Mastering IRB Submissions:
Key Points to Note for Effective Response

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IRB Insights: What You Need to Know at a Glance

IRB Insights: What You Need to Know at a Glance

If you're unsure about your study's governance, visit the following websites to confirm that your research complies with the required standards.

- **Clinical Trial:** If the study is regulated by Health Products Act / Medicines Act. Please refer to https://www.hsa.gov.sg/clinical-trials for more information.
- **Human Biomedical Research:** If the study falls under the scope of Human Biomedical Research Act. Please refer to the MOH Decision Tree on Human Biomedical Research Framework for more information.
- **Restricted Human Biomedical Research:** If the study falls under the scope of restricted human biomedical research. Please refer to the MOH Decision Tree on Human Biomedical Research Framework for more information.

Reminder: If the research does not fall under any of the above regulations, please ensure that the research comply with the approving IRB and Institutional Guidelines / Standard Operating Procedures (SOPs) / Policy and Procedures (PnPs).

Click here to jump to related topic:
Section D: Study Classification

IRB Insights: What You Need to Know at a Glance

1. Do not select Department with “Do Not Use” Suffix by Study Investigators and Team Members.

- If such department is selected, the system cannot route the form for endorsement, causing delay in submission of IRB application or amendment form.

- PI should
  - Check if the user with the correct department is selected.
  - If unable to find the correct department, inform affected user to update his / her profile with the correct information.
  - Perform “ Mandatory Check ” / remove and re-add user back into Section B.

Study Site	Name	Study Role	Designation	Department	Institution	Profile and Minimum Training	Conflict of Interest
Singapore National Eye Centre		Co-I		Do Not Use - Glaucoma	Singapore Eye Research Institute	Detail	**No**

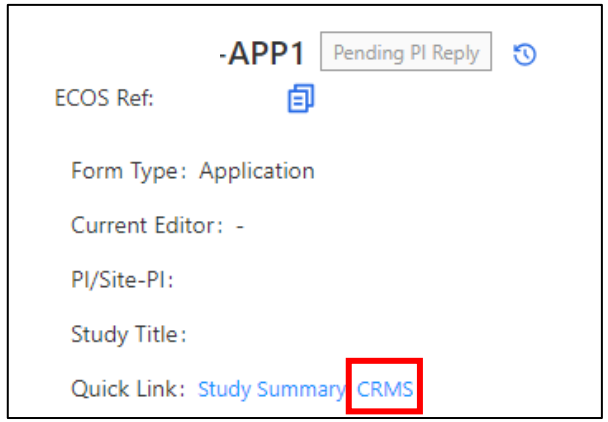
Study Site	Name	Study Role	Designation	Department	Institution	Profile and Minimum Training	Conflict of Interest
Singapore National Eye Centre		PI		Glaucoma	Singapore National Eye Centre	Complete	**No**

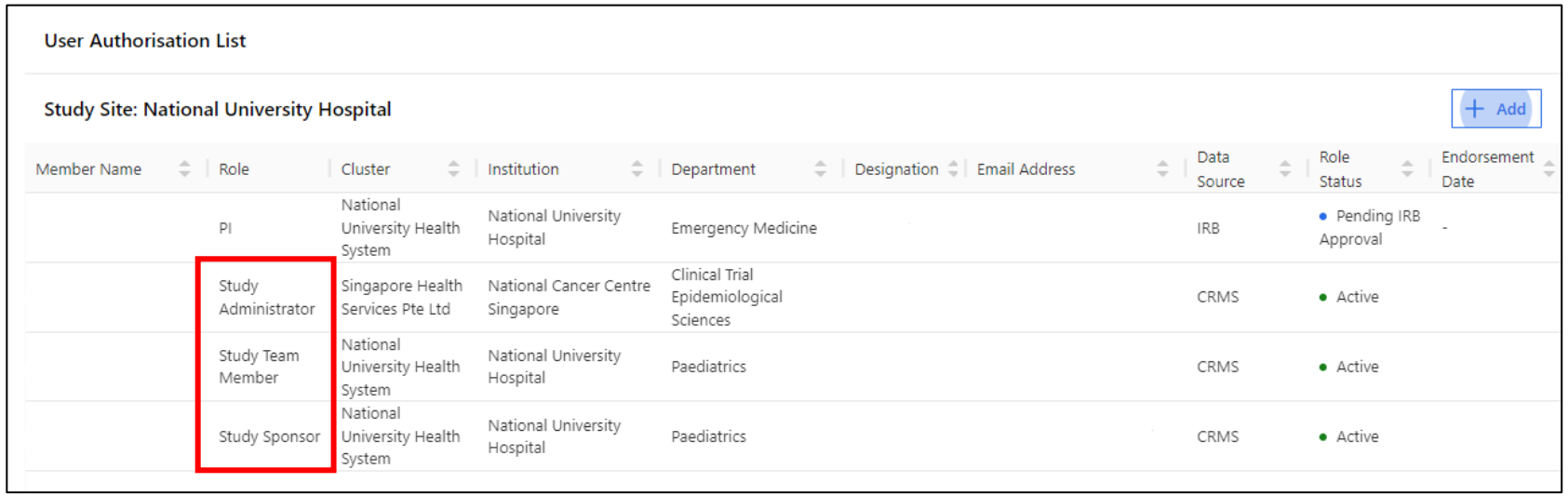
IRB Insights: What You Need to Know at a Glance

2. Add Study Team Members (e.g., Research Assistant, CRC) via Clinical Research Management System (CRMS)

For more information on CRMS:

- For SingHealth CIRB: https://www.singhealthdukenus.com.sg/research/rice/Pages/ECOS.aspx > Clinical Research Management System (CRMS)
- For NHG DSRB refer to https://ecossupport.gri.nhg.com.sg/userguides/ > Managing Your Research Activity





Reminder:

- PI is responsible for ensuring that Study Team Members complete their minimum training requirements prior to carrying out research related procedures / activities.
- Personnel listed in the CRMS or IRB do not replace the Study Delegation Log. Sites must maintain their own delegation / responsibility log detailing personnel roles in the Investigator Files.

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3. ECOS Profile - Submit Your Minimum Training Certificates for Verification

For more information on Minimum Training:

- For SingHealth CIRB: https://www.singhealthdukenus.com.sg/research/rice/Pages/ECOS.aspx > Minimum Training
- For NHG DSRB: https://ecossupport.gri.nhg.com.sg/userguides/ > Managing Your Research Activity

Document Review Status	What the status mean?	How to Resolve?
Draft	▪ The users have not submitted their certificates in their User Profile page yet. ▪ They could have only uploaded and saved the copies of certificates under their "Minimum Training Certificates" section.	▪ Once the certificates are ready for verification, please ensure they have been submitted.
Pending Verification	▪ The certificates are pending verification by the Institution's Minimum Training Secretariats (MTS).	▪ The users can follow-up with the institution's MTS accordingly.
Completed	▪ Users may check their "Minimum Training Certificates" section if the appropriate Training Labels have been given by the MTS.	▪ If no, please contact the Institution's MTS for assistance.
Contact your institutions' Minimum Training Secretariat for other minimum training requirements related issues.		

Reminder:

- For ECOS submissions to NHG: Please do not submit scanned copies of the FCOI declaration forms. Instead, complete the FCOI declarations using the FCOI Module in ECOS.
- For more information, refer to https://ecossupport.gri.nhg.com.sg/userguides/ > Submitting FCOI Declarations

IRB Insights: What You Need to Know at a Glance

3. ECOS Profile - Submit Your Minimum Training Certificates for Verification

Profile and Minimum Training	What the status mean?	How to Resolve?
Incomplete	▪ User may not have completed the required minimum training requirements (e.g., HBR / SBER labels). Note: All listed individuals in Section B2 must have the “completed” status prior to endorsements.	▪ Check on the minimum training status in the User Profile under 'Document Review Status', where it may show as “Draft”, “Pending Verification”, or “Completed”. ▪ PI / ECOS profile owner to click the “Mandatory Check” button, remove and re-add the ECOS profile as investigator again. Tip: Use the “ Mandatory Check ” function in the ECOS Application form to identify the areas requiring update / change prior to submission.
	▪ User added to the Application form could be an inactive account.	▪ If you click on the user profile (from Section B2) and the training certificate was not submitted, it could be that the migrated studies are using an obsolete account (not the current M365 / active account where the certificates were approved under). In this case, please remove the user with the obsolete account and re-select the user with the active account.

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4. Ensure that information is consistent across all sections of the Application Form and Study Document (e.g., informed consent form, protocol, etc.)

Examples of information inconsistencies between Sections:

- Recruitment of vulnerable population (D4) & inclusion criteria (G13)
- Proposed enrolment targets (E5 / G12) & recruitment restriction (J3)
- Inclusion criteria (G13) & enrolment of non-English speaking participants (J11)
- Sample size calculation (E4 / G11) & proposed enrolment targets (E5 / G12)

Examples of information inconsistencies between Sections & Study Documents:

- Study procedures (G7) & study protocol (G19)
- Study procedures (G7) & data collection form (G7)
- Study procedures (G7) & ICF (J13)
- Incidental findings (G10) & ICF (J13)
- Inclusion criteria / Exclusion criteria (G13 / G14) & recruitment materials (J2)

Reminder:

- Ensure consistency of information.
- Remember to check through different sections of the application form and ensure consistency with the study documents.

IRB Insights: What You Need to Know at a Glance

5. Please provide clear and specific responses.

- Respond according to prompt questions provided.

*G7. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research

Note:

(1) If the study involves research participant's visit, please describe the procedures involved.

(2) If this study involves medical records review, please state the source of data and specify the period of data that will be extracted for review.

Nil

3 characters entered

*G7. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research

Note:

(1) If the study involves research participant's visit, please describe the procedures involved.

(2) If this study involves medical records review, please state the source of data and specify the period of data that will be extracted for review.

Pariticpant will be asked to complete the survey on Visit 1.
Study Coordinators will arrange for the 2nd visit with participants. Trained Study team member will conduct 1 hour interview with participants after they given their informed consent.

245 characters entered

Reminder:

- Provide justifications / rationale according to the question.
- Click on the ⓘ for further elaboration.

ⓘ G7. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research.

1. For period of data, please state in the following format: DDMMMYYYY to DDMMMYYYY. For example: 01 Oct 2016 to 31 Oct 2017.
2. For research using unidentifiable data/samples (e.g. de-identified by program coordinator, or TTP), please describe the process. For instance, why, what, who, where, how the unidentifiable data/sample are obtained.

IRB Insights: What You Need to Know at a Glance

6. Please attach the correct documents in their respective sections

- Include relevant study related materials (e.g., data collection form).

