equal or lower (≤) than sum of male, female, and children.Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min.

Study Site	Enrolment Target Min	Enrolment Target Max	Adults (Male)	Adults (Female)	Children ⓘ	Action
National Neuroscience Institute (NNI)	* 20	* 100	* 40	* 20	* 0	Edit
Singapore National Eye Centre (SNEC)	*	*	*	*	*	Edit

- Please provide the minimum and maximum of the enrolment target.
  - Enrolment Target Min must be equal or lower (≤) than sum of male, female and children.
  - Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min.
- For studies with no recruitment, please state the estimated number of records that would be studied.

Type of Consent for the Study

Section D5: Type of Consent for the Study

NEW

Application Form

- [ ] Use of Software or Mobile Applications
- [ ] Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)
- [ ] Surgical / Radiotherapy Procedure
- [ ] Interventions/ Invasive procedures
- [ ] None of the above

After **Application Form** had been selected as the **Form Type**, please select the applicable type(s) of consent for the study.

*D4. Would the study involve recruitment?

- ( ) Yes
- ( ) No

*D5. Please select the applicable type(s) of consent for the study.

- [ ] Consent will be obtained — Section J5 to J12 will appear
- [ ] Waiver of documentation of consent (Verbal or Implied Consent) - This option mostly applicable for Questionnaire/ Survey/ Interview/ Focus Group Discussion — Section O will appear
- [ ] Waiver of consent during emergency situation — Section P will appear for Clinical Trial and non-HBR studies / Section Q will appear for HBR and rHBR studies
- [ ] Wavier of consent — Section R will appear for Clinical Trial and non-HBR studies / Section S will appear for HBR and rHBR studies
- [ ] Not applicable as study involves De-identified Data
- [ ] Consent obtained from research participants previously — Section D5(a) and D5(b) will appear

Section D5(a) & (b): Consent Obtained from Research Participants Previously

NEW

Application Form

- [ ] No

*D5. Please select the applicable type(s) of consent for the study.

- [ ] Consent will be obtained
- [ ] Waiver of documentation of consent (Verbal or Implied Consent) -
- [ ] Waiver of consent during emergency situation
- [ ] Wavier of consent
- [ ] Not applicable as study involves De-identified Data
- [x] Consent obtained from research participants previously

- Please state the source where consent had been obtained from research participants previously.
- Submit a copy of the approved Informed Consent Document template for reference.

*D5. (a) Please state the source. For approved study, please state the protocol title, IRB reference number and name of approving IRB. Please submit a copy of the approved Participant Information Sheet and Consent Form/ Informed Consent Document.

0 characters entered

*D5. (a) Please submit a copy of the approved Participant Information Sheet and Consent Form/ Informed Consent Document.

Upload

Study involves De-identified Data

NEW

Application Form

- [ ] Use of Software or Mobile Applications
- [ ] Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)
- [ ] Surgical / Radiotherapy Procedure
- [ ] Interventions/ Invasive procedures
- [ ] None of the above

