National Healthcare Group

Adding years of healthy life

NHG ROAM

Research Online Administration & Management

Online DSRB Application Form Guidebook for Biomedical Study
Version 5.0

NHG Research
Translating Research into Highest Quality Patient Care
www.research.nhg.com.sg

CONTENT

Online ROAM Application Form – Section-by-section Guide

Application Form: Selection of Application Form

Sect / No	Question
-	**Please select the appropriate form for submission to the DSRB. Please refer to the explanatory notes below if you need more information.**
Definition/ Explanation	• **DSRB Application Form 1 – Non Exempt category** Principal Investigators should use this form (Application Form 1) if their research activity does not qualify under the Exempt Category. Submissions using this form will be reviewed via the Full Board or Expedited route. • **DSRB Application Form 2 – Exempt category** Principal Investigators should use this form (Application Form 2) if their research activity qualifies for Exempt review under **one or more of the following categories**. **Category 1** – Normal Educational Practices and Settings Research conducted in established or commonly accepted educational settings, involving normal educations practices, such as: (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **Category 2** - Anonymous Educational Tests, Surveys, Interviews, or Observations Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behaviour, unless: (i) information obtained in recorded in such a manner that human subjects can be identified, directly or indirectly through identifiers linked to the subjects; **and** (ii) any disclosure of the human subjects' responses outside of the research could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Category 3** – Identifiable Subjects in Special Circumstances Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviour that is not exempt under Exemption Category 2, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **Category 4** – Collection of Existing Data Research involving study of existing data, documents, records, pathological specimens, or diagnostic specimens, if: (i) these sources are publicly available* (e.g. data accessible to general public such as library literature or internet) or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; **and** (ii) the reviewed material should be in existence at the time the research is proposed and should not be prospectively collected. **Medical records are not publicly available because they are restricted to designated doctors and healthcare professionals only.*

	Note: Data is considered identifiable if any of the following information are present: a. Subject Name b. Address - Street c. Address - Postal Code d. Elements of Dates related to a subject in combination with other identifiers. For example, date of birth, admission or discharge dates, date of death e. Telephone Number f. Fax Number g. Electronic Mail Address h. NRIC Number i. Medical Record Numbers j. Health Plan Beneficiary Numbers k. Account Numbers l. Certificate/License Numbers m. Vehicle Identification Number and Serial Numbers Including License Plate n. Medical Device Identifiers and Serial Numbers o. Web URLs p. Internet Protocol (IP) Address q. Biometric Identifiers (finger and voice prints) r. Full Face Photographic Images s. Any Unique Identifying Number, Characteristic or Code Link to Identifier (code) **Category 5** – Public Benefit or Service Programs Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. **Category 6** – Taste and Food Evaluation and Acceptance Studies Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed; or 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.
	If Exempt **Category 2 and/or 4 is chosen**, please confirm which of the following is applicable: **Option 1:** Identity of subjects is publicly available **Option 2:** Identity of subjects cannot be determined / traced **Option 3:** Identity of the subjects can be determined / traced To qualify for Exempt Application under Category 2 and/or Category 4, you cannot collect information that allows you to identify the subjects (whose cells/tissue/data are being used this study) directly or through identifiers linked to the subjects, unless information is publicly available (i.e. the study will only quality for Exempt Application under Category 2 and/or Category 4 if Option 1 or Option 2 is selected). If the information is not publicly available and you wish to collect identifiers, your study will not qualify for Exemption. Please choose the DSRB Application Form 1 - Non Exempt Category. **IMPORTANT NOTE:** 1. The criteria for the Exempt category do not apply when the research activity:-

	(i) involves prisoners (ii) involves children, when the research involves survey or interview procedures or observations of public behaviour, except when the investigator(s) do not participate in the activities being observed (iii) is a US FDA-regulated research activity. 2. If the application does not fall under any of the above categories and is submitted using the DSRB Application Form 2 for Exempt Review, the application has to be re-submitted using the DSRB Application Form 1 for Non - Exempt Review when it reaches DSRB.
-	**Please declare if the study falls under the purview of the Human Biomedical Research Act.**
Definition / Explanation	Please declare if your study falls under the purview of the Human Biomedical Research Act (HBRA) (Yes/No). When 'Yes' is selected, the following section will appear so that you can select the criteria that the human biomedical research fulfils. Please tick all the boxes that apply. 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; or (c) the performance or endurance of human individuals, Where the research involves — (i) 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; or (ii) the use of any individually-identifiable human biological material; or (iii) the use of any individually-identifiable health information. My human biomedical research involves — (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); or (e) any entity created as a result of any process referred to in paragraph (c) or (d). (f) None of the Above When at least one of the options in (a)-(e) in the paragraph above is selected, there will be an additional section for you to declare if your study is restricted human biomedical research. My human biomedical research involves - 1. Human biomedical research involving human eggs or human embryos 2(a)(i) cytoplasmic hybrid embryos 2(a)(ii) human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells) 2(a)(iii) human-animal combination embryos created in-vitro by using: (A) human gametes and animal gametes; or (B) one human pronucleus and one animal pronucleus; 2(b) the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo 2(c) 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 2(d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal 2(e) any entity created as a result of any process referred to in sub-paragraphs (b), (c) and (d) 3. None of the above The meaning of human biomedical research is described in Section 3 of the HBRA, whereas the types of research deemed to be restricted human biomedical research is described in the Fourth Schedule of the HBRA.

