ECOS

IRB Guidebook: Application Form

Application Form

Version 2 dated: 9 Dec 2024

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

Table of Contents

Section 1: How to Complete Application Form

Section 1 of this guidebook will provide guidance for researchers to draft the Application Form. Do note that the guidance is only specific to some sections. Please approach your respective IRBs if you require further guidance.

You may refer to Section 2 of the guidebook for the sample questions of the Application Form.

1.1 Reviewing IRB

The reviewing IRB would be based on the Overall Principal Investigator (PI). Cross-cluster research applications can be submitted to either SingHealth CIRB, NHG DSRB, A*STAR IRB[1], NUS IRB[1] and NTU IRB[1], depending on the Overall PI cluster.

Example:

- If it is a grant-awarded study, the Overall PI, would be the person who is awarded the grant, and the application should be submitted to his/her cluster's IRB.
- If it is an industry or commercially sponsored study, the Overall PI would have to be selected and application to be submitted to his/her cluster's IRB.
- If it is an investigator-initiated study (no grant/ funding required), the Overall PI would be the person who initiated the study, and the application should be submitted to his/ her cluster's IRB.

Note:

- The Overall PI's institution will be the Lead Research Institution (RI) for the cross-cluster research application (Lead RI is for the purpose of coordinating the research as defined in Section 16 of the Human Biomedical Research Act).
- There should be proper documentation on the appointment of the Lead RI and common IRB. The common IRB will be the primary appointed IRB of the Overall PI's institution (i.e. the primary appointed IRB of SingHealth PIs is SingHealth CIRB and for NHG PIs is NHG DSRB).

- For restricted research, the Lead RI will also put up the application in TIARAS in addition to the IRB Application Form.
- Other than the reporting to IRB, the respective RIs will also be responsible for the reporting of contravention and SAE to MOH.

Please refer to the mutual recognition program for more information.

[1]These IRBs will not be available for selection until the mutual recognition program takes effect.

1.2 Study Site

Study site under the purview of the 5 IRBs should be added under Section B2 (a) of the Application Form if the study site is engaged in research.

- More than 1 study site can be selected if the study involved multi-site. Please note that each study site should appoint a site-PI.

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

  For example: If the study would only be conducted in NNI@SGH Campus, please select NNI@SGH Campus. If the study would be conducted in both NNI@SGH Campus and NNI@TTSH Campus, please select both options.

- For study involving SingHealth Polyclinics, please indicate in Section B2 (a) if endorsement is required. Only 1 SingHealth Polyclinic site is required to perform the endorsement. Please note that this is only applicable for SingHealth Polyclinic only. For other sites, the default selection would be endorsement is required.

  Note: Indicating "Yes" means that study site would need to perform endorsement. Please refer to Section 1.18 (Declaration and Endorsement) for details on when endorsement is required.

For other local/overseas site not under the 5 IRB's purview, you may list them under Section B2 (b) of the Application Form. Please note that these sites listed here is for the IRB's information only. IRB's approval will not include any of these sites. The sites should apply for their own IRB approval if required.

For study site which is not listed in B2(i) but require NHG DSRB or SingHealth CIRB for review:

- Studies submitting to NHG DSRB

  Please complete Section B2(c) of the Application Form. Please submit a Notice of Intent from the External Study Site expressing their intention to rely on NHG DSRB for IRB Approval, for DSRB's assessment. The external study site will be required to sign a Project Based Service Agreement with DSRB and will be advised on addition of the external study site to Section B2(i). Please note that DSRB cannot provide ethics review for overseas study sites.

- Studies submitting to SingHealth CIRB

  Please contact IRB@singhealth.com.sg to obtain CIRB's agreement.

1.3 Study Investigators

The Principal Investigator (PI) is the overall person responsible for the proper conduct of research. He or she will be the primary contact person for IRB (i.e. only PI would be able to submit (re-submit, in the case of query raised) the Application Form.)

- For multi-site study, each study site should have a site-PI appointed. The site-PI should be from the selected study site.

  i.e. SGH study site should have an investigator from SGH institution appointed as site-PI. It should not appoint an investigator from TTSH as site-PI.

- For facility sites (for example IMU and P.H. Feng Research Centre), the site-PI could be from other institutions.

  Example 1: Dr Tan is the PI for NCC site. At the same time, he also oversees the research activities that would be conducted in IMU. Dr Tan would also be the Site-PI for IMU (using his NCC appointment) as well.

Co-Investigators (Co-Is) are members of the research/clinical trial team designated by the Principal Investigator to perform study-related procedure and/or make important research related decisions.

PI and Co-Is should be added under the study site(s) (Section B2(a) of the Application Form) where they would be performing the research through their registered ECOS accounts so that they will be notified of their participation in the study when the Application Form is submitted.

For users with multiple appointments, the correct appointment should be selected when users are being added to the Application Form.

- Example 2: Dr Tan is a consultant at SGH and visiting consultant at KKH. The study will be conducted in KKH and Dr Tan is involved in the study in his KKH capacity. The study should add Dr Tan's KKH visiting consultant appointment under KKH study site. The study should not add Dr Tan's SGH consultant appointment under KKH study site.

For investigators who are involved in research in more than 1 study site, the investigator should be listed in the sites where he/she is involved.

- Example 3: Dr Tan is a consultant at SGH and visiting consultant at KKH. Dr Tan would be recruiting patients in SGH and KKH. Dr Tan should be listed as an investigator (PI/Site-PI/Co-I, depending on role) under SGH site with his consultant appointment and under KKH site with his visiting consultant appointment.

1.4 Profile and Minimum Training

Each user is required to complete their profile and minimum training if you are involved in a research study.

- When user is added to a study, the user profile and their minimum training can be viewed via the link “Details”.
- After clicking “Mandatory Check” on the Application Form, it will display if it’s “Completed” or “Incomplete” with hyperlink view user profile and their minimum training. For Incomplete status, the Application Form cannot be submitted.

Please refer to your institution/cluster on the minimum training requirements.

1.5 Study Funding Information

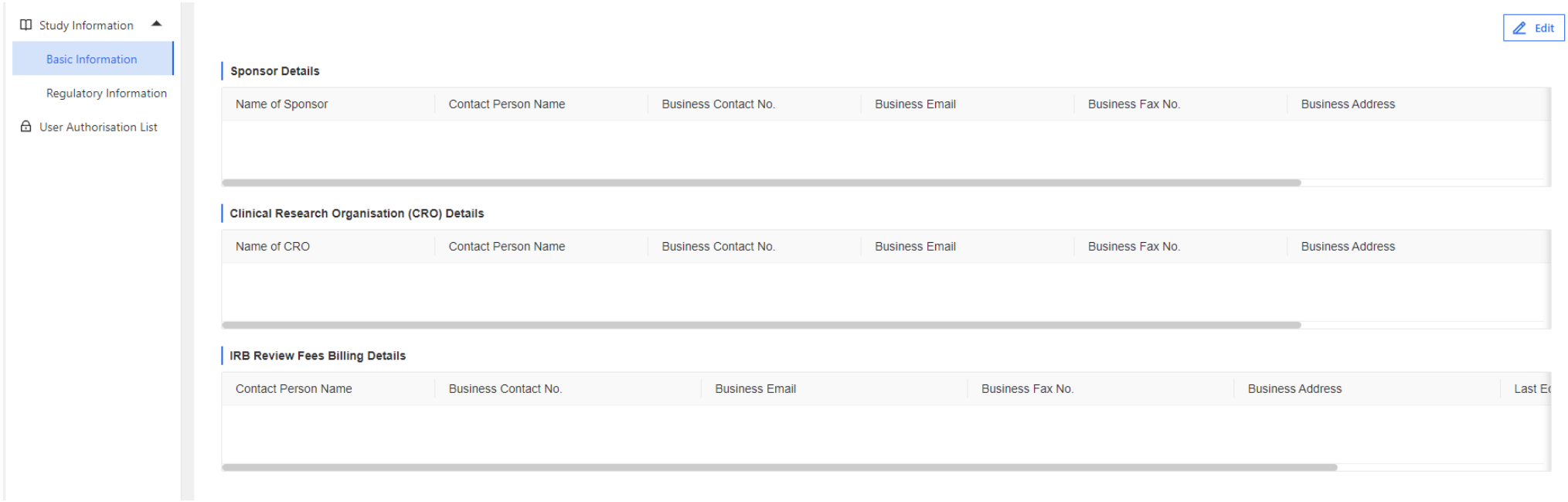
Please indicate the funding information under Section C of the Application Form.

- **Department Fund or No funding is required for this study to be carried out**
- **Grant**
    - Name of Grant Agency: If you are unable to locate the name of the grant agency in the dropdown list, please select others and specify the name of the grant agency.
    - Grant Amount: Please input the awarded grant amount. If the value is not in SGD, please input the currency or convert into SGD value.
    - Only the initial grant is required to be listed on the Application Form. The subsequent grants, please manage them under the CRMS Study List.

    Note: The IRB will only start reviewing the study when preliminary result for the Grant Application is available. Please contact the IRB once you have received information on the grant results to start the review process. If your grant application was not successful, please advise on your next course of action (e.g. withdrawal of the study, look for alternative funding etc.).