Reminder:

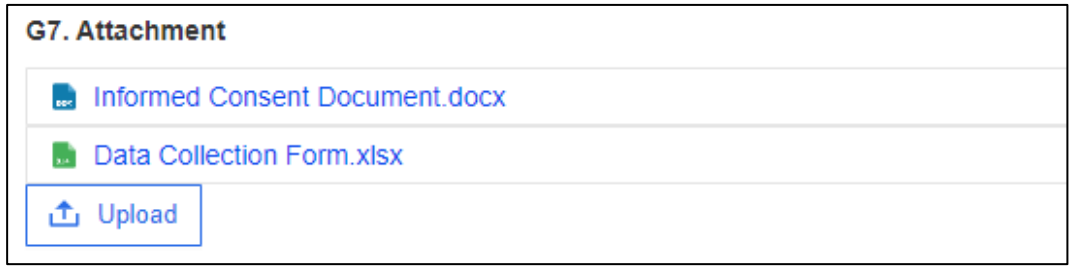
- Ensure there are supporting literature for the proposed study procedures (e.g., administration of Drug A in 2-hour interval has shown minimal side effects as compared to other time intervals).

Section	Document(s)
Section E3 Section G7	Data Collection Form, Questionnaire(s), Telephone Script(s), Interview Guide(s)
Section G5	Study Relevant Publications
Section J2	Recruitment Material(s)
Section J13	Informed Consent Form(s)
Section O2	Participant Information Sheet(s)

IRB Insights: What You Need to Know at a Glance

7. Please ensure proper version control of study documents.

- Include version control (version number and date) on all research related documents, especially for data collection & informed consent forms.
- Rationale:
  - Proper version control helps prevent confusion. It helps ensures that study team members are using the correct documents. It also facilitates collaboration among team members.
  - It also ensures proper documentation for audit purposes.



IRB Insights: What You Need to Know at a Glance

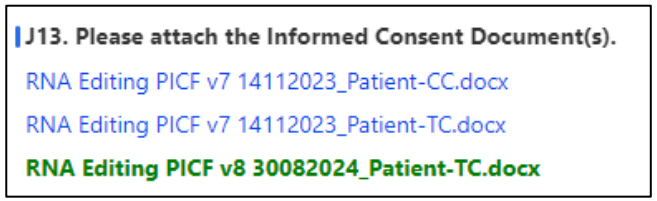
8. Please submit Clean copy of attachment(s) when the document is submitted for the 1st time / Clean and Track change copy of the attachment(s) when the document is being re-submitted.

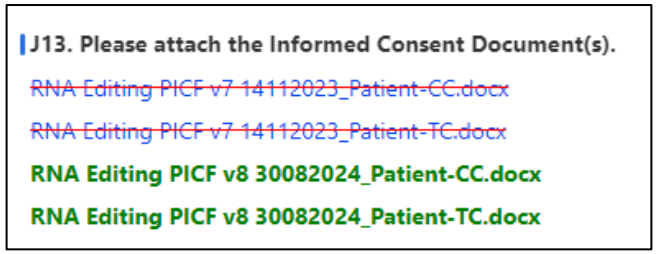
At Initial Submission

- Submit clean copies of the attachment(s).

For Re-submission (due to Query) / Amendment

- Submit both tracked changed and clean copies of the attachment(s).
- The track change copy should be tracked from the last submitted version or last approved version submission.
- Update version number and date on revised document(s).
- Remove superseded attachment(s) when updated versions are submitted.

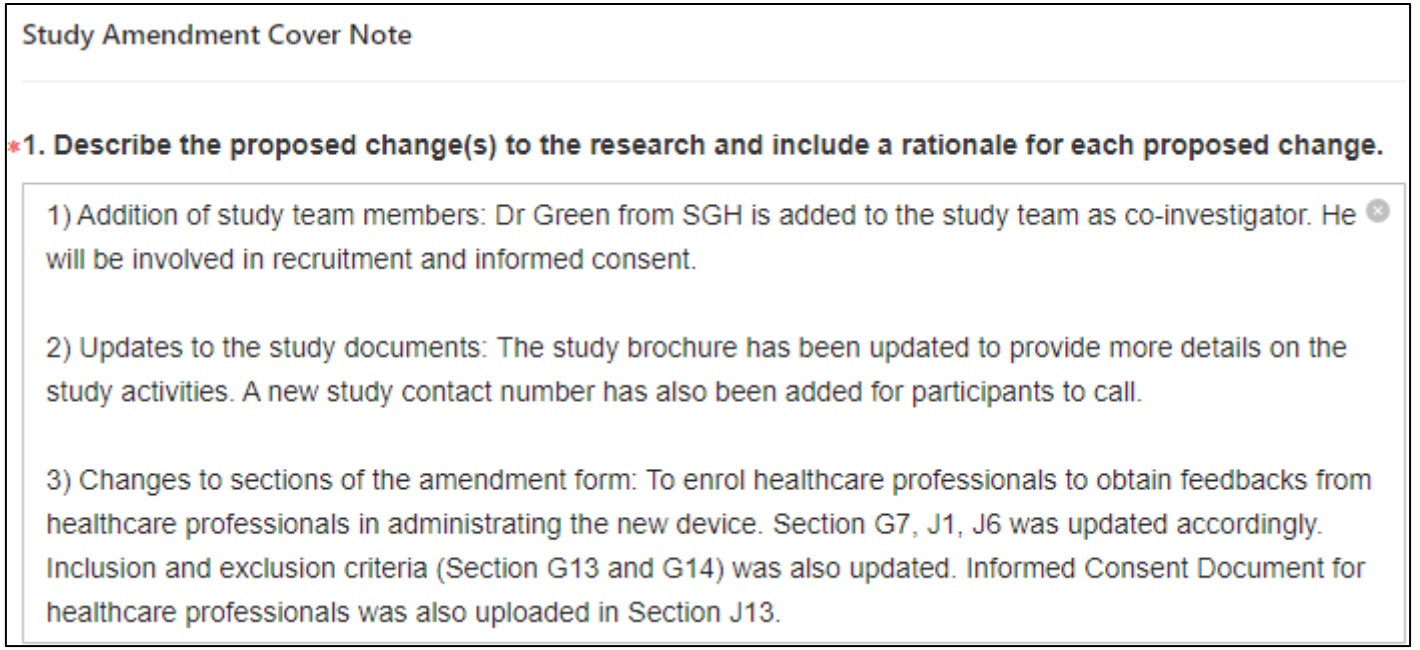




IRB Insights: What You Need to Know at a Glance

When submitting an **Amendment**, include an Amendment Cover note detailing the following:

- State and describe the proposed changes.
- Provide a rationale for each amendment change.



Study Amendment Cover Note

*1. Describe the proposed change(s) to the research and include a rationale for each proposed change.

1) Addition of study team members: Dr Green from SGH is added to the study team as co-investigator. He will be involved in recruitment and informed consent.

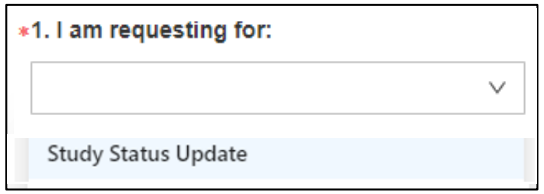
2) Updates to the study documents: The study brochure has been updated to provide more details on the study activities. A new study contact number has also been added for participants to call.

3) Changes to sections of the amendment form: To enrol healthcare professionals to obtain feedbacks from healthcare professionals in administrating the new device. Section G7, J1, J6 was updated accordingly. Inclusion and exclusion criteria (Section G13 and G14) was also updated. Informed Consent Document for healthcare professionals was also uploaded in Section J13.

IRB Insights: What You Need to Know at a Glance

An approved study site cannot be deleted / removed via amendment.

If the PI wishes to delete / remove the approved site (because the site has completed the research / decided to terminate the site), he / she will need to submit a **Study Status Report**.

	If the study will be expiring within 90 days:	**If the study expiry date is more than 90 days:**
What Should the PI do?	On the Study Status Report:  i. Select “Study Renewal" ii. Update the site status to “Terminated” for the site to be removed iii. Submit the annual Study Status Report	On the Study Status Report:  i. Select “Study Status Report” ii. Update the site status to “Terminated” for the site to be removed iii. Submit the Study Status Report

Before the new application is approved (e.g., during the draft stage), adding or removing a site is permitted.

Transform Your Responses with Clarity, One section at a Time

Section D. Study Type and Nature

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

When "Others" is selected:

- Please provide justifications for why the study is not regulated by Health Products Act / Medicines Act (HSA) nor Human Biomedical Research Act (MOH).
- Justifications should be based on study aims and methodology and why none of the criteria in Section D2. (b)(i), (ii) and (iii)] is met. E.g., *"The research is not intended to study the diagnosis, prognostication and alleviation of any disease and does not involve any identifiable information or biological samples. Thus, it is not under the purview of HBRA."*

IMPORTANT: PI should refer to the following sites to determine their study's classification based on the applicable regulations. Click here for more information.

Section D3. Does the study involve any of the following?

- Please select "Medical Records Review“ for studies involving the collection of health information.

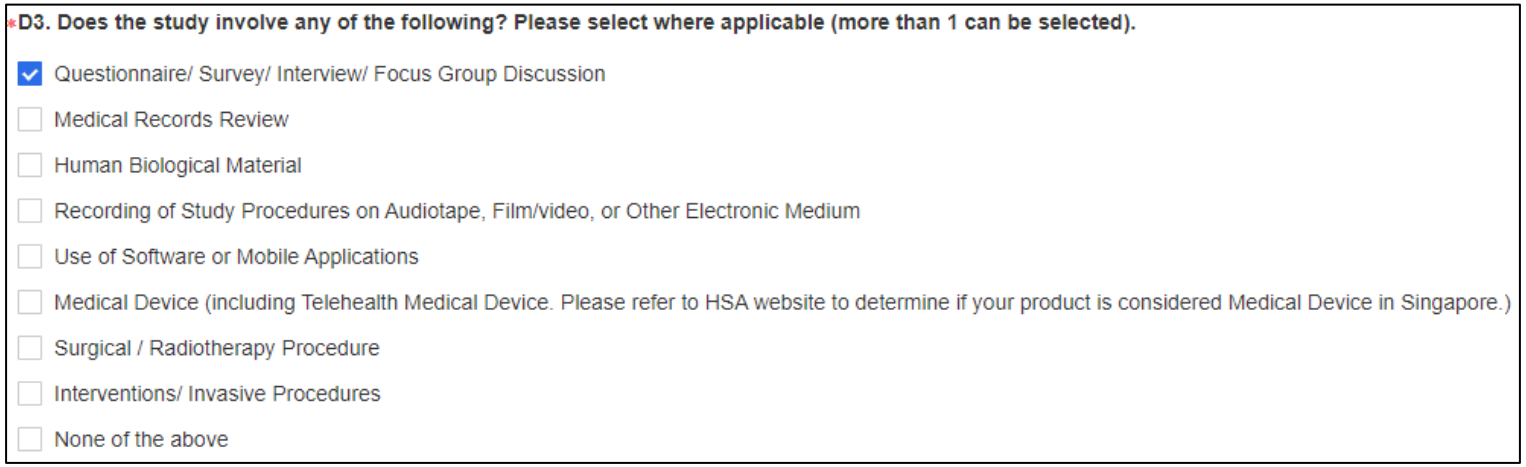
*D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).