***D4. Would the study involve recruitment?**

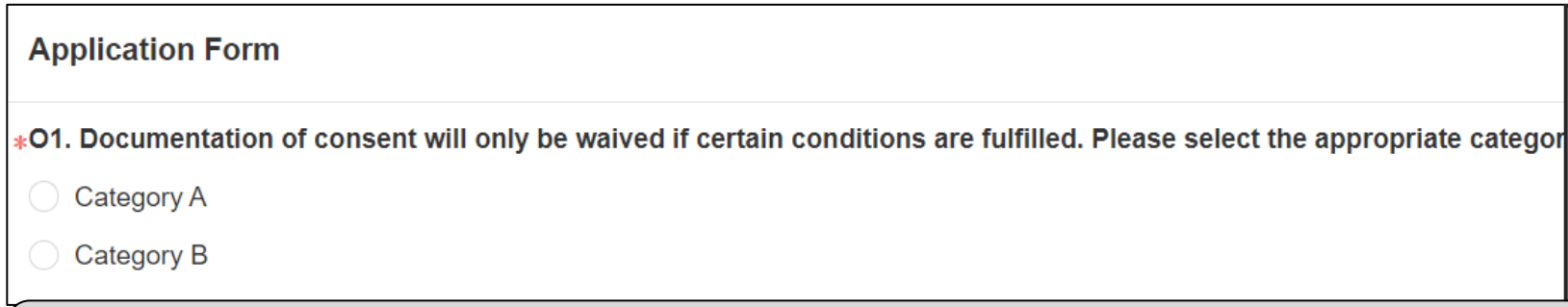
- ( ) Yes
- ( ) No

***D5. Please select the applicable type(s) of consent for the study.**

- [ ] Consent will be obtained
- [ ] Waiver of documentation of consent (Verbal or Implied Consent) - This
- [ ] Waiver of consent during emergency situation
- [ ] Wavier of consent
- [x] Not applicable as study involves De-identified Data
- [ ] Consent obtained from research participants previously

- 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 de-identifiable data/samples (e.g. de-identified by Trusted Third Party), please describe the process such as why, what, who, where and how the de-identifiable data/samples are obtained.

Section O:
Waiver of Documentation of Informed Consent



The questions are similar to the questions from Section P6 of the iSHaRe Application Form but it is now in Section O on its own.

In **Section O1**, please select the appropriate category for the request for waiver of documentation of informed consent and provide the justification accordingly.

Category A

- The only record linking the participant and the research would be the consent document.
- The principal risk would be potential harm resulting from a breach of confidentiality.
- If the research is subjected to FDA regulations, your study does not qualify for waiver of documentation of consent under Category A.
- If the participant will not be asked whether the participant wants documentation linking the participant with the research, your study do not qualify for waiver of documentation of consent under Category A.

Category B

- The research presents no more than minimal risk of harm to participants.
- The research involves no procedures for which written consent is normally required outside of the research context.

Section O:
Waiver of Documentation of Informed Consent

Application Form

*O1. Documentation of consent will only be waived if certain conditions are fulfilled. Please select the appropriate category.

- ○ Category A
- ○ Category B

*O2. Will information sheet be provided?

- ○ Yes
- ○ No

The questions are similar to the questions from Section P6 of the iSHaRe Application Form but it is now in Section O on its own.

- If information sheet would be provided, please submit the information sheet in **Section O2**.

Section R: Consent Process - Waiver of Consent (Non-HBR)

Application Form

*R1. The study poses no more than minimal risk to research participants.

s entered

*R2. Waiver of informed consent will not adversely affect the rights and welfare of research participants.

s entered

*R3. The study cannot be practically conducted without the waiver of informed consent.

0 characters entered

*R4. Whenever appropriate, will the research participants be provided with additional pertinent information after participation?

- Yes
- No

*R5. Do you have any additional comments supporting the waiver of informed consent?

The questions are similar to the questions from Section Q1(I) of the iSHaRe Application Form.

Section S: Consent Process - Waiver of Consent (HBR)

Application Form

*S1. Please select the type of waiver required.

- ☐ I. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3 (individually identifiable health information or human biological material obtained or compiled before, on and/ or after 1 Nov 2017)
- ☐ II. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4 (individually identifiable health information obtained or compiled before 1 Nov 2017)
- ☐ III. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5 (individually identifiable human biological material obtained or compiled before 1 Nov 2017)

- Not required to submit PDPA Practicability Calculator.
- Please ensure that the study meets the 'Greater Public Good' criteria.
  - ➢ You may refer to the 'Guidance on Greater Public Good' for more information.

Section P: Consent Process - Waiver of Informed Consent during Emergency Situation (Clinical Trial)

Application Form

Note: For the conduct of clinical trials in emergency situation, please be reminded to submit to Health Sciences Authority written certifications by the PI and 2 independent specialists as stipulated in Section 8(3) of the Health Products/ Medicines (Clinical Trials) Regulations.

P1. Please justify why this study meets the following as a clinical trial in an emergency situation.

***P1 (a) The trial needs to be conducted on potential participants who are facing a life-threatening situation to determine the safety or efficacy of an investigational product.**

0 characters entered

***P1. (b) Available treatments or procedures are unproven or unsatisfactory.**

0 characters entered

***P1 (c) There is a reasonable prospect that participation in the trial will directly benefit the potential participants because**
i. the potential participants are facing a life-threatening situation that necessitates intervention
ii. the appropriate non-clinical and clinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the proposed use of the therapeutic product to provide a direct benefit to the potential participants; and
iii. the risks associated with the trial are reasonable in relation to what is known about:
A. the medical condition of the potential participants
B. the risks and benefits of standard therapy, if any; and
C. the risks and benefits of the proposed used of the therapeutic product.