Application Form: Section A - Study Title & Study Administrators

Sect / No	Question
A1	**Please enter the full study title.***
Definition / Explanation	Please enter your full study title here. **IMPORTANT NOTE:** Study title provided in all other relevant documents (e.g. Informed Consent Forms, Questionnaires) should be the same as the study title stated here.
A2	**(Optional) Please assign Study Administrators below.**
Objective	Adding Study Administrators with their registered ROAM accounts in this section will enable them to have editorial access to the application, and receive ROAM notifications (e.g. email reminders to submit a study status report prior to study expiration; emails to notify that a submission has been accepted for review by DSRB).
Definition / Explanation	Study Administrators are persons who are responsible for administrative matters related to the Study. They can be the Study Coordinators, Research Nurses or Clinical Research Associates, and need not be part of the Study Team. While the Principal Investigator remains the primary contact person, the DSRB may contact the Study Administrators for clarification of administrative matters related to the Study. Study Administrators may also assist the PI in drafting the various online forms and reports, however, only the PI may 'submit' these online forms and reports to the DSRB. PIs are encouraged to nominate at least one Study Administrator.

Application Form: Section B - Study Team & Submission Domain

Sect / No	Question
B1	**Study Sites & Study Team Members** **(i) (Optional) Overall Principal Investigator** **(ii) Submitting Principal Investigator (Main Contact for DSRB)*** **(iii) Study Sites under the oversight of NHG DSRB*** **(iv) External Study Sites under the supervision of the 'Submitting Principal Investigator' (e.g. Nursing Home, Community Hospitals, Community Centres etc.)**
Definition / Explanation	**<u>For multi-centre studies within NHG institutions and/or institutions under the oversight of NHG DSRB</u>** Each institution must have a Site Principal Investigator who is responsible for the conduct of the

	study in his/her institution. One of the Site PIs should be designated as the Submitting Principal Investigator. The role of the Submitting Principal Investigator: 1. Responsible for the conduct of the study in his/her own institution 2. Primary contact person for the DSRB 3. Responsible for the submission of the initial application form and subsequent amendments/supplementary forms (Study Status Report forms, Non-compliance reports, UPIRTSO forms, Other Notifications forms) Each Site Principal Investigator must ensure that any reports (Non-compliance reports, UPIRTSO forms, Other Notifications forms) pertaining to their site are submitted to the Submitting Principal Investigator in a timely manner to meet the reporting timelines (if any). If the Overall Principal Investigator is different from the Submitting Principal Investigator, then the Submitting Principal Investigator may provide the name, designation and institution of the Overall Principal Investigator in this section. This is optional. Please use the following as a guide in determining the addition of a co-investigator, or a collaborator: **Co-Investigator**: Any individual member of the research study team designated and supervised by the PI at a site to perform critical trial-related activities and/or to make important trial-related decisions (e.g. associates, residents). For clinical trials regulated by Health Sciences Authority (HSA), the person(s) obtaining informed consent should also be listed as Co-Investigators. **Collaborator**: Any individual member of the research team designated by the PI to assist with research-related activities that do not involve subject contact (e.g. scientists, research fellows, data analyst). **IMPORTANT NOTE:** 1. All Principal Investigators and Co-Investigators from NHG institutions or institutions under the oversight of NHG DSRB have to complete the mandatory minimum training requirement, i.e. CITI Training Program/GCP. 2. NHG investigators and study team members involved in the design, conduct and reporting of the study should also complete the minimum training for Financial Conflict of Interests (FCOI) modules on CITI Training Program. 3. Study Team Members should be added through their registered user accounts so that they will be notified of their participation in this study when the Application is submitted. Adding the study team members with their registered ROAM accounts will also enable them to have editorial access to the application. **For External Study Sites under the supervision of the 'Submitting Principal Investigator'** Please add the name of the institution (e.g. Nursing Home, Community Hospitals, Community Centres) and declare if approvals from the institution and its IRB have been obtained. If the external study site is not under the oversight of any IRB and would like to engage NHG DSRB as the IRB of Record, a Project-based Service Agreement between NHG and the external study site which is under supervision of the Submitting Principal Investigator may be required. Please submit a 'Notice of Intent' (available for download on NHG Research Website https://www.research.nhg.com.sg -> Resources -> Ethics Forms & Templates) or contact the DSRB for further clarifications.