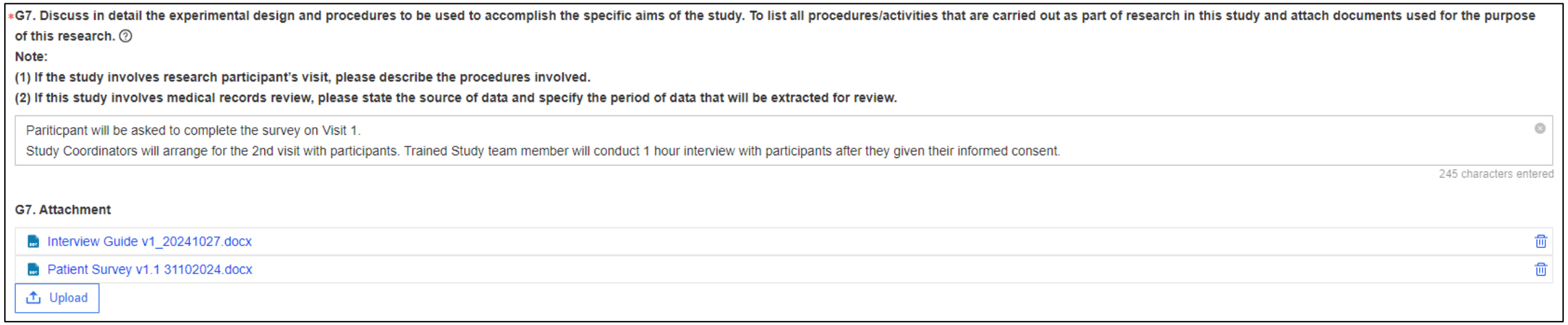
- [ ] Questionnaire/ Survey/ Interview/ Focus Group Discussion
- [x] Medical Records Review
- [ ] Human Biological Material
- [ ] Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium
- [ ] Use of Software or Mobile Applications
- [ ] Medical Device (including Telehealth 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

Click here to jump to related topic:
Section G: Research Methodology (Medical Records Review)

Section D3. Does the study involve any of the following?

- Please select “Questionnaire, Survey, Interview, or Focus Group Discussion” for studies involving questionnaire, survey, interview, or focus group discussion.
- Attach questionnaires / surveys / interviews / focus group discussion questions (where applicable) in Section E3 / G7.



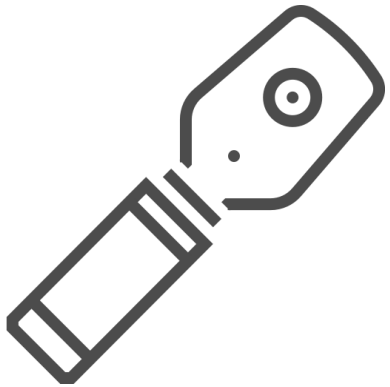


Section D3. Does the study involve any of the following?

- Please select "Medical Device" when the device is new / a prototype or being tested in the study.

*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
- [ ] Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium
- [ ] Use of Software or Mobile Applications
- [x] 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

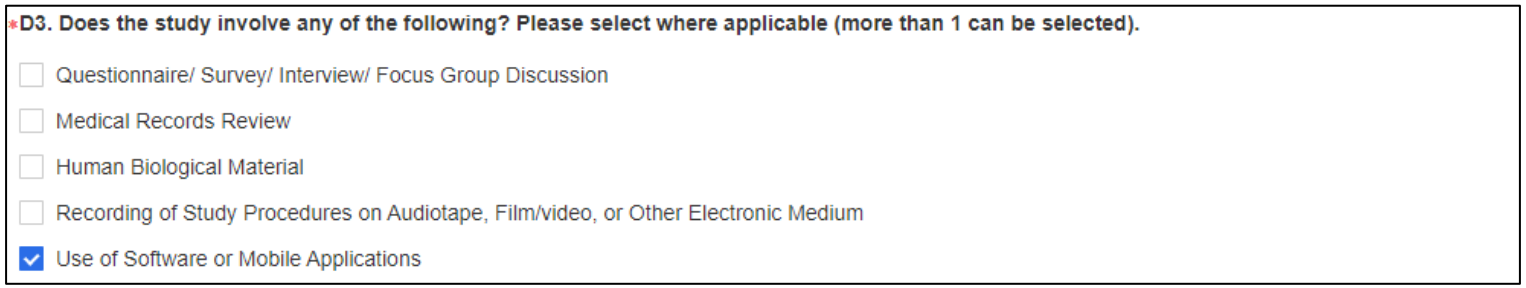


Reminder: Please refer to the HSA's Medical device tool to determine whether your device is considered a medical device in Singapore: https://www.hsa.gov.sg/medical-devices/registration/is-it-a-medical-device.

Click here to jump to related topic:
Section I: Research Details - Medical Device

Section D3. Does the study involve any of the following?

- Select “Use of Software or Mobile Application” if the study involves use of Software or Mobile Applications.



Reminders:

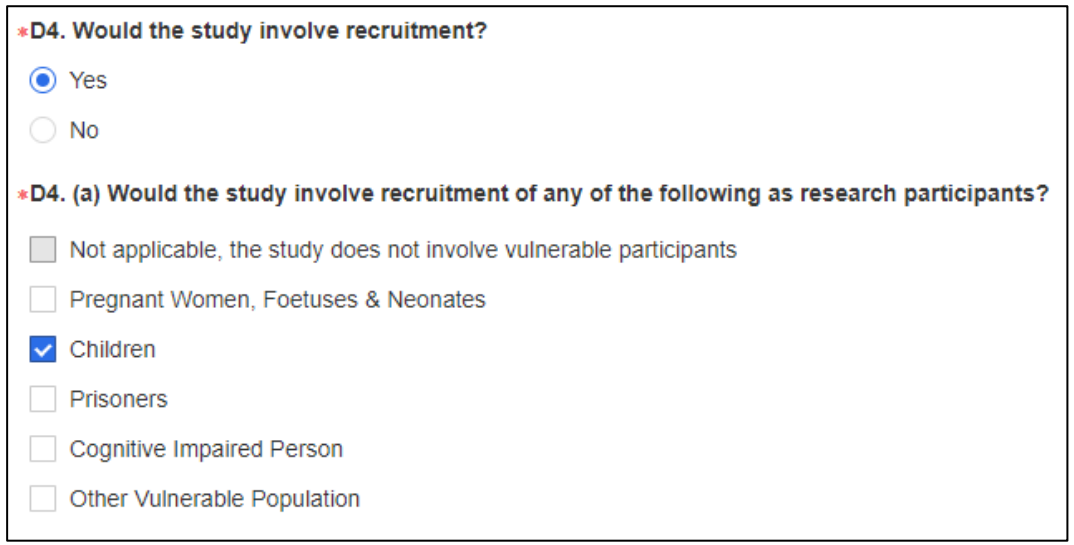
- For software or mobile applications which are classified as medical device and are regulated by HSA, please select “Use of Software or Mobile Applications” **and** “Medical Device” in Section D3 of the Application Form.
- Requirements of CIRB and DSRB for this section differs:

SingHealth CIRB	NHG DSRB
▪ This option should be selected if Software and / or Mobile Applications are involved in the study. ▪ This includes common software & mobile applications (e.g., REDCap, FormSG, ePRO, Qualtrics) and novel software & mobile applications.	▪ Only select this option if the study involves: a) novel software & mobile applications or b) common software & mobile applications used for new purposes in research. ▪ Do not select this option if a) common software & mobile applications are used for common purposes. For example, - Studies using Microsoft Teams to conduct interview - Studies using tablets to complete patient reported outcome (PRO) questionnaires electronically - Studies involving use of applications like YouTube to watch research-related videos

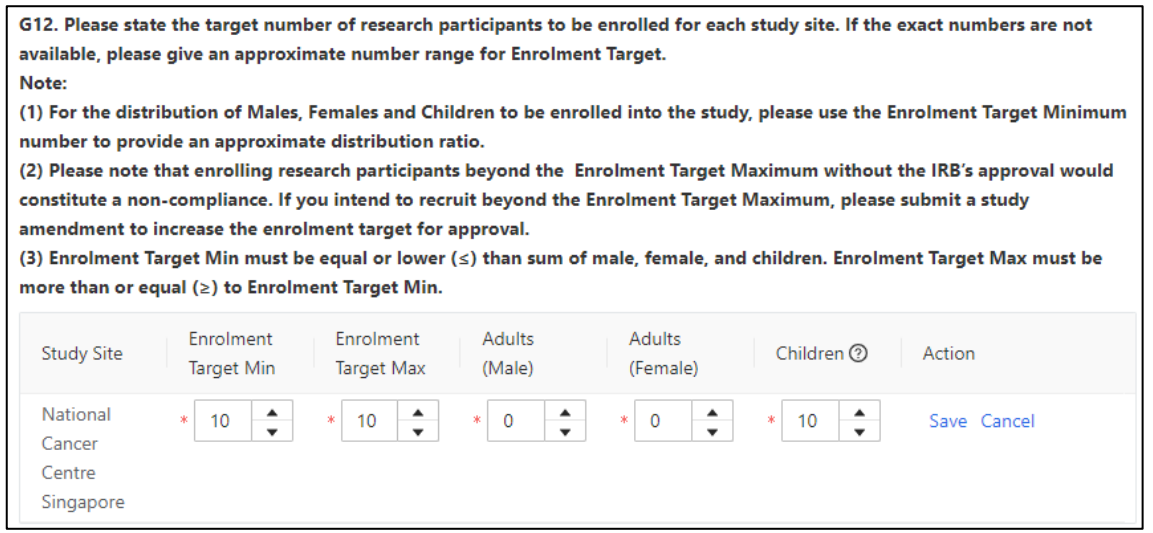
Click here to jump to related topic:
Section V: Use of software or mobile applications

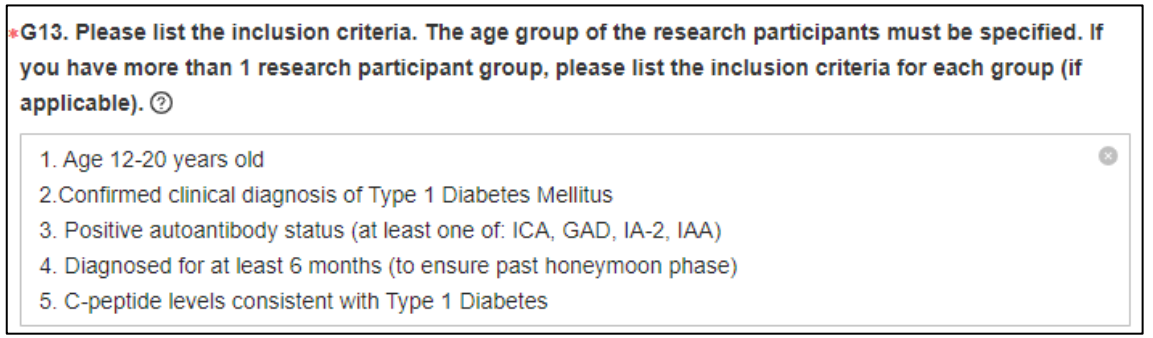
Section D4. (a) Would the study involve recruitment of any of the following as research participants?