Application Form

***P1 (d) The trial participants are unable to consent to being trial participants in the trial as a result of their medical condition.**

0 characters entered

***P1 (e) It is not feasible to obtained consent from the legal representatives of the potential trial participants within the window period.**

0 characters entered

***P1 (f) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the trial.**

0 characters entered

***P2. Please explain what the window period is in relation to the amount of time to be devoted to seeking informed consent.**

0 characters entered

***P3. If the prospective trial participant is unable to consent, please describe the procedures to obtain informed consent from the prospective trial participant's legal representative or inform the prospective trial participant's family member of their participation at the earliest feasible opportunity.**

Section P: Consent Process – Waiver of Informed Consent during Emergency Situation (Clinical Trial)

NEW

Application Form

*P4. If consent cannot be obtained from the prospective trial participant or participant's legal representative, and no family member has objected to the trial participant's trial participation, provision is made for an Investigator (who is a specialist) and 1 independent specialist to certify, prior to the enrolment of the trial participant that:
a) The prospective trial participant is facing a life-threatening situation which necessitates intervention;
b) The prospective trial participant is unable to consent as a result of his/her medical condition;
c) It is not feasible to obtain consent from the legal representative of the prospective trial participant within the window period; and
d) Neither the prospective trial participant nor the legal representative of the prospective trial participant nor any member of the prospective trial participant's family has informed the Principal Investigator of any objection to the prospective trial participant being a trial participant in the clinical trial.

☐ Yes, the trial will be conducted in compliance with the above pre-enrolment certification

*P5. After enrolment of a trial participant in a clinical trial in emergency situation, if the trial participant is unable to consent, describe the procedures for obtaining the trial participant's legal representative informed consent at the earliest feasible opportunity. If informed consent cannot be obtained from the trial participant or his/ her legal representative, describe the procedures to contact his/her family member about his/her trial participation at the earliest feasible opportunity.

0 characters entered

*P6. If anytime during the clinical trial in an emergency situation, the trial participant regains capacity to give consent, a full explanation of the clinical trial will be explained to the trial participant to seek the trial participant's consent to continue participation in the clinical trial.

☐ Yes, informed consent will be sought from the trial participant when he/she regains capacity, at the earliest feasible opportunity.

P7. Please submit the supporting documents relevant to this section.

Section Q: Consent Process - Waiver of Informed Consent during Emergency Situation (HBR)

NEW

Application Form

Please justify that the study meets the following criteria for emergency research.

*Q1. The research participants are facing a life-threatening situation.

0 characters entered

*Q2. There is no professionally accepted standard of treatment, or the available treatment are unproven or are unsatisfactory.

0 characters entered

*Q3. The collection of valid scientific evidence is necessary to determine the safety and effectiveness of a particular intervention or treatment.

0 characters entered

*Q4. Participation in the proposed research holds out the prospect of direct benefit to the research participants.

0 characters entered

Application Form

*Q5. Obtaining appropriate consent is not feasible because:

a. The research participant will not have capacity within the time available to give their appropriate consent as a result of their medical condition or situation; and,

b. The research participant's legal representative is not available.

0 characters entered

*Q6. After enrolment of a participant in a study in emergency situation, if the participant is unable to consent, describe the procedures for obtaining the participant's legal representative informed consent at the earliest feasible opportunity.

0 characters entered

*Q7. The research participant is to be informed as soon as is practicable after he or she regains capacity of his or her participation in the research and given an opportunity to withdraw from further participation in the research.

☐ Yes, consent for continued participation will be sought from the research participant when he/she regains capacity.

*Q8. Provision is made for a specialist in the specialty relating to the research and who is not involved in the research as a researcher to certify, prior to the enrolment of the research participant that Sections Q1 to Q5 above have been complied with.

○ Yes, consent for continued participation will be sought from the research participant when he/she regains capacity.