<table>
<tr><th>B2</th><th>Research Specialty</th></tr>
<tr><td>Definition / Explanation</td><td><u>Primary Specialty</u>
Please select the Primary Specialty, and then choose the relevant Sub specialty that has been matched according to the Primary Specialty selected.

If the Primary Specialty and/or Sub specialty cannot be found from the list, please choose ‘Others‘ and specify.

<u>Secondary Specialty</u>
Please add Secondary Specialty, and then choose the relevant Sub specialty that has been matched according to the Secondary Specialty selected

If the Secondary Specialty and/or Sub specialty cannot be found from the list, please choose ‘Others’ and specify.</td></tr>
<tr><th>B3</th><th>Which Domain Specific Review Board (DSRB) is this application being submitted to? *</th></tr>
<tr><td>Definition / Explanation</td><td>The DSRB is based on broad but related disease groupings and disciplines. Please submit the Application to the Domain that is most relevant to the proposed research activity. If you are unable to decide, please contact the DSRB for assistance. The Domain groupings are as follows:

DSRB Domain groupings

<table>
<tr><th>Domain A</th><th>Domain B</th><th>Domain C</th><th>Domain D</th><th>Domain E</th></tr>
<tr><td>Ophthalmology
Psychiatry
Neurology
Neurosurgery
Genetics^
Geriatric Medicine
Palliative Medicine</td><td>Oncology
Haematology
Pathology
Paediatrics
Respiratory Medicine</td><td>Cardiology
Cardiovascular
Surgery
Pharmacology
Emergency Medicine
Endocrinology
Diagnostic Imaging
Family Medicine*</td><td>Obstetrics Gynaecology
Anaesthesia
Surgery#
ENT
Dentistry
Sports & Rehabilitation Medicine
Allied Health</td><td>Infectious Disease
Gastroenterology
Renal Medicine
Rheumatology/ Immunology
Dermatology</td></tr>
</table>
*Non organ/disease specific Family Medicine studies only.
^Non organ/disease specific Genetics studies only.
#Includes General Surgery, Orthopaedic Surgery, Plastic Surgery and Urology.

The DSRB secretariat may triage your application to another Domain if it is deemed more appropriate. In some cases, this will be done in consultation with the Chairperson or a ‘Triage Board’, which comprises the Chairpersons of all Domains.</td></tr>
<tr><th>B4</th><th>Has the application been previously rejected by any IRB? (Including NHG DSRB)*</th></tr>
<tr><td>Definition / Explanation</td><td>If this proposal or a similar proposal had been submitted and disapproved by any IRB/DSRB in the past, please state the name of the IRB/DSRB and provide the reason for the rejection.</td></tr>
</table>

Application Form: Section C - Conflict of Interest Declaration

Sect / No	Question
C1	**Does the Principal Investigator or any study team member have any potential conflict of interest? The Declaration is also for the immediate family members of the person(s) listed below.***
Objective	To review the extent of the conflict and recommend the PI to implement an appropriate

	management plan.
Definition / Explanation	The Conflict of Interest Declaration section must be completed by the PI on behalf of the Study Team if any member of the Study Team has any potential conflicting interest while conducting the research. This Declaration also includes any Conflict of Interests of their immediate family members (includes parents, siblings, spouse and each dependent child). Any such member(s) must complete and submit their Declarations when this application is submitted. The PI is responsible for checking and ensuring that accurate information is submitted to the DSRB. **Conflicting Interest** – A conflicting interest can be broadly defined to refer to any interest of the investigator and/or study team member or immediate family (includes parents, siblings, spouse and each dependent child) that competes with the investigator's/ study team member's obligation to protect the rights and welfare of research participants. **Financial Interest** – Financial interest related to the research means financial interest in the sponsor, product or service being tested. Significant 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 DSRB **within 30 days** via study amendments if any of the circumstances relevant described herein change during the conduct of the research. If any of the study team members has a Conflict of Interest, please select 'Yes' for the respective person who has Conflict of Interest. Note that there are 3 additional questions if 'Yes' is selected. **(i)** Please tick all the applicable boxes. Please declare the type(s) of Conflict of Interests applicable to this study: ▪ Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any organisation 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. ▪ Employment or executive relationships with 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 subject recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff. ▪ Others, to specify (financial/non-financial conflict). **(ii)** Please provide details of all of the above Conflict of Interest. Please describe in greater details (e.g. the amount/extent/frequency) of Conflict of Interest. **(iii)** Please describe the plan to manage all of 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). Additionally, Study Team Members involved in the design, conduct and reporting of the research

	will be required to declare Financial Conflict of Interest (Form is available for download from the NHG Research Website).