- Children was not selected when the inclusion criteria specify recruitment of individuals aged 18 and older.
- Individual below 21 years old and not married are considered minors in Singapore. Please select “Children” in Section D4. (a) if you are recruiting minors.



IMPORTANT: Enrolment number should not exceed what was approved by the IRB. Submit an amendment via ECOS if you anticipate your enrolment number would exceed the IRB-approved enrolment target for section E5 & G12.

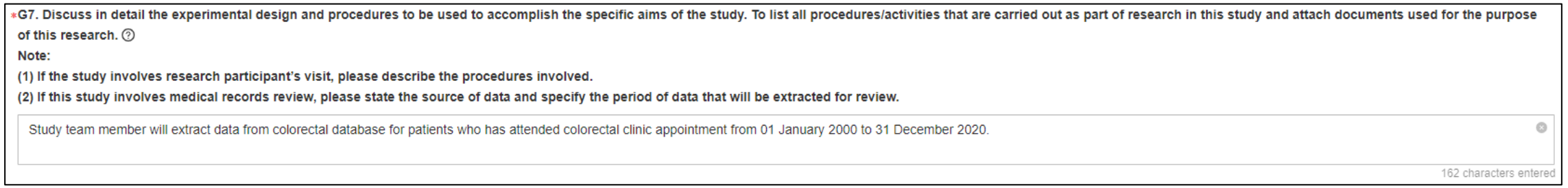




Section E. Research Methodology [For Exemption Application Form]
Section G. Research Methodology

Section E3. / G7. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures / activities that are carried out as part of research in this study and attach documents used for the purpose of this research.

- If study includes retrospective medical records review, kindly indicate:
  - The period for which medical records data that will be extracted for review (DDMMMYYYY to DDMMYYYY) AND
  - The personnel extracting the data.


*G7. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research.
Note:
(1) If the study involves research participant's visit, please describe the procedures involved.
(2) If this study involves medical records review, please state the source of data and specify the period of data that will be extracted for review.
Study team member will extract data from colorectal database for patients who has attended colorectal clinic appointment from 01 January 2000 to 31 December 2020.
162 characters entered

Reminder: Do not attach Data Collection Form / Questionnaires in Section G9. These Documents should be attached in Section G7.

IMPORTANT: Collection of prospective data requires informed consent to be taken from participants.
Please comply with your Research Institution's / Institution's policies on data usage for research.

Click here to jump to related topic:
Section D3: What is involved in the study (Medical Records)

Section G8. Please list all activities that are performed for routine diagnostic or standard medical treatment as part of the research participant's standard care.

- Do not include research activities which are done specifically for the research.
- Do not list the standard of care treatment for the potential participants.

*G8. Please list all activities that are performed for routine diagnostic or standard medical treatment as part of the research participant's standard care.

Standard treatment for triple negative breast cancer typically involves neoadjuvant chemotherapy (commonly using anthracyclines and taxanes), followed by surgery (lumpectomy or mastectomy), radiation therapy, and potentially immunotherapy (such as pembrolizumab) for high-risk patients or those with PD-L1-positive tumours.

- List down what will be done even if participant is not involved in the research.
- Describe the research activities which are also part of research participants standard of care.

*G8. Please list all activities that are performed for routine diagnostic or standard medical treatment as part of the research participant's standard care.

Initial Assessment/Screening
- Complete medical history
- Physical examination
- Mammogram and breast ultrasound
- Breast MRI
- Core needle biopsy with pathology review
- Immunohistochemistry testing (ER, PR, HER2)
- Chest X-ray/CT scan
- Bone scan
- Blood tests (CBC, liver function, kidney function)
- ECOG performance status
- Cardiac assessment (ECHO/MUGA scan)

Section G10. Please select the option(s) for re-identification in the case of incidental findings. More than 1 option can be selected if there are different plans for re-identification for different population of research participants.

- Commonly seen response: The selected option does not align with the information provided in the Informed Consent Document.
- Ensure the chosen option aligns with the details in the informed consent document.

*G10. Please select the option(s) for re-identification in the case of incidental findings. More than 1 option can be selected if there are different plans for re-identification for different population of research participants.

- [x] Yes, there are plans to re-identify and notify research participants.
- [ ] No, there is no plan to re-identify and notify research participants.
- [ ] There will not be any incidental findings arising from this study.

INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. "Incidental findings" are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

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Informed Consent Document: Version 1 dated 10 Jan 2025

*G10. Please select the option(s) for re-identification in the case of incidental findings. More than 1 option can be selected if there are different plans for re-identification for different population of research participants.

- [ ] Yes, there are plans to re-identify and notify research participants.
- [ ] No, there is no plan to re-identify and notify research participants.
- [x] There will not be any incidental findings arising from this study.

INCIDENTAL FINDINGS

There will not be any incidental findings arising in this research. "Incidental findings" are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

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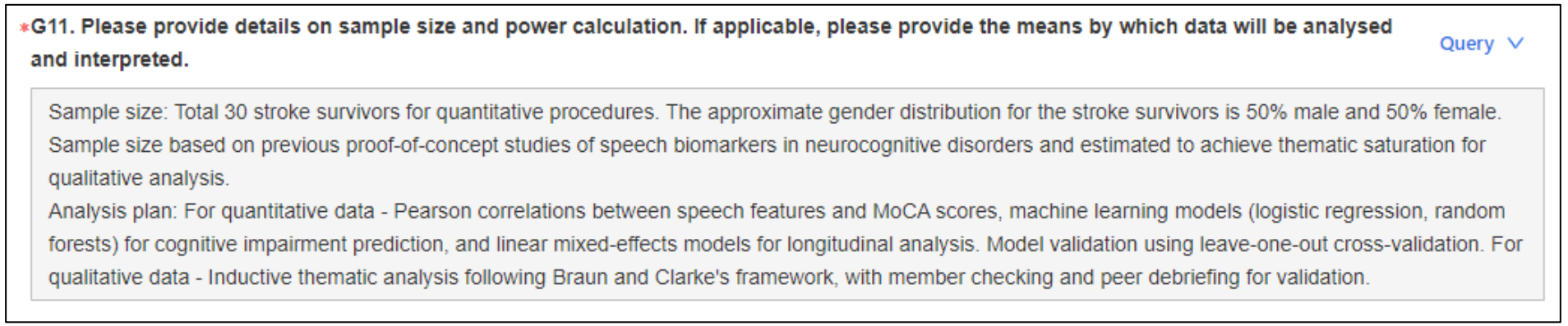
Informed Consent Document: Version 1 dated 10 Jan 2025

Reminder: Comply with your institutions' Incidental Findings Policy / SOP for managing incidental findings.

Section G11. Please provide details on sample size and power calculation. If applicable, please provide the means by which data will be analysed and interpreted.

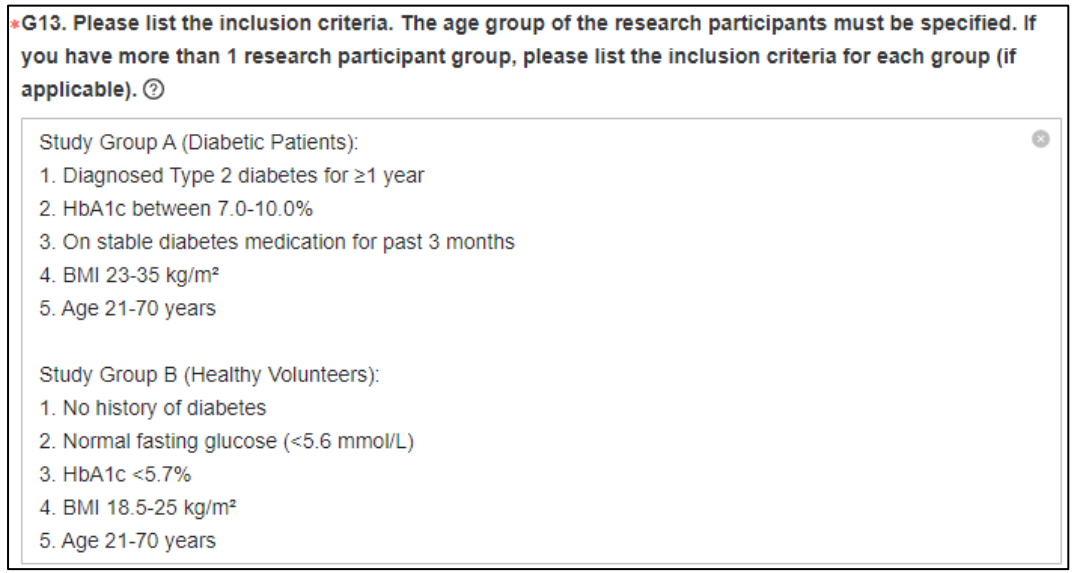
- Explain the sample size calculations clearly and ensure that they tally with the recruitment targets.
- If no sample size power calculation is performed (i.e. pilot studies), the PI may indicate the following:
  - Sample size is chosen based on a realistic estimation of the number of patients that that may be recruited over the study period.
  - Sample size is derived from previous similar studies.
  - Data analysis–state the software (e.g., SPSS, imaging software, etc.) and / or methods that will be used to analyse relevant data.



IMPORTANT: The IRB must understand the rationale behind the study team's decision to recruit proposed number of participants. Research can pose risks to participants, and from an ethical standpoint, it is essential to balance these risks (including the number of individuals exposed) with the knowledge gained from the research. For instance, inviting all HIV patients for interviews may not be practical, could increase the risk of confidentiality breaches, and may not yield better research outcomes.

Section G13. Please list the Inclusion criteria.
Section G14. Please list the exclusion criteria.