- **Pharmaceutical/ Industry Sponsored**
    - Sponsor and/or CRO contact information would be managed under the CRMS module. Please enter the contact information in CRMS module before submission of Application Form. For changes to the contact information, please manage it under the CRMS under the CRMS module.
    - Please note that finder's fees and recruitment bonuses paid to research staff are not allowed.

CRMS Module: Basic Information



Please include the relevant information in the above CRMS module before submission of application form. For more information on CRMS module, please refer to the CRMS Training Slides.

1.6 Payment and Compensation of injury or illness to research participants arising from participation in the study

As a guide, both sponsored and investigator-initiated research studies which are approved by the NHG DSRB/SingHealth CIRB and whose principal investigators (PIs) are from public healthcare institutions are declared for insurance under the National Clinical Trial (CT) Group Insurance Policy. Please check with your respective institutions on the scope of the coverage.

For Sponsored Studies: Sponsors should be responsible for ensuring that research participants receive reimbursement and compensation in the event of injury or illness as a result of their participation in a research study, according to the Association of British Pharmaceutical Industry (ABPI) guidelines, or offer a no-fault compensation to research participants.

As such, the National CT Group Insurance Policy is arranged on the understanding that the pharma-sponsors arrange their own CT Policies, including coverage for the PIs and Sites. In the event of any injury or illness to research participants arising from their participation in the trials, the pharma-sponsors' CT Policies shall be the primary policies to provide compensation to the research participants.

It is therefore important that PIs check to ensure that pharma-sponsors have in place the necessary CT Policies including coverage to the PIs and the Sites.

1.7 Conflict of Interest

All study investigators must complete and submit their Declarations when the application is submitted. Please indicate under Section B2 of the Application Form if the Investigators have any potential conflict of interest. The Declaration is also for the immediate family members of the Investigators. The Principal Investigator is responsible for checking and ensuring that accurate information is submitted to the IRB.

- Conflicting Interest – A conflicting interest can be broadly defined to refer to any interest of the investigator or immediate family (includes spouse, children, parent(s) and sibling(s)) that competes with the investigator's obligation to protect the rights and welfare of research participants.
- Financial Interest – Financial Interest means anything of monetary value, including but not limited to, salary or payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g. patents, copyrights and royalties from such rights), and board or executive relationships. The Conflict of Interest Declaration Section must be submitted to the IRB via study amendments if any of the circumstances relevant described herein change during the conduct of the research.

For all submissions (except for submissions to NHG DSRB), please note that the questions will appear for each study investigator who needs to declare conflict of interest.

For submissions to NHG DSRB, please declare the conflict of interest via the FCOI module.

1.8 Application Form and Exemption Application Form

PI should select the appropriate type of option for their study:

- **Application Form:** If your study does not meet any categories under the Exemption Application Form, please select "Application Form".

- **Exemption Application Form:** This category is for the submission of application meeting at least one of the following categories:

    - **Category S1 – Research in Established or Commonly Accepted Educational Settings:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

      The exemption may only be used for studies about normal educational practices.

    - **Category S2 – Research that Only Involves Educational Tests, Surveys, Interviews, or Observation of Public Behaviour:**
      Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if 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, employability, educational advancement, or reputation.
c) The 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.

- **Category S3 – Research Involving Benign Behavioural Interventions:**

  Benign behavioral interventions 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.

  Examples of such benign behavioural interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

  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.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

This exemption is only for benign behavioral research with adults and is not applicable to children.

Submission to NUS IRB: Research involving deception and/ or withholding of information do not qualify for exemption. Please select the Application Form option at Section D1.

- **Category S4 – Secondary Research Using Biospecimens or Private Information:** Secondary research using identifiable private information or biospecimens, if
  a) It uses publicly available identifiable private information or identifiable biospecimens.
  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.

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

- **Category S5 – Taste and Food Quality Evaluation and Consumer Acceptance Studies:**

  Taste and food quality evaluation and consumer acceptance studies:

  a) If wholesome foods without additives are consumed.
  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.

1.9 Study Classification

PI should select the study classification based on the applicable regulations.

- 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.

- Others: If the study does not fall under any one of the above.

1.10 Recruitment and Consent

For study with recruitment, the recruitment strategy should be described in the Application Form, for example:

- How potential research participants would be identified?
- Advertising/recruitment strategies, including recruitment materials (for example, flyer, poster, advertisement in newspaper, letter of invitation to potential participants, institution's website and social media platform).

The study should select the applicable type of consent for the study.

- Consent will be obtained.
    - Informed Consent Document(s) would be used. Please ensure the Informed Consent Document meets the required regulatory requirements, e.g. the required consent elements are included.

    - Obtaining Informed Consent:
        - For clinical trials, informed consent must be obtained by an investigator who is qualified practitioner and delegated by the Principal Investigator to obtain informed consent. A qualified practitioner is a registered medical practitioner under the Medical Registration Act or a registered dentist under the Dental Registration Act. The investigator must be approved by IRB (listed on the Application Form).

        - For studies that are under the purview of the HBRA, consent can be obtained by study team members approved by IRB (listed on the Application Form) or delegated by PI (listed on CRMS module – User Authorisation List).

- Requirement for Witness during Informed Consent Discussion

	Participant or Participant's Legal Representative is **unable** to read and/or sign on consent form	Participant or Participant's Legal Representative is **able** to read and/or sign on consent form
Clinical Trials regulated by HSA	Impartial Witness[2]	Not Required
Human Biomedical Research[1] under the scope of HBRA	Impartial Witness[2]	Witness[3]

[1] Human Biomedical Research that is not interventional, not invasive and not restricted research does not require witness during the informed consent discussion.

[2] Impartial witness - A person who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study.

[3] Witness - A person who is 21 years of age or older, has mental capacity, who may be/ may not be a member of the team carrying out the research.

- <u>Waiver of documentation of consent (Verbal or Implied Consent)</u>
  - For some research projects, the IRB may approve a request to waive the documentation of informed consent. This means that the study team must provide a research participant with the required information, but the study team is not required to obtain the participant's signature. Such research should meet the criteria listed in either Category A or Category B:
    - **<u>Category A</u>**
      - 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.

▪ **<u>Category B</u>**

- 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.

o Note: Principal Investigators should consider giving a copy of the research information to the participants even when a signed document is not required.

- <u>Waiver of consent during emergency situation</u>
  - When seeking IRB approval for waiver of consent during emergency situation, study must meet the regulatory requirements:
    - For Human Biomedical Research, please refer to the Human Biomedical Research Act (HBRA) Fifth Schedule Part 3 for more information.
    - For Clinical Trial regulated by HSA, please refer to Section 8(3) of the Health Products/ Medicines (Clinical Trials) Regulations.

- <u>Waiver of consent</u>
  - For Human Biomedical Research, please refer to the Human Biomedical Research Act (HBRA) Fifth Schedule Part 2 for more information. Justifications should be provided in Sections S for the request of waiver of consent.

- Consent obtained from research participants previously.
    - Research participants may have consented to tissue bank consent document to allow their human tissue to be used for future research.
    - Research participants may have consented under specific study for their leftover human biological materials to be used for future research.
    - For Human Biomedical Research, it is important that the consent obtained previously met the HBRA Section 12 (1) and/or (2) requirements.
    - A sample of the consent document should be submitted in the Application Form for the IRB's information.

1.11 Research involving De-identified data

"De-identified data" refers to a data set from which personal identifiers have been extracted, which will disallow re-association with any of the people mentioned in the original record. It should be noted that de-identified data sets often contain a newly created unique identifier completely separate from any identifying characteristics in the original study data sets. This created identifier is not capable of being translated so as to identify the individual except through a Record Linkage Data, which links the created unique identifier with an established identifier. The record linkage data should be held by an individual who is not in the study team.

For research using unidentifiable data (e.g. de-identified by program coordinator, or Trusted Third Party), please describe the process. For instance, why, what, who, where, how the unidentifiable data are obtained.

1.12 Enrolment target

For study with recruitment:

Please state the enrolment target under Section E5 of the Exemption Application Form or Section G12 of the Application Form:

1. 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 enrol beyond the Enrolment Target Maximum, please submit a study amendment to increase the enrolment target for approval.
2. For the distribution of Males, Females and Children to be enroled into the study, please use the Enrolment Target Minimum number to provide an approximate distribution ratio.
3. Enrolment Target Min must be equal or lower (≤) than sum of male, female, and children.
4. Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min. i.e. Enrolment Target Min and Enrolment Target Max could be the same number.
5. Please note: an error message would appear if values entered does not meet the requirement.

For study without recruitment:

Please provide the estimated number of records/ samples that would be used in the study under Section E5 of the Exemption Application Form or Section G12 of the Application Form.

For study with combination of recruitment and use of data/samples with consent obtained previously:

Please provide the total number under Section E5 of the Exemption Application Form or Section G12 of the Application Form. This total enrolment target should include the number of participants to be enroled in the study and the number of records/samples that would be used in the study. Details of the breakdown of the enrolment target should be elaborated in the Application Form as well.

1.13 Potential Risk

Potential risk should be classified under one of the below categories. Example of potential risk to research participants:

- Economic risk: Additional expenses to be borne by research participants due to participation in research.
- Physical risk: bruising after blood draw, study drug related adverse events.
- Psychological risk: Emotional distress, e.g. feeling threatened or humiliated
- Social risk: Breach of confidentiality or invasion of privacy.
- Legal risk: Self-incrimination, e.g., disclosure of illegal activities committed.