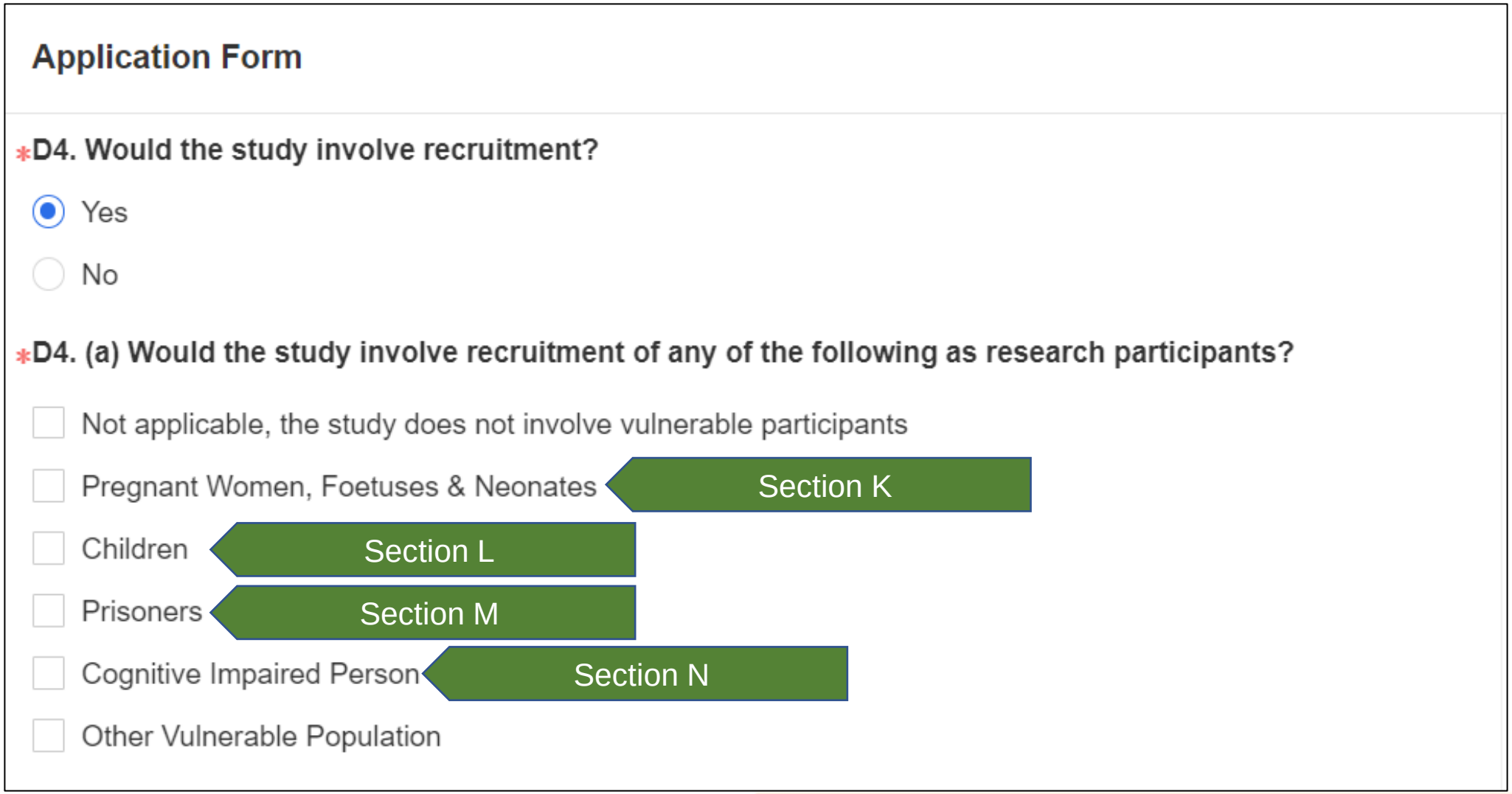
○ No, please describe the process of certification that Q1 to Q5 have been complied with.

Q9. Please submit the supporting documents relevant to this section.

Study Involving Vulnerable Populations

- Pregnant Women, Foetuses & Neonates
- Children
- Prisoners
- Cognitively Impaired Persons

Study Involving Vulnerable Populations



Section K: Pregnant Women, Foetuses & Neonates

Application Form

*K1. Please indicate if your research involves:

Note: If the study involves Viable Neonates, please select "Children" under Section D4.

- [ ] Pregnant Women and Foetuses
- [ ] Neonates of Uncertain Viability and/or Nonviable neonates

NEW

If the study involves Viable Neonates, please select 'Children' under Section D4(a) instead.