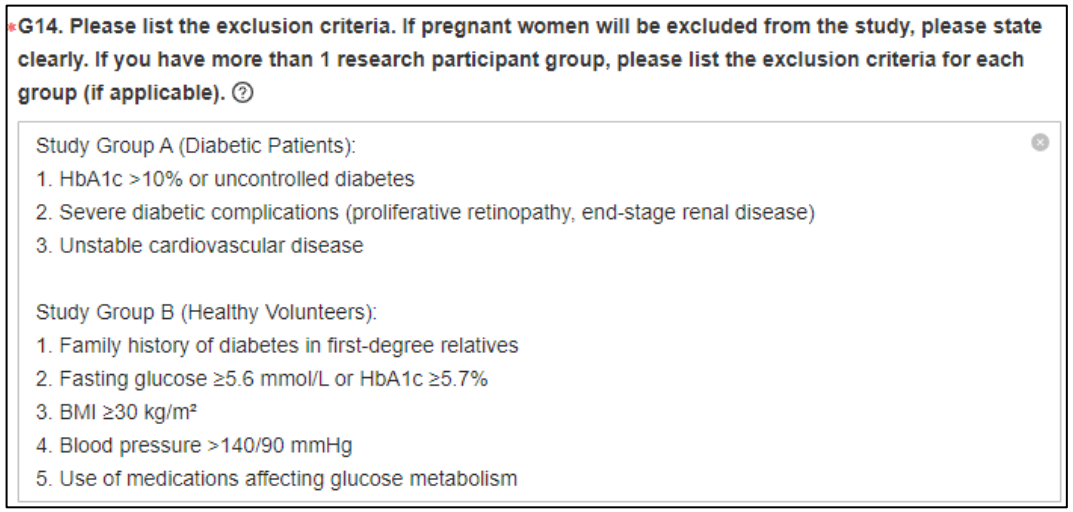
- Provide a separate list of inclusion and exclusion criteria for each study population if the study involves different participant groups (e.g., healthy volunteers, patients, caregivers, healthcare professionals, etc.).
- Ensure consistency with the protocol (if any).
- Define ‘healthy volunteers / controls’ if they will be involved in the study & State the inclusion and exclusion criteria of healthy volunteers / controls in Section G13 and G14.



*G13. Please list the inclusion criteria. The age group of the research participants must be specified. If you have more than 1 research participant group, please list the inclusion criteria for each group (if applicable).

Study Group A (Diabetic Patients):
1. Diagnosed Type 2 diabetes for ≥1 year
2. HbA1c between 7.0-10.0%
3. On stable diabetes medication for past 3 months
4. BMI 23-35 kg/m²
5. Age 21-70 years

Study Group B (Healthy Volunteers):
1. No history of diabetes
2. Normal fasting glucose (<5.6 mmol/L)
3. HbA1c <5.7%
4. BMI 18.5-25 kg/m²
5. Age 21-70 years



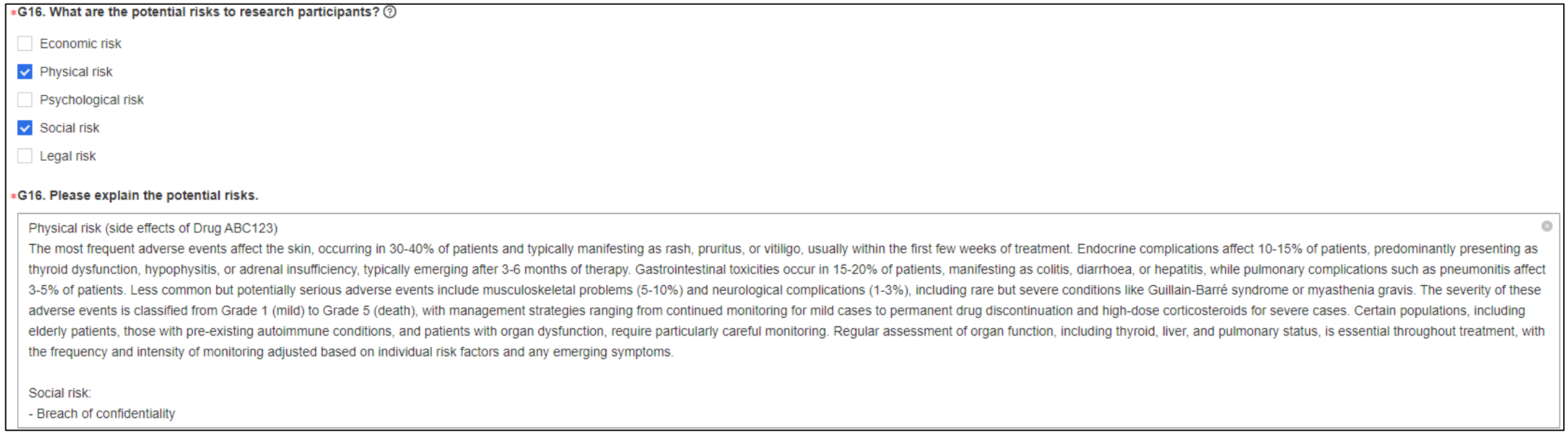
*G14. Please list the exclusion criteria. If pregnant women will be excluded from the study, please state clearly. If you have more than 1 research participant group, please list the exclusion criteria for each group (if applicable).

Study Group A (Diabetic Patients):
1. HbA1c >10% or uncontrolled diabetes
2. Severe diabetic complications (proliferative retinopathy, end-stage renal disease)
3. Unstable cardiovascular disease

Study Group B (Healthy Volunteers):
1. Family history of diabetes in first-degree relatives
2. Fasting glucose ≥5.6 mmol/L or HbA1c ≥5.7%
3. BMI ≥30 kg/m²
4. Blood pressure >140/90 mmHg
5. Use of medications affecting glucose metabolism

Section E7. / G16. What are the potential risks to research participants?

- For studies with more than 1 category of risk selected
  - Select the appropriate risk AND
  - elaborate in the free text for the categories selected.



*G16. What are the potential risks to research participants?

- [ ] Economic risk
- [x] Physical risk
- [ ] Psychological risk
- [x] Social risk
- [ ] Legal risk

*G16. Please explain the potential risks.

Physical risk (side effects of Drug ABC123)
The most frequent adverse events affect the skin, occurring in 30-40% of patients and typically manifesting as rash, pruritus, or vitiligo, usually within the first few weeks of treatment. Endocrine complications affect 10-15% of patients, predominantly presenting as thyroid dysfunction, hypophysitis, or adrenal insufficiency, typically emerging after 3-6 months of therapy. Gastrointestinal toxicities occur in 15-20% of patients, manifesting as colitis, diarrhoea, or hepatitis, while pulmonary complications such as pneumonitis affect 3-5% of patients. Less common but potentially serious adverse events include musculoskeletal problems (5-10%) and neurological complications (1-3%), including rare but severe conditions like Guillain-Barré syndrome or myasthenia gravis. The severity of these adverse events is classified from Grade 1 (mild) to Grade 5 (death), with management strategies ranging from continued monitoring for mild cases to permanent drug discontinuation and high-dose corticosteroids for severe cases. Certain populations, including elderly patients, those with pre-existing autoimmune conditions, and patients with organ dysfunction, require particularly careful monitoring. Regular assessment of organ function, including thyroid, liver, and pulmonary status, is essential throughout treatment, with the frequency and intensity of monitoring adjusted based on individual risk factors and any emerging symptoms.

Social risk:
- Breach of confidentiality

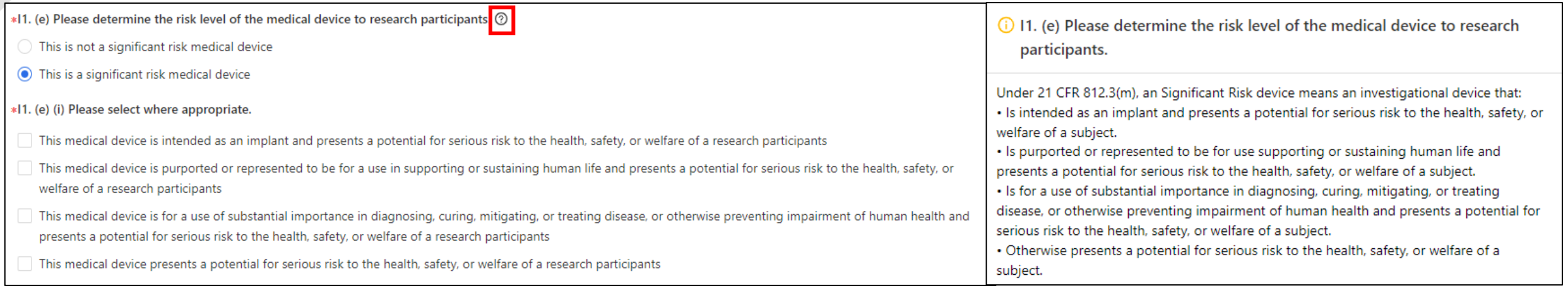
Reminder:

- Information in this section must be consistent with the research procedures outlined in the Application Form and relevant study documents (if applicable).
- Only research related risks should be described.

Section I. Research Details- Use of Medical Device

Section I1. (e) Determine the risk level of the medical device to research participants.

- To access the risk level of the medical device, click on the ⓘ for further elaboration.



*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. (e) (i) Please select where appropriate.

- ☐ This medical device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a research participants
- ☐ This medical device is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a research participants
- ☐ This medical device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a research participants
- ☐ This medical device presents a potential for serious risk to the health, safety, or welfare of a research participants

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

Under 21 CFR 812.3(m), an Significant Risk device means an investigational device that:
• Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
• Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.
• Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.
• Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Reminder: You may refer to FDA guidance document for more information: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf.

Click here to jump to related topic:
Section D3: What is involved in the study (Medical Device)

Section I1. (f) Please provide information on the medical device / prototype.

- Provide response to the guiding questions.
- If any of the responses to the above guiding questions is 'not applicable', please indicate and justify accordingly.
- If the medical device / prototype is still in development and information is not yet available (e.g., this is the initial phase of the study), please indicate and specify that the information will be submitted for IRB review when it becomes available.

*I1. (f) Please provide information on the medical device/prototype.

For example:

- **How the device achieves its goal?**
- **Safety/ effectiveness data to date in human trials, if available.**
- **Safety/ effectiveness data to date in preclinical data, if applicable.**
- **Instruction on the proper use of the device.**
- **Summary of device's adverse effects and potential risks (including adverse effects due to misuse of the device).**
- **How device operator will be trained in proper administration/ use of device?**

Note: For investigational medical device that requires electrical connection (e.g. plug-in to wall outlet) within SingHealth Institutions, the device should be commissioned by Biomedical Engineering (BME). Please indicate if the device had been commissioned or the study team will be doing so.