Potential risks should be described in the textbox provided.

1.14 Inclusion and Exclusion Criteria

Inclusion Criteria

Kindly state the inclusion criteria (set of conditions that must be met in order to participate in the study) for research participants relevant to this study (e.g. age, gender, blood sugar levels, blood pressure, type and stage of disease etc.).

Exclusion Criteria

Kindly state the exclusion criteria (set of conditions that research participants must not have) for research participants relevant to this study (e.g. age, gender, blood sugar levels, blood pressure, type and stage of disease etc.).

1.15 Medical device

According to First Schedule of the Health Products Act 2007, "Medical device" means —

(a) any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of —

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information by means of in-vitro examination of specimens derived from the human body, for medical or diagnostic purposes,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means, and which is not a cell, tissue or gene therapy product; and

(b) the following articles:

(i) any implant for the modification or fixation of any body part;

(ii) any injectable dermal filler or mucous membrane filler;

(iii) any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.

According to HSA, medical devices are health products which have a physical or mechanical effect when used on human bodies. These devices are used to:

- Diagnose, alleviate or treat a medical condition (e.g. X-ray machines, contact lenses, prosthetic knee implants)
- Measure or monitor functions of the body (e.g. blood pressure or blood sugar monitoring machines)

Products used to maintain or support general well-being without specific medical claims, such as body toning equipment, magnetic accessories and massagers, are not medical devices.

For more information, please refer to: https://www.hsa.gov.sg/medical-devices

Please select "Medical Device" in Section D3 of the Application Form and elaborate on the medical device in Section I (Research Details – Use of Medical Device) of the Application Form.

Below is some information which may help you to complete Section I of the Application Form:

- Medical Device Registration: https://www.hsa.gov.sg/medical-devices/registration
- Clinical Research Material Notification: https://www.hsa.gov.sg/clinical-trials/crm-notification
- US FDA Investigational Device Exemption (IDE): https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide
- Under 21 CFR 812.3(m), 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.

1.16 Software or Mobile Application

Telehealth products are instruments, apparatus, machines or software (including mobile applications) that are involved in the provision of healthcare services over physically separate environments via infocomm technologies (including mobile technology).

- Telehealth product intended for medical purposes by the Product Owner (PO), will be classified as a medical device and are regulated by HSA. Please refer to above Section 1.15 for definition on medical device.
    - 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.
    - Please note that the information submitted in Section I (Research Details – Use of Medical Device) and Section V (Research Data – Use of Software or Mobile Application) of the Application Form should not be duplicated.
- Telehealth Wellness Device achieve its intended purpose by encouraging users to improve or maintain a healthy lifestyle.

For more information, please refer to: https://www.hsa.gov.sg/medical-devices/digital-health

For studies involving the use of Software or Mobile Applications, please select "Use of Software or Mobile Applications" in Section D3 of the Application Form and elaborate in Section V (Research Data – Use of Software or Mobile Application) of the Application Form.

The use of software and/or mobile applications for research should be in compliance with institution policy. Please check with your respective institutions for more information.

1.17 Research involving Children

Research involving children will be classified into one of the following three categories:

Category 1 – Research that does not involve more than minimal risk.

Category 2 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual research participant and the relation of the anticipated benefit to the risk is at least as favourable to the research participants as that presented by alternative approaches.

Category 3 – Research involving greater than minimal risk and no prospect of benefit to the individual research participant. In order to approve research in this category, the IRB must determine that:

ii. The risk of the research presents no more than a minor increase over minimal risk.
iii. The intervention or procedure presents experiences to the research participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.
iv. The intervention or procedure is likely to yield generalisable knowledge about the research participant's disorder or condition which is of vital importance for the understanding or the amelioration of the disorder or condition.

For research involving children, the IRB must determine adequate provisions are made for soliciting the consent/ assent of the children and the consent of their parents or guardians (or the legal representative as stipulated in the applicable regulations if different).

Parental Permission – IRB will use the following guidelines to determine parental permission/ consent requirements:

a. If both parents are available and willing to provide permission, the Principal Investigator should obtain consent from both parents.
b. For research approved under Category 1 and 2 (see Section K2), permission from at least one parent or legal guardian must be obtained.
c. For research approved under Category 3 (See Section K2), permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

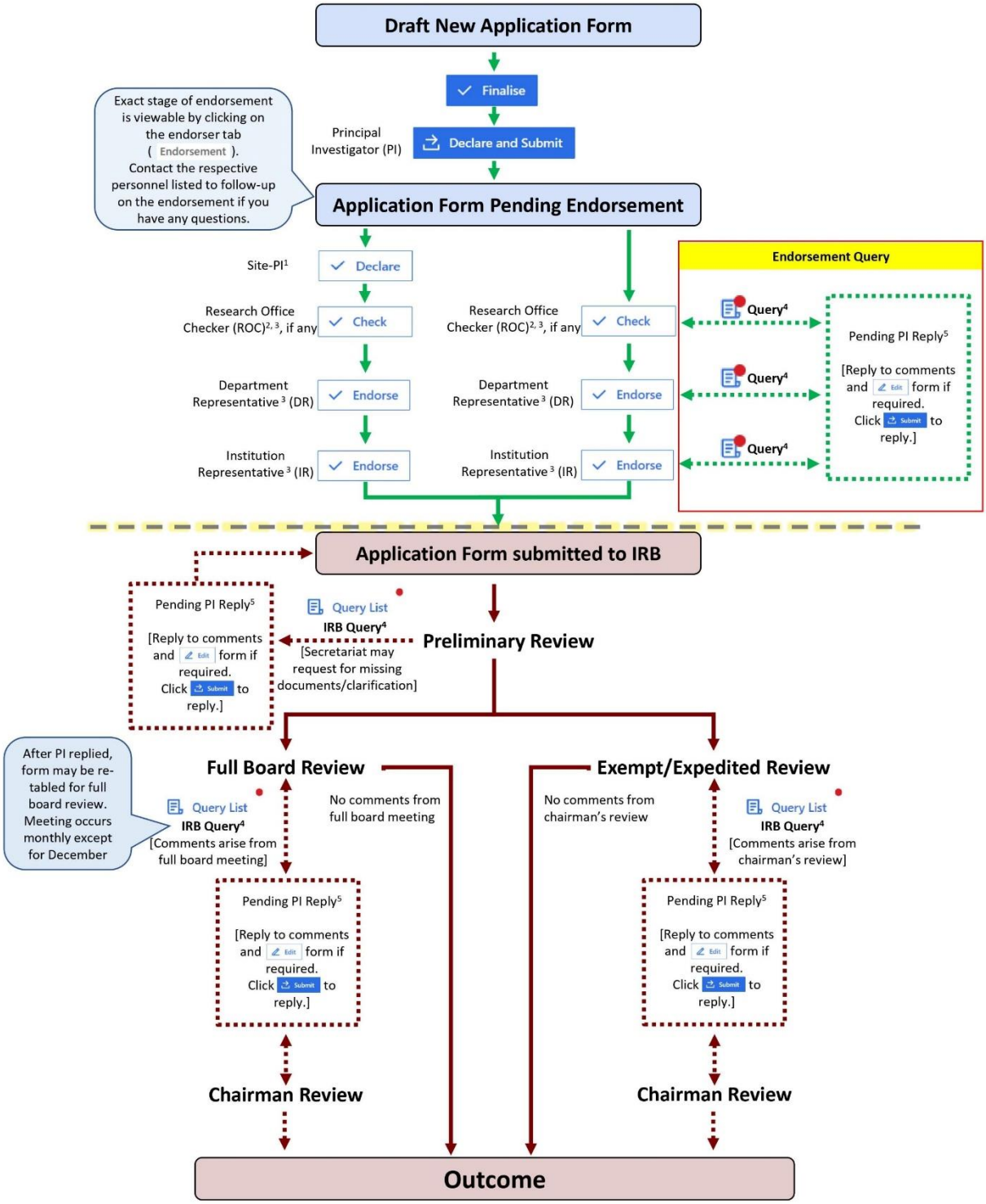
1.18 Declaration and Endorsement

All Application Forms would require PI/site-PI declaration and endorsement from the respective institutions before the Application Form reaches the IRB for review. It would include the following:

- PI Declaration
- Site-PI Declaration
- Research Office Checker (if applicable)
- Department Representative (DR) Endorsement
- Institution Representative (IR) Endorsement

Note:

1. Research Office Checker, DR and IR may raise queries during the endorsement process. The endorsement process will be halt when there are queries pending PI reply.
2. When query (during the endorsement process or during IRB review process) is raised, the Application Form becomes editable and study team could update the Application Form.
3. When there are significant changes to the following section as described, the Application Form will be unlocked for re-endorsement.
    - Section B2: Addition of study sites (Endorsement for the additional sites only)
    - Section B2: Change/ Addition of PI/ Site-PI (Endorsement for the sites involved only)
    - Section D2 : Change Study Classification to “Clinical Trial”
    - Section D3: Inclusion of Vulnerable Participants
    - Section H4: Change to Placebo Controlled Trial
4. The IRB may also unlock the Application Form for re-endorsement if there are major changes made besides the scenario described in point 3.