*K2. Describe if preclinical studies, including studies on pregnant animals, and clinical studies including studies on non-pregnant women, have been conducted and data is available to assess risks to pregnant women and foetus.

Section L: Children

Application Form

*L3. Does the study involve removal of human tissues not primarily for therapeutic or diagnostic purpose from children who lacks sufficient understanding and intelligence to give consent?
Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)

- (●) Yes
- ( ) No

*L3. (a) Please state the type of human tissues.

*L3. (b) The removal of the tissue involves no more than minimal risk to children who lacks sufficient understanding and intelligence to give consent. Please justify how your study meets this criterion.

0 characters entered

*L3. (c) There are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue from children who lacks sufficient understanding and intelligence to give consent. Please justify how your study meets this criterion.

NEW

Please provide more information if study involved **removal of human tissues not primarily for therapeutic or diagnostic purpose** from children who lacks sufficient understanding and intelligence to give consent. Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)

Section M: Prisoners

Application Form

*M1. How does the research purpose justify enrolling prisoners?

0 characters entered

*M2. Is there any evidence of duress, coercion, or undue influence in the particular prison(s) from which research participants will be recruited?

*M3. Are potential research related risks to prisoners comparable to risks that would be accepted by non-prisoner volunteers?

*M4. Describe the systems in place to ensure research participant and data confidentiality.

*M5. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants?

The questions are similar to the questions from Section N of the iSHaRe Application Form.

Section N: Cognitive Impaired Person

Application Form

*N2. Does the study involve removal of human tissues not primarily for therapeutic or diagnostic purpose from (1) an adult who lacks mental capacity; OR (2) children who lacks mental capacity?
Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)

- (●) Yes
- ( ) No

*N2. (a) Please state the type of human tissues.

*N2. (b) The removal of the tissue involves no more than minimal risk to this group of participants. Please justify how your study meets this criterion.

0 characters entered

*N2. (c) There are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue to this group of participants. Please justify how your study meets this criterion.