0 characters entered

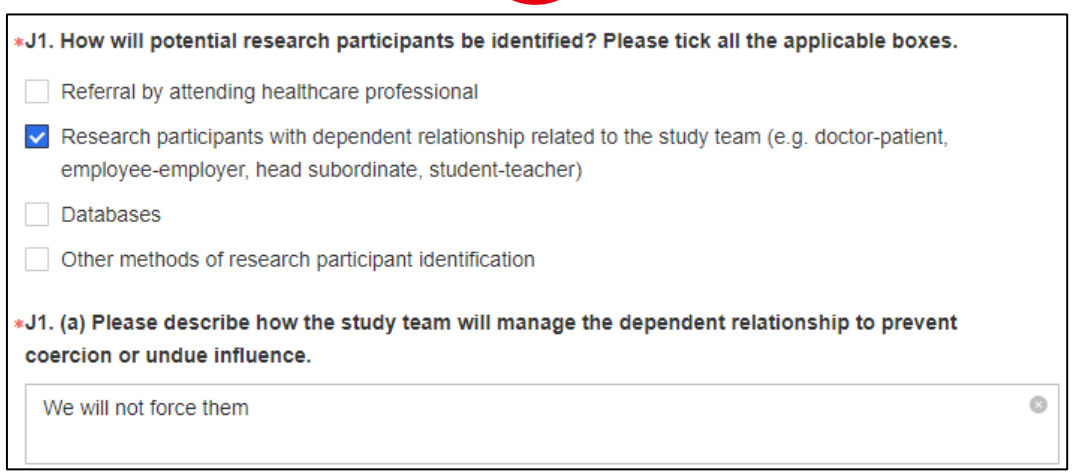
Click here to jump to related topic:
Section D3: What is involved in the study (Medical Device)

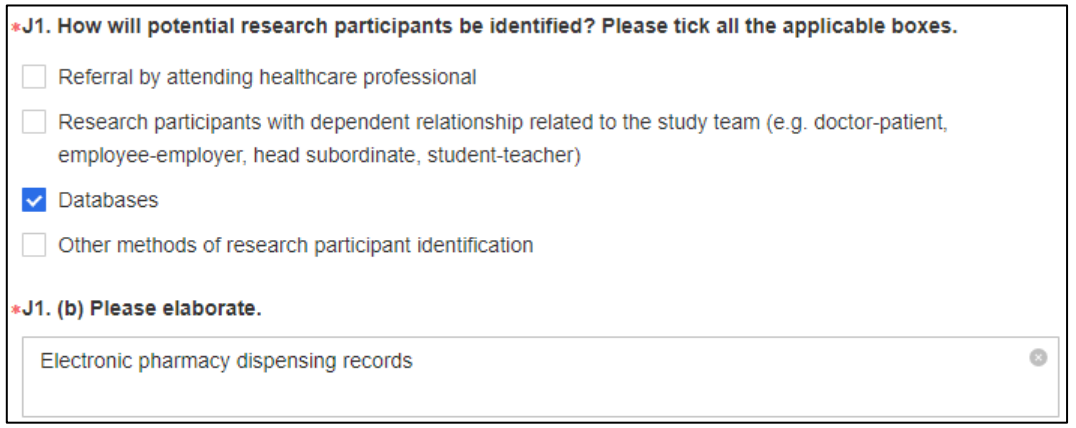
Section J. Recruitment Details and Process

Section J1. How will potential research participants be identified?

- Please select the appropriate options on how potential research participants will be identified and provide elaboration for its selection.

E.g., *"The retrospective cohort study aims to evaluate medication adherence patterns among patients with chronic conditions using pharmacy dispensing records. Approval will be sought from data custodian for the conduct of identifying potential research participants using pharmacy dispensing records."*





⚠ National Electronic Health Record (NEHR) must not be used for research!

Section J1. (a) Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence.

- Elaborate the nature of the dependent relationship.
- Describe:
  - How study team members will manage this dependent relationship to avoid coercion or undue influence.
  - Measures to prevent undue influence.

*J1. How will potential research participants be identified? Please tick all the applicable boxes.

- [ ] Referral by attending healthcare professional
- [x] Research participants with dependent relationship related to the study team (e.g. doctor-patient, employee-employer, head subordinate, student-teacher)
- [ ] Databases
- [ ] Other methods of research participant identification

*J1. (a) Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence.

We will not force them

*J1. How will potential research participants be identified? Please tick all the applicable boxes.

- [ ] Referral by attending healthcare professional
- [x] Research participants with dependent relationship related to the study team (e.g. doctor-patient, employee-employer, head subordinate, student-teacher)
- [ ] Databases
- [ ] Other methods of research participant identification

*J1. (a) Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence.

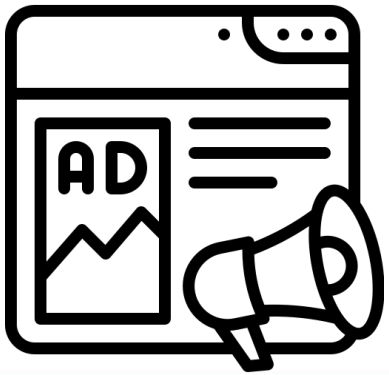
Doctor patient relationship
The informed consent process must be conducted by a study team member who is not the patient's primary physician, allowing subjects adequate time to consider participation and ask questions, while ensuring that patients who decline participation or withdraw from the study continue to receive full standard medical care without prejudice.

Section J2. Please describe the advertising strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster / brochure / advertisement in newspaper / radio, etc.) to be used to recruit research participants.

- Please describe the advertising strategy in Section J2.

*J2. Please describe the recruitment strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster/brochure/advertisement in newspaper/radio, etc.) to be used to recruit research participants. Note: PI should also obtain clearance from institution and Communication department on the publication location and/or platform, if applicable.

Research participants will be recruited from the wards. Participants who fulfil the inclusion criteria will be approached by the study team members.



*J2. Please describe the recruitment strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster/brochure/advertisement in newspaper/radio, etc.) to be used to recruit research participants. Note: PI should also obtain clearance from institution and Communication department on the publication location and/or platform, if applicable.

Posters for clinical trial recruitment should be placed in approved hospital areas like clinic waiting rooms, patient education corners, and notice boards.

Or

*J2. Please describe the recruitment strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster/brochure/advertisement in newspaper/radio, etc.) to be used to recruit research participants. Note: PI should also obtain clearance from institution and Communication department on the publication location and/or platform, if applicable.

NA - no advertising strategies will be used.

Section J2. Please describe the advertising strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster / brochure / advertisement in newspaper / radio, etc.) to be used to recruit research participants.

- Include explanation of how advertising materials would be utilized.

Advertising Materials	Description for use
 Poster and brochures	Where the posters will be placed and how brochures will be placed / used.
 Advertisements in Newspapers / Magazines / Publications	Which publications will be carrying the advertisements and how many times the advertisement will run for.
 Advertisements on Radio / TV	Radio / TV stations will be carrying the advertisements and how many times the advertisement will be aired.
 Letter of Invitation to potential research participants	How the letter of invitation would be used. Note: Submit a study invitation letter for IRB's review if the research team wishes to recruit patients who visited the clinic in the past but are no longer undergoing follow-up at the clinic / hospital.

Reminder:

- Mode & content of the recruitment advertisement must be approved by the IRB and / or institution's corporate communication (where applicable) before use.
- Recruitment advertisement content should not contain any sensitive information of the study.
- Please comply with institution's recruitment guidelines.

Section J2. Please describe the advertising strategies (e.g., talks in public place, societies etc.) and if any, attach the recruitment materials (e.g., poster / brochure / advertisement in newspaper / radio, etc.) to be used to recruit research participants.

- Include explanation of how advertising materials would be utilized.

Advertising Materials		Description for use
	Email Message	How the email message would be sent, the targeted recipient and along with caption that will be used in the email (if any).
	Institutions' websites and Studies' websites	How the materials would be used.
	Social media platforms	What is the social media platforms to be used, along with caption that will be used in the social media post. Note: for the publication channels of the recruitment materials, it should be approved by Institution and Communications Department, where applicable.
	Event (e.g., Public Forum, Webinars)	Provide details of event (e.g., Where & when it will be held, what is the agenda, etc.)

Reminder:

- Mode & content of the recruitment advertisement must be approved by the IRB and / or institution's corporate communication (where applicable) before use.
- Recruitment advertisement content should not contain any sensitive information of the study.
- Please comply with institution's recruitment guidelines.

Section J4. Who will make the first contact with research participants and how will the research participants be contacted?

- Explain who will initiate contact with research participants and the method of communication used to reach them.
- The response should also describe how will the research participant be contacted. This refers to the mode of contact with the research participant (e.g., face to face, invitation letter, etc.).

***J4. Who will make the first contact with research participants and how will the research participants be contacted?**

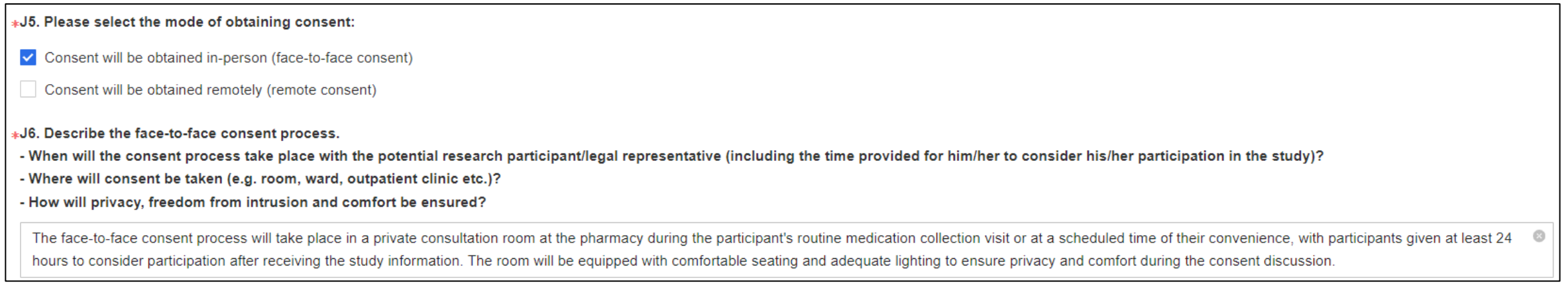
Stroke care providers (e.g. neurologist, rehab physicians, nurses) introduce study. If interested contact information will be passed to study team.

The study team will only approach potential participants if they have expressed interest in participating after viewing the recruitment materials. No cold calling or unsolicited contact will be made. Interested participants will reach out to the study coordinator who will then arrange an in-person meeting to discuss the study further.

Reminder: Attending physicians / clinical care providers should make the first contact with eligible research participants. Only research participants who express interest could then be referred to the study team.

Section J6. Describe the face-to-face consent process.

- Describe the face-to-face consent process adequately.
- Responses should include:
  - Ensure a suitable venue for consent taking (e.g., a quite empty consultation room) to respect participant's privacy.
  - Ensure adequate time provided to consider participation.
  - Participants should be in right frame of mind to give consent.
  - Consent process will occur prior to the initiation of any research related activities.
  - The PI is responsible for ensuring that all research participants give informed consent before enrolling into the study.
  - Research participants will be approached in a quiet and conducive environment to allow the participant to be in the right frame of mind to consider participation.
  - The PI will ensure to protect the privacy of the research participant when approaching them to participate in the research.