Note:

[1] This is only applicable for study involving multi-sites.
[2] ROC check is only applicable for certain 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 application and reply.
[5] Re-declaration / Re-endorsement is required if there are major changes to the application form.

Section 2: Application Form (For Reference Only)

Below listed all the sections and questions of the IRB Application Form. Depending on the options selected, only certain sections and questions will be displayed. Only questions with "#" indicated are optional.

Section A: Study Title

A1. Please enter the Study Title for this Study.

- Insert text-

Section B: Submission Board, Study Site, Study Investigator and Conflict of Interest

B1. Submission IRB and Board

B1. (a) The reviewing IRB would be:

-Choose from Dropdown list-
A*STAR IRB
NHG DSRB
NUS-IRB
NTU-IRB
SingHealth CIRB

B1. (b) Please select the board.

-Choose from Dropdown list- Available options will be based on the IRB selected in Section B1. (a)

SingHealth CIRB CIRB A CIRB B CIRB C CIRB D CIRB E CIRB F	**NHG DSRB** Domain A Domain B Domain C Domain D Domain E Domain F	
NTU IRB NTU IRB	**NUS IRB** NUS IRB	**A*STAR IRB** A*STAR IRB

B1. (c) Please select the specialty.

-Choose from Dropdown list- Available options will be based on the IRB selected in Section B1 (a)

A*STAR IRB – Auto-populated based on selection in Section B1. (b)	**NUS IRB –** Auto-populated based on selection in Section B1. (b)
SingHealth CIRB – Auto-populated based on selection in Section B1. (b)	**NTU IRB –** Auto-populated based on selection in Section B1. (b)

NHG DSRB –
Primary Specialty:

Anaesthesia	Nutrition & Dietetics	Rheumatology, Allergy and Immunology
Cardiology	Obstetics & Gynaecology	Sports Medicine
Cardiothoracic & Vascular Surgery	Oncology	Surgery - Colorectal Surgery
Dentistry	Ophthalmology	Surgery - General Surgery
Dermatology	Others	Surgery - Hand & Reconstructive Microsurgery
Diagnostic Radiology	Otolaryngology	Surgery - Hepatobilliary and Pancreatic Surgery
Emergency Medicine	Paediatrics	Surgery – Neurosurgery
Endocrinology	Palliative Medicine	Surgery - Oral & Maxillofacial Surgery
Family Medicine	Pathology	Surgery - Orthopaedic Surgery
Gastroenterology	Pharmacy	Surgery - Plastic, Reconstructive and Aesthetic Surgery
Geriatric Medicine	Psychiatry	Urology
Infectious Diseases	Public Health	
Laboratory Medicine	Rehabilitation Medicine	
Neurology	Renal Medicine	
Nursing	Respiratory & Critical Care Medicine	

Secondary Specialty[#]: available options will be based on Primary Specialty selection
Secondary Sub-specialty[#]: available options will be based on Primary Specialty selection

B1. (d) Has the study been submitted to another IRB?

- ○ No
- ○ Yes

B1. (d) (i) Please state the name of the IRB. **(If "Yes" is selected in B1. (d))**

- Insert text-

B1. (e) Has the application been previously rejected by any IRB?

- ○ No
- ○ Yes

Please state which IRB had rejected the study and provide reason(s) for the rejection.
(If "Yes" is selected in B1. (e))

B1. (e) (i) Name of the IRB: **(If "Yes" is selected in B1. (e))**

- Insert text-

B1. (e) (ii) Reason(s): **(If "Yes" is selected in B1. (e))**

- Insert text-

B2. Study Site and Study Investigator

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

Study Site	Location[#]	Endorsement needed	Action

Study Site	Name	Study Role	Designation	Department	Institution	Profile and Minimum Training	Conflict of Interest

B2. (i) Conflict of Interest: Please tick all the applicable boxes. **(If "Yes" is selected under "conflict of interest" for each of the Study Team Member(s) above)**

- ❑ Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any organization that may benefit from the research activity.
- ❑ Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any organisation that may benefit from the research activity.
- ❑ Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.
- ❑ Options or other compensation arrangements that could be affected by the outcome of the research.
- ❑ The sponsor company supporting this study offers incentives 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.
- ❑ Others (financial/non-financial conflict).

B2. (a) (I) Please specify: **(If "Others" is selected in B2. (i))**

- Insert text-

B2. (ii) Please provide details of all of the above Conflict of Interest. **(If "Yes" is selected under "conflict of interest" for each of the Study Team Member(s) above)**

- Insert text-

B2. (iii) Please describe the plan to manage all the above Conflict of Interest. You may include the mechanism and processes in place to manage the Conflict of Interest (e.g., resignation of position, independent data analysis, data safety monitoring, blinded study, ad hoc review committee). You may also include if the Conflict of Interest will be disclosed to the research participants (e.g. through the written Informed Consent Form, oral presentation etc.). **(If "Yes" is selected under "conflict of interest" for each of the Study Team Member(s) above)**

- Insert text-

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.)

- Insert text-

B2. (c) External Study Sites (under the supervision of the Principal Investigator, seeking IRB Approval) #
(if "NHG DSRB" is the reviewing IRB as selected in B1. (a))

Note:

1) External study site(s), under the supervision of the Principal Investigator that has/have not obtained any IRB approval and need to rely on the PI's appointed IRB for ethics oversight.
2) Please submit a "Notice of Intent" for each External Study Site intending to request for IRB Approval.

Study Site	Institutional Authorisation (Yes/No)	Contact Person	Notice of Intent

Section C: Study Funding Information

C1. Please provide information regarding the study's funding source or sponsor information.

- (a) Department Fund or No funding is required for this study to be carried out
- (b) Grant
- (c) Pharmaceutical/ Industry Sponsored

C1. (b) (i) Name of Grant Agency: (If "Grant" is selected in C1)

- Insert text-

C1. (b) (ii) Grant Holder: # (If "Grant" is selected n C1)

- Insert text-

C1. (b) (iii) Grant Amount Applied for: (If "Grant" is selected in C1)

- Insert text-

C1. (b) (iv) Has the grant been approved? (If "Grant" is selected in C1)

- No
- Yes

C1. (b) (iv) Attachment (If "yes" is selected in C1.(b) (iv))	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

C1. (b) (v) Is the study's initiation dependent on grant approval? (If "Grant" is selected in C1)

- Yes
- No

C1. (b) (v) (I) Please state alternate funding: (If "No" is selected in C1. (b) (v))

- Insert text-

C1. (b) (vi) Grant Reference Number # (If "Grant" is selected in C1)

- Insert text-

C1. (c) (i) Name of Sponsor Company (If "Pharmaceutical/ Industry Sponsored" is selected in C1)

- Insert text-

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? (If "Pharmaceutical/ Industry Sponsored" is selected in C1)

- No
- Yes

C1. (c) (ii) (I) Please elaborate: (if "yes" is selected in C1. (c) (ii))

- Insert text-

C1. (c) (iii) Will the sponsor be providing monitoring? (if "Pharmaceutical/ Industry Sponsored" is selected in C1)

- 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? (if "Pharmaceutical/ Industry Sponsored" is selected in C1)

- Yes
- No

C1. (c) (iv) (I) Please elaborate: (if "No" is selected in C1. (c) (iv))

- Insert text-

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

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

C2. (a) Please explain. (if "no" is selected in C2)

- Insert text-

Section D: Study Type and Nature

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

- Application Form
- Exemption Application Form

D1. (a) Please select the exemption application categories. (If "Exemption Application Form" is selected in D1)

- ❑ Category S1 – Research in Established or Commonly Accepted Educational Settings
- ❑ Category S2 – Research that Only Involves Educational Tests, Surveys, Interviews, or Observation of Public Behaviour
- ❑ Category S3 – Research Involving Benign Behavioural Interventions
- ❑ Category S4 – Secondary Research Using Biospecimens or Private Information
- ❑ Category S5 – Taste and Food Quality Evaluation and Consumer Acceptance Studies

D1. (a) (i) Category S4: Please select: (If "Category S4" is selected in D1. (a))

- a. Identities of subjects are publicly available
- b. Identities of subjects cannot be determined/ traced

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

D2. (a) Please indicate the Phase of the Trial. (If "Clinical Trial" is selected in D2)

- Insert text-

D2. (b) Select the checkbox(es) that apply. (If "Human Biomedical Research" is selected in D2)

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.

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.

D2. (c) Select the checkbox(es) that apply. My restricted human biomedical research involves:
(If "Restricted Human Biomedical Research" is selected in D2)

Category A

- ❑ a. human eggs or human embryos (includes derivation of new human embryonic stem cell lines from donate human embryos).

Category B

Research involving any of the following human-animal combination embryos:

- ❑ a. cytoplasmic hybrid embryos.
- ❑ b. human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells).
- ❑ c. human-animal combination embryos created in-vitro by using human gametes and animal gametes.
- ❑ d. human-animal combination embryos created in-vitro by using one human pronucleus and one animal pronucleus.

Note: Research involving the development of human-animal combination embryos referred to in (a) or (c) beyond 14 days or the appearance of primitive streak, whichever is earlier, is prohibited.