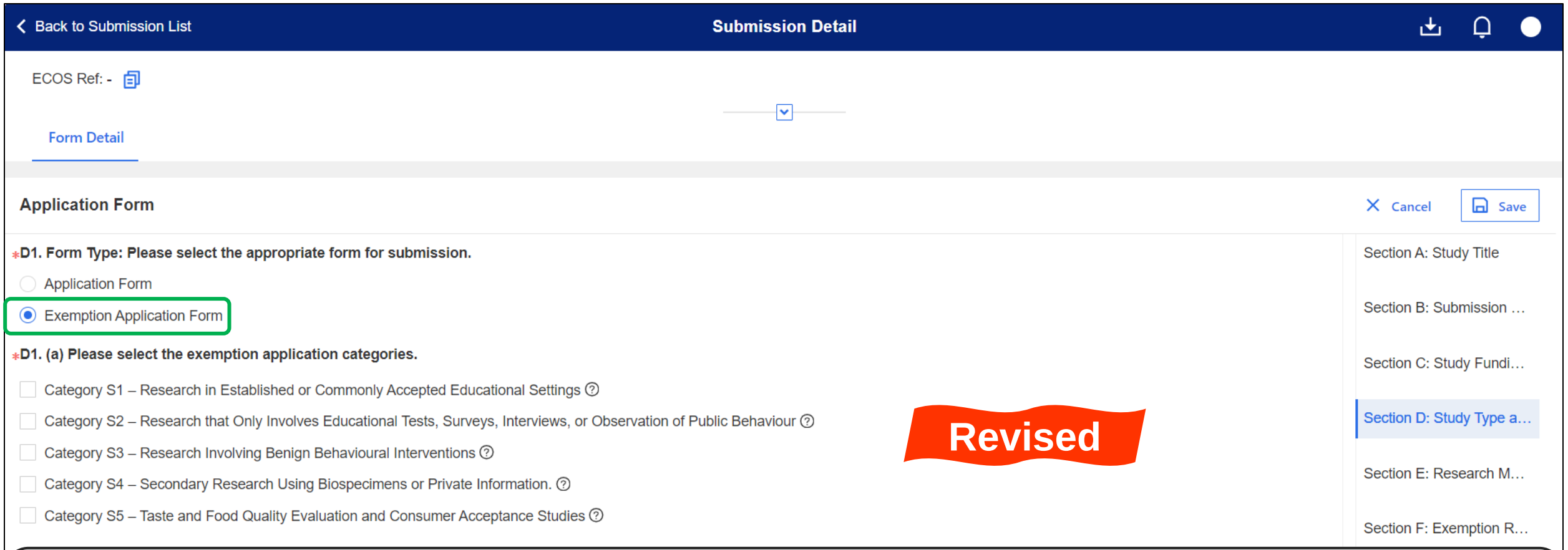
0 characters entered

NEW

Please provide more information if study involved **removal of human tissues not primarily for therapeutic or diagnostic purpose** from an adult who lacks mental capacity. Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)

Exemption Studies

Exemption Studies



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

Exemption Category S1

- Research 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 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.

Example

- 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 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.

Example

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

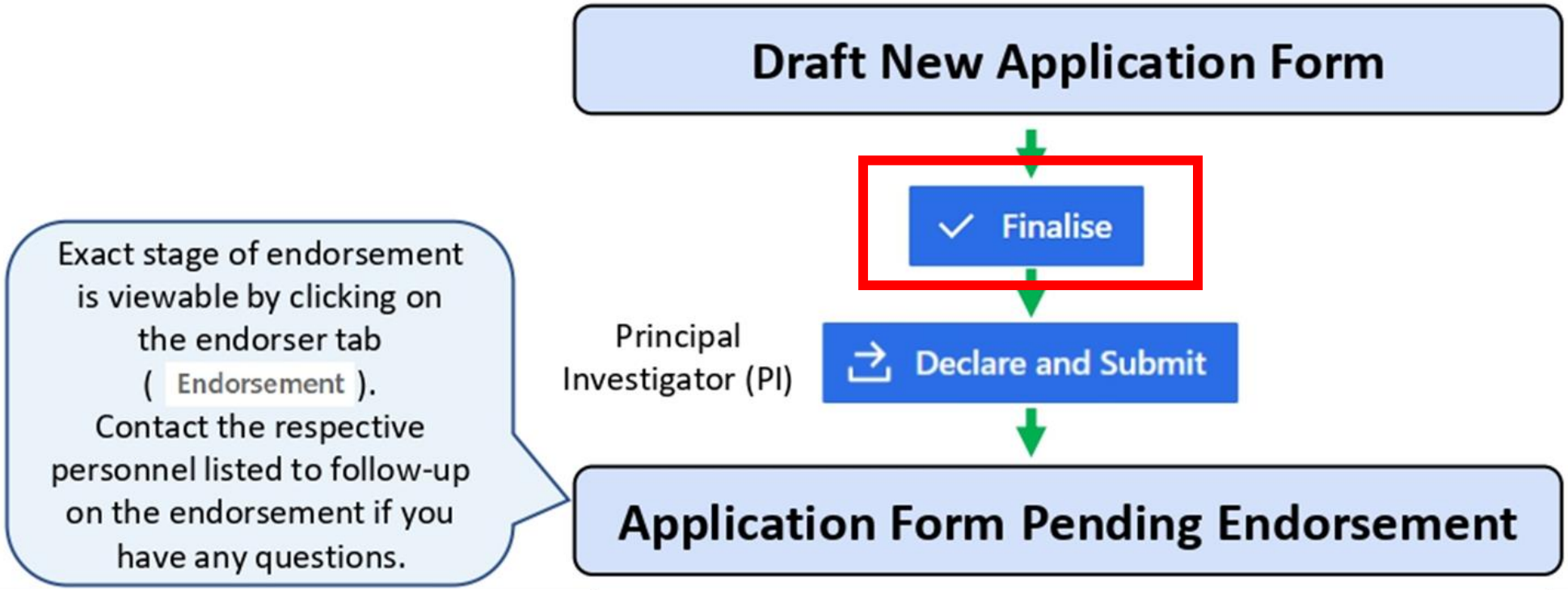
Exemption Category S5

- 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.