*J5. Please select the mode of obtaining consent:

☑ Consent will be obtained in-person (face-to-face consent)

☐ Consent will be obtained remotely (remote consent)

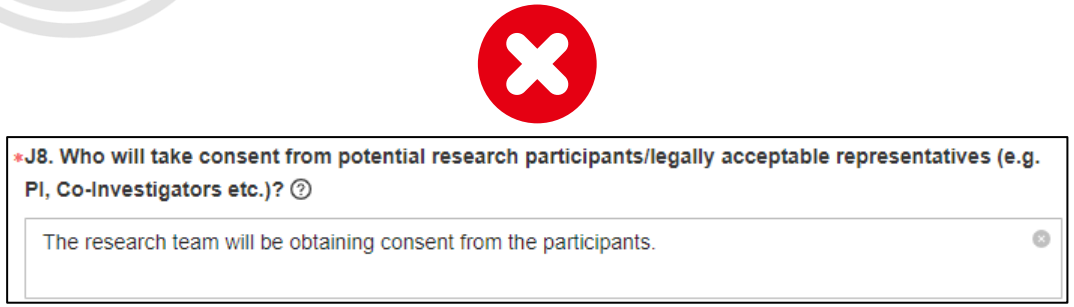
*J6. Describe the face-to-face consent process.

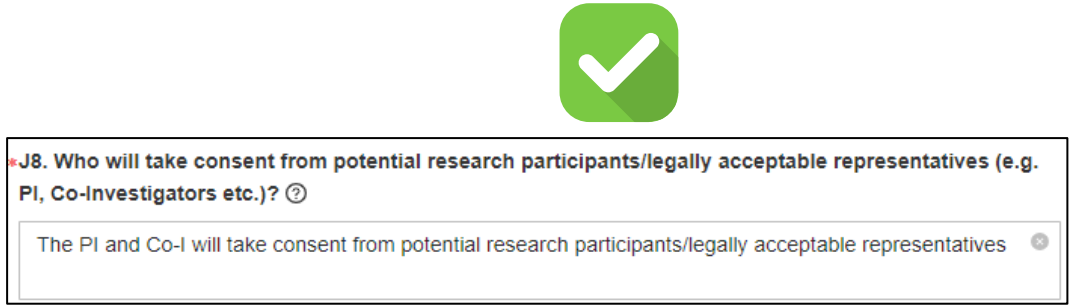
- When will the consent process take place with the potential research participant/legal representative (including the time provided for him/her to consider his/her participation in the study)?
- Where will consent be taken (e.g. room, ward, outpatient clinic etc.)?
- How will privacy, freedom from intrusion and comfort be ensured?

The face-to-face consent process will take place in a private consultation room at the pharmacy during the participant's routine medication collection visit or at a scheduled time of their convenience, with participants given at least 24 hours to consider participation after receiving the study information. The room will be equipped with comfortable seating and adequate lighting to ensure privacy and comfort during the consent discussion.

Section J8. Who will take consent from potential research participants / legally acceptable representatives (e.g., PI, Co-I, etc).

- List the roles of the study team members who will be taking consent, e.g., PI, co-investigator, research coordinator, etc.





Note:

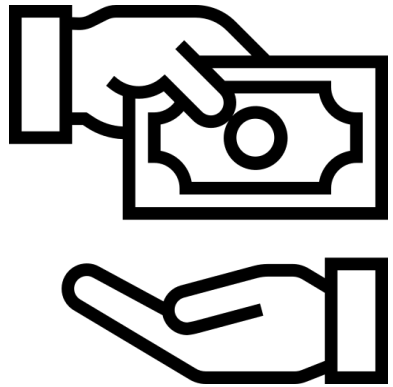
- IRB requires that informed consent must be obtained from all human participants prior to their participation in any research unless the process, or any part thereof, has been waived by the IRB.
- Informed consent should be conducted by the PI, or a qualified member of the study staff who is listed in the Section J8 as the designated person(s) / study role (s) for conducting the informed consent discussion. Any change to the designated person / study role for obtaining consent should be submitted to the IRB for review and approval.
- The PI must ensure that the delegated person is appropriately trained to explain the benefits and risks of the study adequately and conduct the consent process appropriately without compromising on the quality of the consent.

Reminder:

- The study delegation / responsibility log should also indicate all study staff delegated by the PI to take informed consent.
- For clinical trials that are regulated by HSA, only the PI or an investigator authorized by the PI, who is a qualified practitioner, is allowed to obtain informed consent from the participants. Where the clinical trial is led by a pharmacist PI, co-investigators who are qualified pharmacists may also be authorized by the PI to obtain consent. Individuals who are not qualified practitioners or qualified pharmacists are not allowed to obtain consent but may assist in the consent process for such studies.

Section J10. Will research participants receive any monetary payments (e.g., transportation allowances) or gifts for their participation in the study?

- Please clearly describe:
  - Mode(s) of payment (e.g., cash, vouchers, Bank transfers) or gifts.
  - At which study visit(s) participants will be paid, and the amount paid each time.



*J10. Will research participants receive any monetary payments (e.g. transportation allowances) or gifts for their participation in the study?

(•) Yes

( ) No

*J10. (a) Please elaborate.

Research participants will be reimbursed $80 per study visit for transport expenses

Reminder:

- Check with your institution's policy on the mode of reimbursement to research participants.

Table 14: Guidelines for research subject payments

Study Visit Required by Subject	Payment Serves As	Amount Paid to Participant
Outpatient	Reimbursement for transport costs	$20 – $100 per visit
Inpatient	Compensation for inconvenience of hospitalisation and incentive for participation	$200 – $500 per day

The payment amount takes into consideration the current local standard of living (i.e. year 2021) and may be revised when necessary.

Adapted from: NHG Investigator Manual, Chapter 4: Submissions to DSRB.

Section J11. Will the study enroll non-English speaking research participants?

- Remember to check through different sections of the application form and ensure that information to enrol non-English speaking participants is consistent.

Note:

- To ensure equitable selection of research participants, ALL potential participants who meet the inclusion / exclusion criteria should be recruited. Proper justification should be given to restrict recruitment to only English-speaking participants.
- Non-English-speaking participants can be recruited using translated consent documents / short form consent forms (applicable for NHG DSRB) / verbally translated using Informed Consent Form (English) in the presence of impartial witness.

Reminder:

- Translated Informed Consent Forms (including Short Consent Forms - applicable for NHG DSRB) & Translated Study Documents (e.g., Subject Diary) are no longer required to be submitted to the IRBs.

Section T. Research Data Confidentiality

Section T3. Describe who will have access to the research data, and how the access will be controlled and monitored?

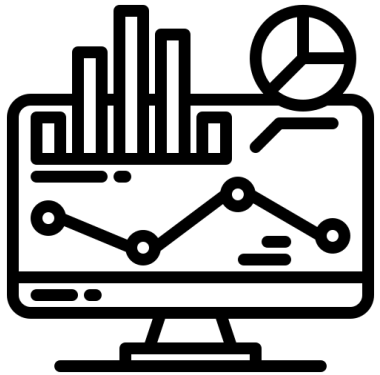
- State clearly who will be granted access to the research data and how the access will be controlled and monitored.

***T3. Describe who will have access to the research data, and how the access will be controlled and monitored?**

Only authorized study team members will have access to the research data, including the Principal Investigator, Co-Investigators, and designated research coordinators. Access will be controlled through password-protected electronic systems with unique user IDs, and all data access will be logged and monitored through audit trails. Physical documents will be stored in locked cabinets within secured rooms accessible only to authorized personnel using electronic key cards.

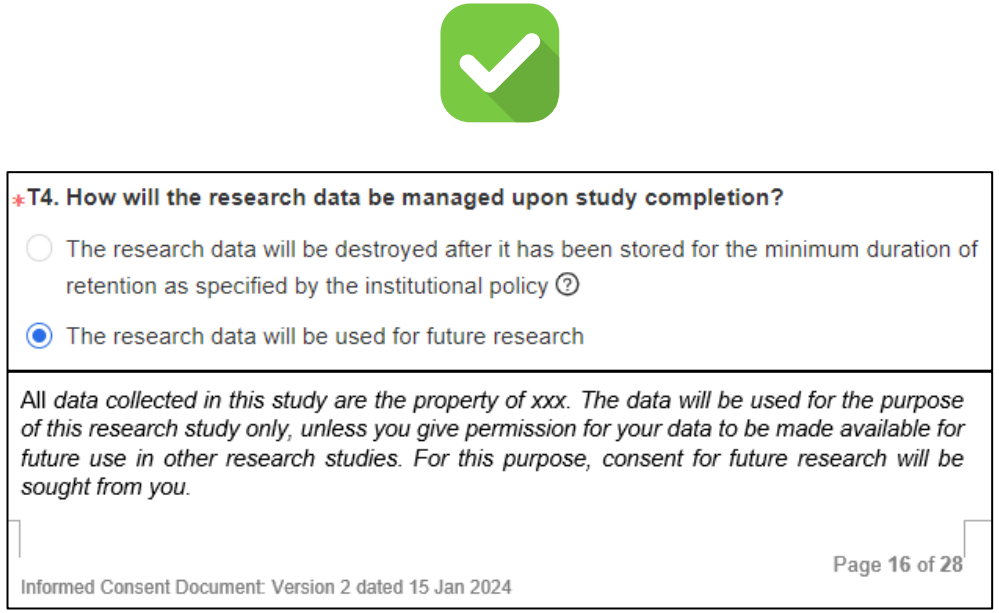
Reminder:

- Some Co-I and collaborators might not be from the same institution as the PI. Therefore, do adhere to your Research institutions' policies and Data Sharing Agreements prior to releasing any data.



Section T4. How will the research data be managed upon study completion?
Section T4.(a) Would the research data be stored in an identifiable format?

- Please ensure that the information in the application form aligns with the information in the informed consent document.



Note: The informed consent document should be updated accordingly based on your own institution / cluster.

Reminder:

- Researchers should refer to their Research Institution's / Institution's policy on research data storage.
- For clinical trials, the ICH GCP E6 (R2) section 4.9.5 stipulates a minimum retention period for clinical trial essential documents.

Section T4. (b) Please state where the research data would be stored.

- Please state the location where the research data will be stored upon completion of the study. E.g., *"Research data will be kept in password-protected file / under lock and key etc. in the XXX department."*

For NHG & NUHS only:

- Standing databases created primarily for the purposes of possible future research should be registered. Databases that are created as part of a previous IRB approved research study that has since been completed, may be stored for possible future research. Such databases should be registered upon completion of the research study. This should be clearly explained in the application form. The ICF should also include a statement to seek the subject's consent on use of his / her data for future research.
- Refer to https://ethics.gri.nhg.com.sg > Conducting Research > Managing Research Data > About NHG Standing Databases (SDB) or Registering Standing Databases (SDB).