Category C

- ❑ a. the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo.
- ❑ b. the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction.
- ❑ c. the use of any entity created as a result of (a) and (b) above.

Category D

- ❑ a. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal.
- ❑ b. the use of any entity created as a result of (a) above.

D2. (d) Please justify why the study is not regulated by Health Products Act/ Medicines Act (HSA) or Human Biomedical Research Act (MOH). (If "others" is selected in D2)

- Insert text-

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
- ❑ 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?

- ○ No
- ○ Yes

D4. (a) Would the study involve recruitment of any of the following as research participants? (If "Yes" is selected in D4)

- ❑ Not applicable, the study does not involve vulnerable research participants
- ❑ Pregnant Women, Foetuses & Neonates
- ❑ Children
- ❑ Prisoners
- ❑ Cognitive Impaired Person
- ❑ Other Vulnerable Population

D4. (a) (i) Please specify the population: (If "Others vulnerable population" is selected in D4. (a))

- Insert text-

D4. (a) (ii) Why does your research need to involve this group of vulnerable research participants? **(If "Others vulnerable population" is selected in D4. (a))**

- Insert text-

D4. (a) (iii) What are the additional safeguards that will be provided to protect the rights and welfare of this group of vulnerable research participants? **(If "Others vulnerable population" is selected in D4. (a))**

- Insert text-

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 option is mostly applicable for Questionnaire/ Survey/ Interview/ Focus Group Discussion
- ❑ Waiver of consent during emergency situation
- ❑ Waiver of consent
- ❑ Not applicable as study involves De-identified Data
- ❑ Consent obtained from research participants previously

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. **(If "Consent was obtained from research participants previously" is selected in D5)**

- Insert text-

D5. (a) Attachment **(If "Consent was obtained from research participants previously" is selected in D5)**	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

D5. (i) Please state which population(s) are involved for the above combination selected. **(If more than 2 checkbox options are selected in D5)**

- Insert text-

Section E: Research Methodology (Exemption Application)

-Section appears only when "Exemption Application Form" is selected in D1-

E1. What are the specific aims of this study?

- Insert text-

E2. What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.

- Insert text-

E3. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. Please 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 study involves research participant's visit, please describe the frequency and procedures involved. For studies with multiple visits, please attach the study schedule.

(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.

- Insert text-

E.3 Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

E4. Please provide details on sample size and power calculation. If applicable, please provide the means by which data will be analysed and interpreted.

- Insert text-

E4. (a) If this is part of an international study, please also state the approximate total number of worldwide research participants targeted for enrolment into this study. #

Number of worldwide research participants: *- Insert number-*

E5. Please state the target number of research participants to be enrolled for each study site. If the exact numbers are not available, please give an approximate number range for Enrolment Target.

Note:

(1) 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 enrol beyond the Enrolment Target Maximum, please submit a study amendment to increase the enrolment target for approval.
(2) 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.
(3) Enrolment Target Min must be equal or lower (≤) than sum of male, female, and children.
(4) Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min. i.e. Enrolment Target Min and Enrolment Target Max could be the same number.

Study Site	**Enrolment Target Min**	**Enrolment Target Max**	**Adults (Male)**	**Adults (Female)**	**Children** *(Persons less than 21 years and not married)*

E6. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

- Insert text-

E7. What are the potential risks to research participants?

- ❑ Economic risk
- ❑ Physical risk
- ❑ Psychological risk
- ❑ Social risk
- ❑ Legal risk

- Insert text-

E8. What are the potential benefits (direct as well as indirect) to research participants? Indirect benefits may refer to the medical knowledge gained in the future, from the research.

- Insert text-

E9. What is the estimated duration required to conduct this study?

No. of years *- Insert number-* **No. of months** *- Insert number-*

Estimated Duration | *- Auto-populate-*

E10. Does this study have a study protocol?

- No
- Yes

E.10 Attachment (If "Yes" is selected in E10)	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

Section F: Exemption Review Criteria

-Section appears only when "Exemption Application Form" is selected in D1-

F1. Please describe and state the source of your research participants/samples/data.

- Insert text-

F2. Criteria to qualify for Exemption from IRB review.

F2. (a) The research involves no more than minimal risks to the research participants:

- Yes
- No

F2. (a) (i) Please justify: (If "No" is selected in F2. (a))

- Insert text-

F2. (b) The selection of research participants is equitable:

- Yes
- No

F2. (b) (i) Please justify: (If "No" is selected in F2. (b))

- Insert text-

F2. (c) Recording of identifiable information:

- No recording of identifiable information.
- Identifiable information is recorded and there are adequate provisions to maintain the confidentiality of the data.

F2. (c) (i) Please justify and state the provisions: **(If "Identifiable information is recorded and there are adequate provisions to maintain the confidentiality of the data" is selected in F2. (c))**

- Insert text-

F2. (d) Privacy interests of the research participants:

- It is not applicable as there are no interactions with research participants.
- There are interactions with research participants and adequate provisions to maintain the privacy interests of the research participants.

F2. (d) (i) Please justify and state the provisions: **(If "There are interactions with research participants and adequate provisions to maintain the privacy interests of the research participants" is selected in F2. (d))**

- Insert text-

F3. Please select the applicable type(s) of consent for the study. **(If" There are interactions with research participants and adequate provisions to maintain the privacy interests of the research participants." is selected in F2. (d))**

- ❑ Consent will be obtained
- ❑ Waiver of documentation of consent (Verbal or Implied Consent) - This option is mostly applicable for Questionnaire/ Survey/ Interview/ Focus Group Discussion
- ❑ Waiver of consent
- ❑ Not applicable as study involves De-identified Data
- ❑ Consent obtained from research participants previously.

F3. (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. **(If "Consent was obtained from research participants previously" is selected in F3)**

- Insert text-

F3. (a) Attachment **(if "Consent was obtained from research participants previously" is selected in F3)**	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

F3. (i) Please state which population(s) are involved for the above combination selected. **(If more than 2 checkbox options are selected in F3)**

- Insert text-

F4. 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 participants. **(If "Consent will be obtained" is selected in F3)**

- ❑ (a) Yes, there are plans to re-identify and notify research participants.
- ❑ (b) No, there are no plans to re-identify and notify research participants.
- ❑ (c) There will not be any incidental findings arising from this study.

F4. (a) Please describe the management of incidental findings. **(If "Yes, research participants will be re-identified and notified" is selected in F4)**

- Insert text-

F4. (b) Please describe the rationale why research participants will not be re-identified and notified. **(If "No, research participants will not be re-identified and notified" is selected in F4)**

- Insert text-

F4. (c) Please elaborate why there will not be any incidental findings arising from this study. **(If "There will not be any incidental findings arising in this study" is selected in F4)**

- Insert text-

Section G: Research Methodology

-Section appears only when "Application Form" is selected in D1-

G1. What are the specific aims of this study?

- Insert text-

G2. What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.

- Insert text-

G3. Please state concisely the importance of the research described in this application by relating the specific aims to the long term objectives.

- Insert text-

G4. Please briefly describe the background to the current study proposal. Critically evaluate the existing knowledge and specifically identify the gap(s) that the proposed study is intended to fill.

- Insert text-

G5. Please provide a list of relevant references and attach at least two relevant publications that support the conduct of the study. #

- Insert text-

G5. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

G6. Please provide an account of the Principal Investigator's preliminary studies and progress reports (if any) pertinent to this application.

- Insert text-

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.

- Insert text-

G7. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

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

- Insert text-

G9. Please state how long will each research participants will be expected to be directly involved (from screening procedures till completion of follow-up tests or examinations) in the study?

Note: If the study involves research participant's visit, please describe the frequency. For studies with multiple visits, please attach the study schedule.

- Insert text-

G9. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

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.

- ❑ (a) Yes, there are plans to re-identify and notify research participants.
- ❑ (b) No, there is no plan to re-identify and notify research participants.
- ❑ (c) There will not be any incidental findings arising from this study.

G10. (a) Please describe the management of incidental findings. **(If "Yes, research participants will be re-identified and notified" is selected in G10)**

- Insert text-

G10. (b) Please describe the rationale why research participants will not be re-identified and notified. **(If "No, research participants will not be re-identified and notified" is selected in G10)**

- Insert text-

G10. (c) Please elaborate why there will not be any incidental findings arising from this study.
(If "There will not be any incidental findings arising in this study" is selected in G10)

- Insert text-

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

- Insert text-

G11. (a) If this is part of an international study, please also state the approximate total number of worldwide research participants targeted for enrolment into this study. #

Number of worldwide research participants: *- Insert number-*

G12. Please state the target number of research participants to be enrolled for each study site. If the exact numbers are not available, please give an approximate number range for Enrolment Target.

Note:

(1) 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.
(2) 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.
(3) Enrolment Target Min must be equal or lower (≤) than sum of male, female, and children.
(4) Enrolment Target Max must be more than or equal (≥) to Enrolment Target Min. i.e. Enrolment Target Min and Enrolment Target Max could be the same number.

Study Site	**Enrolment Target Min**	**Enrolment Target Max**	**Adults (Male)**	**Adults (Female)**	**Children** *(Persons less than 21 years and not married)*

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).

- Insert text-

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).

- Insert text-

G15. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

- Insert text-

G16. What are the potential risks to research participants?