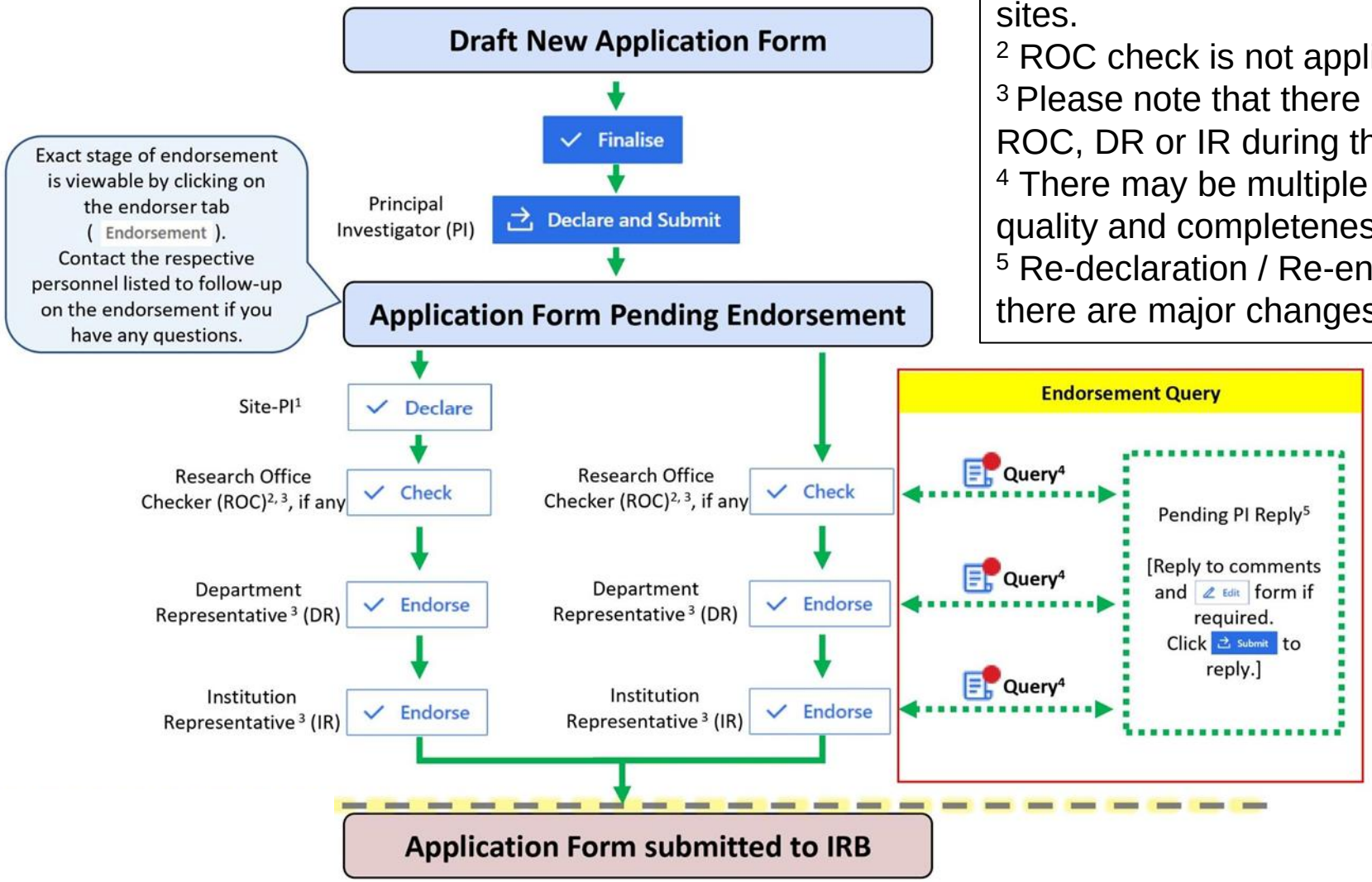
Example

- 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.

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.

Summary

- Prepare your application form in advance to facilitate submission.

- Ensure that you and your team had completed the minimum training requirement prior to the launch of ECOS.

Industry Sponsored Study Review Fees

From 1st Apr 2024, studies initiated by industry or commercial entities, the following review fee would be charged:

- Initial application involving Single Cluster institution(s) – S$3,000 **REVISED**
- Initial application involving Cross Cluster institution(s) – S$4,000 **REVISED**
- Subsequent amendments – S$200
- Subsequent site addition from Cross Cluster institutions – S$1,000
- Renewal for submission of study renewal/study reactivation report form – S$1,000

Thank you!