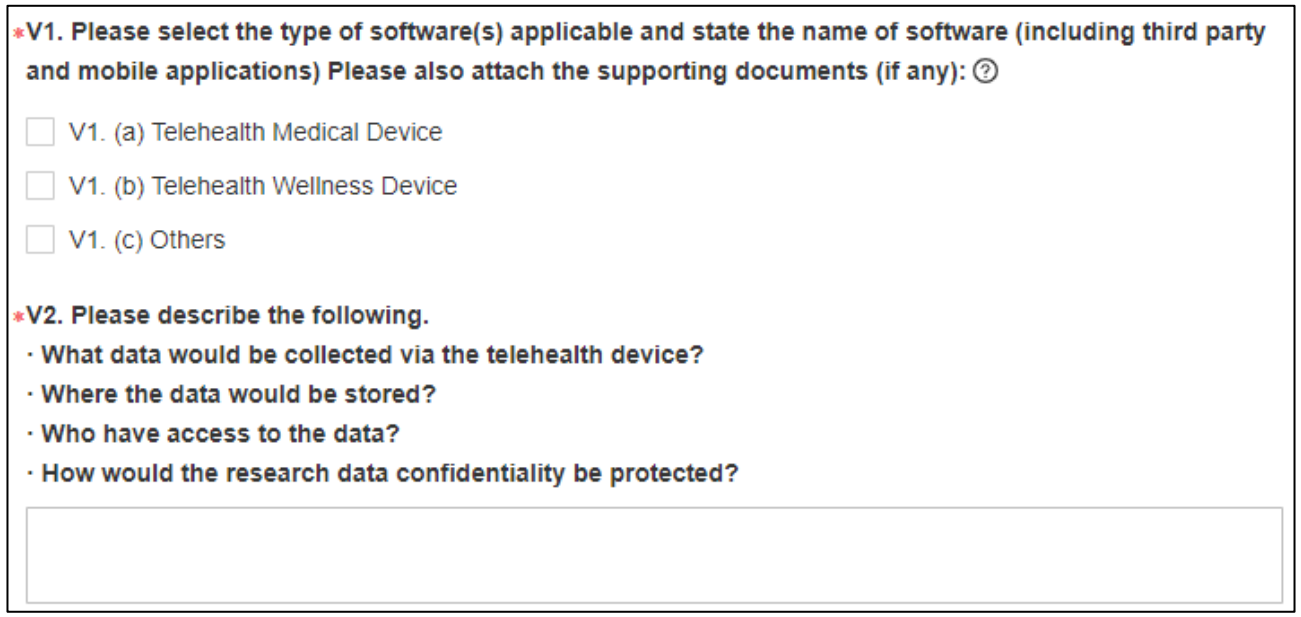
Alternatively,

- Researchers may consider using REDCap to collect their data (If Data collected into Data Collection Form contains identifiable information, study team should collect the data in RedCap. However, NRIC and full name should not be collected in RedCap).
- Researchers are required to comply with RI requirements / policies and / or Data Sharing Agreements prior to releasing / sharing of any data.
- Researchers are strongly advised to consult with the Research Office if in doubt.
- Click here https://ethics.gri.nhg.com.sg/data-governance/ for more information on NHG Research Data Policy.

Section V. Use of Software or Mobile Applications

Section V. Research Data - Use of software or mobile applications

- Please answer all prompts provided.
  - If not applicable, please indicate and justify accordingly.
  - If not yet available (e.g., this is initial phase of the study), please indicate and specify that the information will be submitted when available for IRB review.



*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

*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?

Click here to jump to related topic:
Section D3: What is involved in the study (Software or Mobile Applications)

Section W. Biological Materials Usage & Storage

Section W1. Please select where applicable.

- For each type of Human Biological Material, please separate them into individual entries. E.g., create one entry for blood, then click 'Add' to create another entry for a tissue sample.

1) Urine
2) Blood
3) Tissue

*W1. (a) (i) Type of human biological material:

1) Urine
2) Blood
3) Tissue

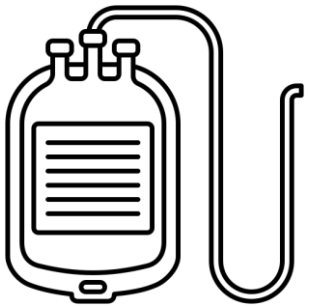
Urine

*W1. (a) (i) Type of human biological material:

Urine

Blood

Tissue

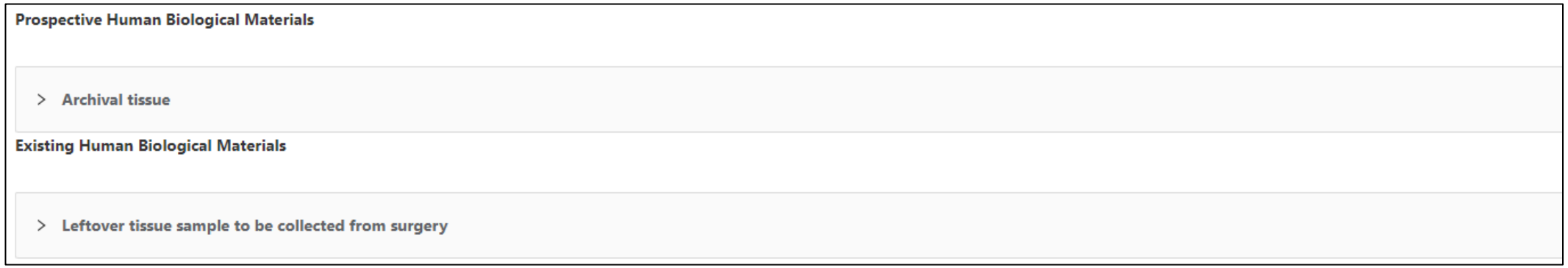


Section W1. Please select where applicable.

- Do not include responses like “Refer to study document”.
- Specify the amount of Human Biological Materials to be collected, the frequency of collection, and the total amount required for the entire study.

Section W1. (a) Human biological materials will be obtained prospectively.
Section W1. (b) Existing human biological materials will be used.

- Know the difference between obtaining human biological materials **prospectively** vs obtaining from **existing** human biological materials.



Examples of Prospective Human Biological Materials	Examples of Existing Human Biological Materials
Blood Urine Saliva Stools samples Leftover tissue sample to be collected from surgery / clinical procedure Fresh Tissue Biopsy	FFPE Tissue Archival Tissue Human Tissue from MOH-Notified Tissue Bank Leftover samples from other studies where participants provided consent to use leftover samples for future research Legacy Tissue

Section X. Data & Safety Monitoring

Section X1. Who will perform the data and safety monitoring?

- If the study involves a DSMB, select DSMB instead of “Other”.

Note: Data Monitoring Committee (DMC) and Data Safety Monitoring Board (DSMB) are used interchangeably.

*X1. Who will perform the data and safety monitoring?

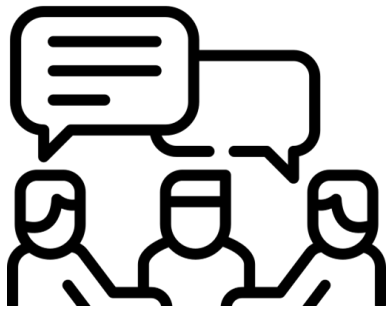
- ○ Principal Investigator and/or Study Team
- ○ Data Safety Monitoring Board (DSMB), please attach the DSMB charter, if available.
- ◉ Other

*X1. (a) Please elaborate.

Data Monitoring Committee (DMC) will be used.

*X1. Who will perform the data and safety monitoring?

- ○ Principal Investigator and/or Study Team
- ◉ Data Safety Monitoring Board (DSMB), please attach the DSMB charter, if available.
- ○ Other



Section X2. Please describe the Data and Safety Monitoring Plan.

- Do not include responses such as “Not Applicable”, “NA” etc.
- Refer to the prompts as a guide when completing the response.
- Include a description of a Data and Safety Monitoring Plan instead of stating “Not Applicable”.

*X2. Please describe the Data and Safety Monitoring Plan.
The following should be included:
1. Safety monitoring: Frequency of review, Type of data (e.g. adverse events/serious adverse events/ unanticipated problems involving risk to participants or others/ other safety parameters) that will be monitored and rules for withdrawing participants from study intervention(s).
2. Data Monitoring Plan: Frequency of review (e.g. daily, weekly, quarterly) and how data integrity is assured?
3. Stopping criteria for the research study based on efficacy, futility and safety criteria.
4. Please state the route of dissemination of any data and safety information to the study sites, as well as the person/ team responsible for doing so.

Not Applicable

*X2. Please describe the Data and Safety Monitoring Plan.
The following should be included:
1. Safety monitoring: Frequency of review, Type of data (e.g. adverse events/serious adverse events/ unanticipated problems involving risk to participants or others/ other safety parameters) that will be monitored and rules for withdrawing participants from study intervention(s).
2. Data Monitoring Plan: Frequency of review (e.g. daily, weekly, quarterly) and how data integrity is assured?
3. Stopping criteria for the research study based on efficacy, futility and safety criteria.
4. Please state the route of dissemination of any data and safety information to the study sites, as well as the person/ team responsible for doing so.

The study team will conduct monthly safety reviews, with adverse events reported to the Principal Investigator within 24 hours and serious adverse events requiring immediate reporting. Participants will be withdrawn if they experience Grade 3 or higher adverse events, develop any exclusion criteria, or request withdrawal. Weekly data integrity checks will be performed by the research coordinator, including verification of data entry, missing data identification, and range checks, with daily data backup on secure servers. The study will be stopped if more than 30% of participants experience serious adverse events, interim analysis shows no possibility of achieving study objectives, or new safety information indicates unacceptable risks. The Principal Investigator will communicate safety concerns to all study sites via email within 48 hours of identification, with monthly safety reports distributed to all study team members. The research coordinator will maintain a central log of all safety events and ensure all site investigators receive updates.

Reminder:

- The purpose of the Data and Safety Monitoring Plan is to ensure the safety and well-being of research participants, and the integrity of the data collected for the study. Depending on the type and risk level of the study, this may include the Principal Investigator, experts within the department or institution, independent consultants or a combination of the said persons.

For more information:

SingHealth	SingHealth Research Integrity, Compliance & Ethics (RICE)
	SingHealth ECOS Resources
	SingHealth CIRB: irb@singhealth.com.sg
NHG	NHG Office of Human Research Protection Programme (OHRPP)
	ECOS End-User Support Portal for NHG Research Community
	NHG DSRB: OHRPP@nhg.com.sg