- ❑ Economic risk
- ❑ Physical risk
- ❑ Psychological risk
- ❑ Social risk
- ❑ Legal risk

- Insert text-

G17. What are the potential benefits (direct as well as indirect) to research participants? Indirect benefits may refer to the medical knowledge gained in the future, from the research.

- Insert text-

G18. What is the estimated duration required to conduct this study?

No. of years	*- Insert number-*	**No. of months**	*- Insert number-*
Estimated Duration	*- Auto-populate-*		

G19. Does this study have a study protocol?

- No
- Yes

G.19 Attachment (If "Yes" is selected in G19)	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

Section H: Research Details- Clinical Trials (Drug)

-Section appears only when "Clinical Trial" is selected in D2-

H1. Is this a US FDA IND study or data is intended to be reported to FDA in support of an IND Application?

- Yes
- No

H2. Please provide information on the study drug that will be used, and describe how you plan to manage the receipt, handling, storage, utilization, and disposal of the study drug.

- Insert text-

H3. Describe standard/alternative treatments used at your institution for this condition.

- Insert text-

H4. Is this a placebo-controlled trial?

- No
- Yes

H4. (a) Explain what 'standard of care' therapy is available for this condition. **(If "Yes" is selected in H4)**

- Insert text-

H4. (b) Discuss the ethical implications of using placebo instead of 'standard of care' therapy in this situation. **(If "Yes" is selected in H4)**

- Insert text-

H4. (c) Address the issues of safety and efficacy of other available therapies. **(If "Yes" is selected in H4)**

- Insert text-

H4. (d) What is the total duration the research participant would be on the placebo arm of the study? **(If "Yes" is selected in H4)**

- Insert text-

H4. (e) What is the greatest potential harm that the research participant might be exposed to as a result of not receiving effective therapy? **(If "Yes" is selected in H4)**

- Insert text-

H4. (f) What are the procedures in place to safeguard research participant receiving placebo? **(If "Yes" is selected in H4)**

- Insert text-

H4. (g) Do you have any other comments supporting the use of a placebo in your study? **(If "Yes" is selected in H4)**

- Insert text-

H5. Please attach the Investigator's Brochure, product catalogue(s), local product information sheet/leaflet(s), as applicable.

H5. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

Section I: Research Details- Use of Medical Device

-Section appears only when "Medical Device" is chosen in D3 -

-Add Medical Device Button-

I1. Please state the name of the medical device(s) that will be tested or studied in this research (including product name and brand/ manufacturer).

- Insert text-

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?

- (i) Registered as General Medical Device
- (ii) Registered as an In-Vitro Diagnostic (IVD) Medical Device
- (iii) Unregistered

I1. (b) (i) Please indicate: **(If "Registered as General Medical Device" is selected) in I1. (b))**

- Class A
- Class B
- Class C
- Class D

I1. (b) (ii) Please indicate: **(If "Registered as an In-Vitro Diagnostic (IVD) Medical Device" is selected in I1. (b))**

- Class A (IVD)
- Class B (IVD)
- Class C (IVD)
- Class D (IVD)

I1. (b) (iii) Please elaborate why the medical device is not registered. **(If "Unregistered" is selected in I1. (b))**

- Insert text-

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

- o Yes
- o No

I1. (c) (i) Please elaborate. (If "No" is selected in I1. (c))

- Insert text-

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

- o Yes
- o No

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

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

I1. (e) (i) Please select where appropriate. (If "This is a significant risk medical device" is selected in I1. (e))

- ❑ 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. (f) Please provide information on the medical device/prototype. **(If this is a "prototype" as selected in (i))**

- 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.

- Insert text-

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

- Insert text-

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

- ❑ Trained study team member
- ❑ Research participants
- ❑ Others

I1. (h) (i) Please specify. **(If "Others, please specify" is selected in I1. (h))**

- Insert text-

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

- Insert text-

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.)

I1. (j) Attachment	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

Section J: Recruitment Details and Consent Process

-Question J1 to J4 appears only when "Yes" is selected in D4-
-Question J5, J8, J10 to J13 appears only when "Consent will be obtained" is selected in D5 or F3-
-Question J6 appears only when "Consent will be obtained" is selected in D5 or F3 and "Consent will be obtained in-person (face-to-face consent)" is selected at J5-
-Question J7 appears only when "Consent will be obtained" is selected in D5 or F3 and "Consent will be obtained remotely (remote consent)" is selected at J5-
-Question J9 appears only when "Consent will be obtained" is selected in D5 or F3, and "Human Biomedical Research" or "Restricted Human Biomedical Research" is selected at D2 -

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

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

J1. (b) Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence. (If "Research participants related to the study" is selected in J1.)

- Insert text-

J1. (c) Please elaborate. (If "Databases" is selected in J1.)

- Insert text-

J1. (d) Please elaborate on your method(s) of research participant identification (e.g. advertisement, word of mouth etc.). (If "Other methods of research participant identification" is selected in J1.)

- Insert text-

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. Note: PI should also obtain clearance from institution and Communication department on the publication location and/or platform, if applicable.

- Insert text-

J2. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

J3. Are there any recruitment restrictions based on the gender of the research participants (e.g. only males will be included in this study) or race of the research participants (e.g. only Chinese research participants will be included in this study)?

- ○ No
- ○ Yes

J3. (a) Please select where appropriate. **(If "Yes" is selected in J3)**

- ❑ (i) Gender
- ❑ (ii) Race

J3. (a) (i) Gender: Please elaborate. **(If "Gender" is selected in J3. (a))**

- Insert text-

J3. (a) (ii) Race: Please elaborate. **(If "Race" is selected in J3. (a))**

- Insert text-

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

- Insert text-

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)

J5. (a) Please explain why consent must be obtained remotely. **(If "consent will be obtained remotely" is selected in J5)**

- Insert text-

J5. (b) Please elaborate when face to face consent and remote consent would be used. **(If both options are checked in J5)**

- Insert text-

J6. Describe the face-to-face consent process. **(if "consent will be obtained in-person" is selected in J5)**

- Where 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?

- Insert text-

J7. Describe the remote consent process. **(If "consent will be obtained remotely" is selected in J5)**

- Please state the institution-approved platform that would be used.
- Please state if any data would be collected via the platform. If yes, please state what data would be collected, where it would be stored, who would have access to the data and how research data confidentiality will be protected.
- How will consent be obtained (e.g., How identity of research participants will be verified, whether consent will be documented using an e-signature or wet-ink signature will be documented on a hardcopy Informed Consent Form which will be sent back to the study team via mail or email)
- If a witness/ impartial witness is required, how will he/ she join the session and how the study team will ensure that he/ she stays throughout?

- Insert text-

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

- Insert text-

J9. Will a witness be present during the consent process? For studies that are under the purview of the HBRA, consent must be obtained in the presence of a witness, unless the requirements for exemption are met.

- Yes
- No

J9. (a) Please explain. **(If "No" is selected in J9)**

- Insert text-

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

- No
- Yes

J10. (a) Please elaborate. **(If "Yes" is selected in J10)**

- Insert text-

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

- No
- Yes

J11. (a) What are the possible languages that will be understood by the prospective research participant or the legal representative? (If "Yes" is selected in J11)

- ❑ Chinese
- ❑ Malay
- ❑ Tamil
- ❑ Others

J11. (a) (i) Please specify. (If "Others" is selected in J11. (a))

- Insert text-

J11. (b) How will the non-English consent be documented? (If "Yes" is selected in J11)

- ❑ Informed Consent Form (Full) translated to the language understood by the prospective research participant or legal representative.
  Note: Submission of translated consent form and certificate of translation is not required. These documents should be filed in the investigator/study file.
- ❑ Informed Consent Form (English) with DSRB Short Consent Form Template (Translated).
- ❑ Informed Consent Form (English) with other Short Consent Form (Translated).
- ❑ Verbally translated using Informed Consent Form (English) in the presence of impartial witness.

J11. (b) (i) Please state which population(s) are involved for the above combination selected. (If more than one options are selected in Section J11. (b))

- Insert text-

J12. Do you have any additional comments regarding the Informed Consent process?

- o No
- o Yes

J12. (a) Please elaborate. (If "Yes." is selected in J12)

- Insert text-

J13. Please attach the Informed Consent Document(s).

J13. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

Section K: Research Participants- Pregnant Women, Foetuses, & Neonates

-Section appears only when "Pregnant Women, Foetuses, & Neonates" is selected in D4-
-Section should not appear if "medical records review "is the only option is selected in D3-

K1. Please indicate if your research involves:

- ❑ Pregnant Women and Foetuses.
- ❑ Neonates of Uncertain Viability and/or Nonviable Neonates.

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

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.

- Insert text-

K3. Describe how the risks to the foetus will be minimized.

- Insert text-

K4. Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.

- Insert text-

K5. Special Informed Consent Requirements (Check all that apply).

- ❑ Consent will be obtained from the pregnant women.
- ❑ Consent will also be obtained from the father because the research holds out the prospect of direct benefit solely to the foetus.
- ❑ The Informed Consent document(s) will provide information regarding the reasonably foreseeable impact of the research on the foetus or neonate.

K5. (a) Consent will be obtained from the pregnant women because: **(If "Consent will be obtained from the pregnant women" is selected in K5)**

- ❑ Research holds out the prospect of direct benefits to the pregnant women.
- ❑ Research holds out the prospect of direct benefits to both the pregnant women and the foetus.
- ❑ Risk to the foetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

K6. Assurances by Principal Investigator.

- There will be no inducements, monetary or otherwise, offered to terminate a pregnancy.
- Individuals engaged in the research will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- Individuals engaged in the research will not have any part in determining the viability of a neonate.

❑ I agree with the above statements.

Section L: Research Participants- Children

-Section appears only when "Children" is selected in D4-
-Section will appear if other types of research except for "medical records review" is selected in D3
-Question L6 to appear if only "medical records review" is selected in D3 and "consent will be obtained" in D5-

L1. Describe if studies have been conducted on animals and adults first, and data is available to assess risks to children participating in the research.

- Insert text-

L2. Please justify the need to involve children and if the research question can be answered through alternative means (e.g., involving adults only)?

- Insert text-

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)

- ○ No
- ○ Yes

L3. (a) Please state the type of human tissues. **(If "Yes" is selected in L3)**

- Insert text-

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. **(If "Yes" is selected in L3)**

- Insert text-

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. **(If "Yes" is selected in L3)**

- Insert text-

L4. Describe how the relation of potential benefits to risks is at least as favourable as that presented by alternative approaches.

- Insert text-

L5. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.

- Insert text-

L6. What are the provisions for obtaining the child's assent and their legal representative's consent?

- (a) Assent/Consent will be obtained from all children above 6 years old and above and consent will be obtained from their legal representative
- (b) Assent will not be obtained from the children. Consent will be obtained from their legal representative.
- (c) Only assent will be obtained. Consent will not be obtained from their legal representative.
- (d) Neither the child's assent nor consent of their legal representative will be obtained.

L6. (a) Please select where appropriate: **(If "Assent will be obtained from all children above 6 years old and consent will be obtained from their legal representative" is selected in L6)**

- ❑ Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form.
- ❑ Child's agreement regarding participation in the study will be documented using Participant Information Sheet and Consent Form.

L6. (a) Attachment **(If "Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form" is selected in L6 (a))**	**Uploaded Date DDMMYYYY)**
(Upload File Icon)	

L6. (b) Please justify. (If "Assent will not be obtained from the children. Consent will be obtained from their legal representative "is selected in L6)

- Insert text-

L6. (c) (i) Please justify. (If "Only assent will be obtained. Consent will not be obtained from their legal representative "is selected in L6)

- Insert text-

L6. (c) (ii) Please select where appropriate: (If "Only assent will be obtained. Consent will not be obtained from their legal representative "is selected in L6)

- ❑ Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form.
- ❑ Child's agreement regarding participation in the study will be documented using Participant Information Sheet and Consent Form.

L6. (c) (ii) Attachment (If "Child's agreement regarding participation in the study will be documented using a separate Child/ Participant Assent Form" is selected in L6. (c)(ii))	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

L6. (d) Please justify. (If "Neither the child's assent nor consent of their legal representative will be obtained" is selected in L6)

- Insert text-

Section M: Research Participants- Prisoners

-Section appears only when "Prisoners" is selected in D4-
-Section should not appear if only "medical records review" is selected in D3-

M1. How does the research purpose justify enrolling prisoners?

- Insert text-

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

- Insert text-

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

- Insert text-

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

- Insert text-

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

- Insert text-

Section N: Research Participants- Cognitively Impaired Persons

-Section appears only when "Cognitively Impaired Persons" is selected in D4-
-Section should not appear if only "medical records review" is selected in D3-

N1. Please explain why the research cannot be carried out without the involvement of cognitively impaired persons (i.e., justifications for the involvement of cognitively impaired persons).

- Insert text-

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)

- No
- Yes

N2. (a) Please state the type of human tissues. **(If "Yes" is selected in N2)**

- Insert text-

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. **(If "Yes" is selected in N2)**

- Insert text-

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. **(If "Yes" is selected in N2)**

- Insert text-

N3. Are adequate procedures for evaluating the mental status of prospective research participants employed to determine if they can provide consent?

- (a) Yes
- (b) No

N3. (a) Please elaborate. **(If "yes" is selected in N3)**

- Insert text-

N3. (b) Please explain why adequate procedures are not being employed? **(if "No" is selected)**

- Insert text-

N4. Will legal representatives (LRs) be approached to give consent on behalf of the individuals judged incapable of providing consent?

- Yes
- No

N4. (a) Please elaborate. **(If "No" is selected in N4)**

- Insert text-

N5. Will a separate Consent Form be used for cognitively impaired persons?

- (a) Yes, please submit the consent form.
- (b) No

N5. (a) Attachment **(If "(a) Yes, please submit the consent form" is selected in N5)**	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

N5. (b) Please elaborate. **(if "(b) No" is selected in N5)**

- Insert text-

N6. If a research participant is incapable of giving valid consent, will his/her objection to participation be overridden?

- No
- Yes

N6. (a) Please elaborate. **(If "Yes" is selected in N6)**

- Insert text-

N7. Will the research participant's physician or other health care provider be consulted before any individual is invited to participate in the research?

- Yes
- No

N7. (a) Please elaborate. (If "No" is selected in N7)

- Insert text-

N8. Is there a possibility that the request to study participation, may provoke anxiety, stress or any other serious negative response?

- No
- Yes

N8. (a) Please elaborate. (If "yes" is selected in N8)

- Insert text-

N9. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.

- Insert text-

Section O: Consent Process- Waiver of Documentation of Informed Consent (Verbal or Implied Consent)

-Section appears only when "Waiver of documentation of informed consent (Verbal or Implied Consent)" is selected in D5 or F3-

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

- (a) Category A
- (b) Category B

O1. (a) (i) The only record linking the research participant and the research would be the consent document. (If "(a) Category A" is selected in O1)

- Insert text-

O1. (a) (ii) The principal risk would be potential harm resulting from a breach of confidentiality. **(If "(a) Category A" is selected in O1)**

- Insert text-

O1. (a) (iii) The research is not subjected to FDA regulations. **(If "(a) Category A" is selected in O1)**

- o No. The research is subjected to FDA regulations.
- o Yes. The research is not subjected to FDA regulations.

O1. (a) (iv) Each research participant will be asked whether the research participant wants documentation linking the research participant with the research, and the research participants' wishes will govern. **(If "(a) Category A" is selected in O1)**

- o No. The research participant will not be asked.
- o Yes. The research participant will be asked.

O1. (b) (i) The research presents no more than minimal risk of harm to research participants. **(If "(b) Category B" is selected in O1)**

- Insert text-

O1. (b) (ii) The research involves no procedures for which written consent is normally required. **(If "(b) Category B" is selected in O1)**

- Insert text-

O2. Will information sheet be provided?

- o No
- o Yes, please submit the information sheet.

O2. Attachment **(If "Yes, please submit the information sheet" is selected in O2)**	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

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

-Section appears only when "Clinical Trial" is selected in D2 and "Waiver of informed consent during emergency situation" is selected in D5-

Note: For the conduct of clinical trials in emergency situation, please be reminded to submit to the 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.

- Insert text-

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

- Insert text-

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.**

- Insert text-

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

- Insert text-

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

- Insert text-

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

- Insert text-

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

- Insert text-

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.

- Insert text-

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 enrollment 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.

- Insert text-

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. #

P7. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

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

-Section appears only when "HBR" is selected in D2 and "Waiver of informed consent during emergency situation" is selected in D5-

Please justify that the study meets the following criteria for emergency research.
Q1. The research participants are facing a life-threatening situation.

- Insert text-

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

- Insert text-

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

- Insert text-

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

- Insert text-

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.**

- Insert text-

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.

- Insert text-

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.

- o Yes
- o No

  Q8. (a) please describe the process of certification that Q1 to Q5 have been complied with. **(If "No." is selected in Q8)**

  - Insert text-

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

Q9. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

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

-Section appears only when "Clinical Trial" or "Others" is selected in D2 and "Waiver of informed consent" is selected in D5/F3-

Please justify how your study meets the following criteria for Non-HBR Study.

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

- Insert text-

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

- Insert text-

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

- Insert text-

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

- No
- Yes

R4. (a) Please explain. **(if "Yes." is selected)**

- Insert text-

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

- No
- Yes

R5. (a) Please explain. **(if "Yes." is selected)**

- Insert text-

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

-Section appears only when "HBR" is selected in D2 and "Waiver of informed consent" is selected in D5/F3-

S1. Please select the type of waiver required.

- ❑ 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)
- ❑ Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4 (individually identifiable health information obtained or compiled before 1 Nov 2017)
- ❑ Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5 (individually identifiable human biological material obtained or compiled before 1 Nov 2017)

Please justify how your study meets the following criteria:

S1. (a) The use of the individually-identifiable human biological material or health information, as the case may be, involves no more than minimal risk to the research subject or donor. **(if "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3", "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4"or "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5"is selected in S1)**

- Insert text-

S1. (b) The waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor. **(if "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3", "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4"or "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5"is selected in S1)**

- Insert text-

S1. (c) The research cannot reasonably be carried out without the use of the human biological material or health information in an individually-identifiable form. **(if "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3", "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4"or "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5"is selected in S1)**

- Insert text-

S1. (d) The process of obtaining consent from the person, to which the individually-identifiable human biological material or health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements. **(if "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3" or "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4"is selected in S1)**

- Insert text-

S1. (e) Reasonable effort has been made to re-contact the person to which the individually-identifiable human biological material relates for the purpose of obtaining his or her consent. **(if "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5" is selected in S1)**

- Insert text-

S1. (f) The human biomedical research or health information research would reasonably be considered to contribute to the greater public good. Please select the applicable checkbox(es).
if "Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3." is selected in S1)

- ❑ (i) Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large.
- ❑ (ii) Research with apparent or tangible benefits with measurable outcomes to the public at large and may include those less privileged community or a sub-community.
- ❑ (iii) Research that contributes or could contribute to impact at a national, regional or international level with potential to lead to improvement in policy and prevailing standards on innovation, management and practice in healthcare and other human biomedical related fields,

S1 (f) (i) Please explain: **(if "Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large" is selected in S1. (f))**

- Insert text-

S1 (f) (ii) Please explain: **(if "Research with apparent or tangible benefits with measurable outcomes to the public at large and may include those less privileged community or a sub-community" is selected in S1. (f))**

- Insert text-

S1 (f) (iii) Please explain: **(if "Research that contributes or could contribute to impact at a national, regional or international level with potential to lead to improvement in policy and prevailing standards on innovation, management and practice in healthcare and other human biomedical related fields." Is selected in S1. (f))**

- Insert text-

Section T: Research Data Confidentiality

-Section only appears when "Application Form" is selected in D1-

T1. Please select the mode of identification for the research data at the point of collection of research data.

- ○ Research data are coded and the code is maintained by third party
- ○ Research data are coded and the code is maintained by study team
- ○ Identifiers present
- ○ Other methods

T1. (a) Please elaborate. **(if "Other methods" is selected in T1)**

- Insert text-

T2. Please state how the research data will be protected to ensure confidentiality and security.

- ❑ Hardcopy data will be stored in designated locked location (e.g., cabinet(s), room(s), etc) that are accessible to authorized study personnel only.
- ❑ Electronic data will be stored in institution approved secure, and encrypted storage medium, such as databases, encrypted portable media (e.g., USB drives, CD/DVD, hard disks), and/or institution approved online storage platforms. The electronic data will not contain research participant identifiers. Identification code linking electronic data and research participants will be stored separately.

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

- Insert text-

T4. How will the research data be managed upon study completion?

- ○ The research data will be destroyed after it has been stored for the minimum duration of retention as specified by the institutional policy.
- ○ The research data will be used for future research.

T4. (a) Would the research data be stored in an identifiable format? **(if "The research data will be used for future research" is selected in T4)**

- Insert text-

T4. (b) Please state where the research data would be stored. **(if "The research data will be used for future research" is selected in T4)**

- Insert text-

Note: For submission to DSRB, please register a standing database with DSRB when the study has completed.

Section U: Research Data - Recording of study procedures on audiotape, film/video, or other electronic medium.

-Section only appears when " Recording of study procedures on audiotape, film/video, or other electronic medium" is selected in D3-

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

- Insert text-

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

- Insert text-

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

- Insert text-

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

- Insert text-

U5. How will the recording medium be disposed?

- Insert text-

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

-Section only appears when "Use of software or mobile applications" is selected in D3-

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

- ❑ (a) Telehealth Medical Device
- ❑ (b) Telehealth Wellness Device
- ❑ (c) Others

V1. (a) Name of Telehealth Medical Device: (If "(a) Telehealth Medical Device" is selected in V1)

- Insert text-

V1. (a) Attachment (If "(a) Telehealth Medical Device" is selected in V1)	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

V1. (b) Name of Telehealth Wellness Device: (If "(b) Telehealth Wellness Device" is selected in V1)

- Insert text-

V1. (b) Attachment (If "(b) Telehealth Wellness Device" is selected in V1)	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

V1. (c) Name of software: (If "(c) Others" is selected in V1)

- Insert text-

V1. (c) Attachment (If "(c) Others" is selected in V1)	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

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?

- Insert text-

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.

Section W: Biological Materials Usage & Storage

-Section only appears when " Human Biological Material" is selected in D3-

W1. Please select where applicable:

- ❑ (a) Human biological materials will be obtained prospectively
- ❑ (b) Existing human biological materials will be used

-Add type of prospective human biological material Button-

W1. (a) (i) Type of human biological material: **(If "(a) Human biological materials will be obtained prospectively" is selected in W1)**

- Insert text-

W1. (a) (ii) How they will be collected? **(If "(a) Human biological materials will be obtained prospectively" is selected in W1)**

- Insert text-

W1. (a) (iii) Amount to be collected and frequency of collection: **(If "(a) Human biological materials will be obtained prospectively" is selected in W1)**

- Insert text-

W1. (a) (iv) Total amount required for the research study: **(If "(a) Human biological materials will be obtained prospectively" is selected in W1)**

- Insert text-

W1. (a) (v) How human biological material would be identified? **(If "(a) Human biological materials will be obtained prospectively" is selected in W1)**

-Choose from Dropdown list-
No identifiers
Human biological materials are coded and the code is maintained at the source
Identifiers present
Other methods, please elaborate: -Insert text-

W1. (a) (vi) Where will human biological material be stored during the study? **(If "(a) Human biological materials will be obtained prospectively" is selected in W1)**

-Choose from Dropdown list-
Stored within the institution
Transferred out of the institution (locally)
Transferred out of the institution (overseas)

-Add type of Existing human biological material Button-

W1. (b) (i) Type of human biological material: **(If "(b) Existing human biological materials will be used" is selected in W1)**

- Insert text-

W1. (b) (ii) Source*:* **(If "(b) Existing human biological materials will be used" is selected in W1)**

- Insert text-

W1. (b) (iii) How human biological material would be identified? **(If "(b) Existing human biological materials will be used" is selected in W1)**

-Choose from Dropdown list-
No identifiers
Human biological materials are coded and the code is maintained at the source
Identifiers present
Other methods, please elaborate: -Insert text-

W1. (b) (iv) Where will human biological material be stored during the study? **(If "(b) Existing human biological materials will be used" is selected in W1)**

-Choose from Dropdown list-
Stored within the institution
Transferred out of the institution (locally)
Transferred out of the institution (overseas)

W1. (b) (v) Supporting document. **(If "(b) Existing human biological materials will be used" is selected in W1)**

- No
- Yes, please attach the supporting document(s).

W1. (b) (v) Attachment **(If "Yes, please attach supporting documents(s)" is selected in W1. (b) (v))**	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

W2. What tests will be performed on these human biological materials?

- Insert text-

W3. Will results from the tests be communicated to the research participants? If not, please explain.

- Insert text-

W4. Will any cell lines be created from the human biological materials?

- No
- Yes

W4. (a) How will the cell lines be identified? **(if "Yes" is selected at W4)**

- (i) The cell lines are stripped of any identifiers and cannot be linked or traced back to its donor.
- (ii) The cell lines are coded.
- (iii) By other methods.

W4. (a) (ii) Who will maintain the codes linking the cell lines and its donor? **(if "The cell lines are coded" is selected in W4. (a))**

- Insert text-

W4. (a) (iii) Please explain. **(if "By other methods" is selected in W4. (a))**

- Insert text-

W5. How will the biological materials be managed upon study completion?

- The biological materials will be destroyed.
- The biological materials will be stored.

W5. (a) Please indicate the duration and purpose of the storage. **(if "The biological materials will be stored is selected in W5)**

- Insert text-

W5. (b) Please indicate the location of storage. (if "The biological materials will be stored is selected)

- ❑ (i) Tissue Bank under oversight or custodian of SingHealth/NHG/NUHS
- ❑ (ii) Other location

W5. (b) (i) Name of the tissue bank. **(if "Tissue Bank under oversight or custodian of SingHealth/NHG" is selected in W5. (b))**

- Insert text-

W5. (b) (ii) (I) Please state the reason for storage on this location. **(if "other location is selected in W5. (b))**

- Insert text-

W5. (b) (ii) (II) How will these stored biological materials be identified? *(if "other location" is selected in W5. (b))*

- (A) The stored human biological materials are stripped of any identifiers and cannot be linked or traced back to its donor.
- (B) The stored human biological materials are coded.
- (C) By other methods.

W5. (b) (ii) (II) (B) Who will maintain the codes linking the stored human biological materials and its donor? (If "The stored human biological materials are coded" is selected in W5. (b) (ii) (II))

- Insert text-

W5. (b) (ii) (II) (C) Please elaborate: (if "By other methods" is selected in W5. (b) (ii) (II))

- Insert text-

Section X: Data & Safety Monitoring

-Section only appears when "Application Form" is selected in D1 and "Human Biological Material"/ "Medical Device"/ "Surgical / Radiotherapy Procedure"/ "Interventions" and "Invasive procedures"/ selected in D3-

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.

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. Attachment # (If "Data Safety Monitoring Board (DSMB), please attach the DSMB charter, if available" is selected in X1)	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

X1. (a) Please elaborate: ((if "Other" is selected in X1)

- Insert text-

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.

- Insert text-

Other Attachments

Note: Additional documents may be attached here. Documents relevant to the respective sections should not be attached here.

Other Attachments	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	