Application Form: Section D - Nature of Research

Sect / No	Question
Section D1	**Please select one category that best describes your research activities.***
Definition / Explanation	**Clinical Trials** Choose this if your research involves: (1) administering a drug, device, or biologic as part of the research intervention, or (2) performing surgical procedures as part of research intervention. If this category is chosen, please indicate which of the following does the study involve: (1) Drug / Biologic* (2) Device^ (3) Surgical Procedure **If 'Drug/Biologic' is chosen, please indicate the Phase (I/II/III/IV) of the trial.* *^If 'Device' is chosen, please indicate if it is a registered (Class A/B/C/D) or unregistered medical device. If you are unsure of the classification of a medical device, please check with the Health Sciences Authority (HSA). There is also a Medical Device Risk Classification Tool available on the HSA website at https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/risk-classification-tool.html.* **IMPORTANT NOTE:** Approvals from HSA may be required. You should check with HSA if you are unsure. **Questionnaire/ Survey/ Interviews** Choose this if your research involves: (1) administering questionnaires/surveys/interviews. This type of research may also include a medical records review component. **IMPORTANT NOTE:** If a combination of medical record review and questionnaire/survey/interviews are involved, please select 'Questionnaire/Survey/Interviews'. **Medical Records Review** Choose this if your research involves: (1) collection of data for a specific research project by review of medical records including results of routine diagnostic tests performed for standard clinical purposes. The data collection could be done prospectively and/or retrospectively. **Clinical Research** Choose this if your research involves: (1) collection of blood by venepuncture, finger stick etc. or (2) prospective collection of biological specimen by invasive or non-invasive means including biopsies, fine needle aspiration, fundoscopy etc. or (3) collection of data through research procedures such as X rays, MRI, ultrasound, ECG, EEG, etc. or (4) any other research categories that are not listed in the options above.
Section D2	**Is this a US FDA IND/IDE study or data is intended to be reported to FDA in support of an IND/IDE application?***
Objective	This is to ensure that the study also complies with the applicable US Regulations. The DSRB will also

	be required to report any reportable events to the appropriate Regulatory Authorities, including the US Food and Drug Administration (FDA).
Definition / Explanation	The current US Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across the state lines in US. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many US states, it must seek an exemption from that legal requirement. The Investigational New Drug Application (IND) is the means through which the sponsor technically obtains this exemption from the US FDA. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in US in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA. **IMPORTANT NOTE:** US FDA-regulated (IND) research activities cannot qualify for Exemption from DSRB Review and Waiver of Informed Consent. The application must be submitted using the DSRB Application Form 1 – Non Exempt category.
Section D3	**Is this study subjected to any of the following regulations:** **US Code of Federal Regulations 45 CFR 46** **US Code of Federal Regulations 21 CFR 50** **US Code of Federal Regulations 21 CFR 56** **US Code of Federal Regulations 21 CFR 312** **US Code of Federal Regulations 21 CFR 812** **Others**
Definition / Explanation	If your study is US FDA-regulated (IND/ IDE), please tick all the appropriate regulations that apply: • US Code of Federal Regulations 45 CFR 46 – describes the additional protections for Research Involving Foetuses, Pregnant Women, Prisoners and Children • US Code of Federal Regulations 21 CFR 50 – describes the Informed Consent of Human Subjects • US Code of Federal Regulations 21 CFR 56 – describes the Institutional Review Boards • US Code of Federal Regulations 21 CFR 312 – describes the Investigational New Drug Application • US Code of Federal Regulations 21 CFR 812 –describes the Investigational Device Exemption • Others

Application Form: Section E - Study Funding Information

Sect / No	Question
E1	**Who will be responsible for the payment and compensation of injury or illness arising from participation of research participants in the study? ***
Objective	To ensure that the PI has adequate insurance coverage to provide reimbursement and compensation to research participants for any injury or illness arising from their participation in the study.
Definition /	As a guide, both sponsored and investigator-initiated research studies which are approved by the

Explanation	NHG DSRB and whose principal investigators (PIs) are from public healthcare institutions are declared for insurance under the National Clinical Trial (CT) Group Insurance Policy. Currently, the National CT Group Insurance Policy does not cover for investigators or research participants who are not from the public healthcare institutions. It may be necessary for PIs to obtain additional insurance coverage for their co-investigators, collaborators and /or research participants who are not from the public healthcare institutions. You may contact your institutional research office / clinical research unit for more information on available insurance coverage options. **IMPORTANT NOTE:** **For Sponsored Studies:** Sponsors should be primarily 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 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. PIs should also check whether the pharma-sponsors will be providing monitoring for the study.
E2	**Please give information regarding the study's funding source or Sponsor information. ***
Definition / Explanation	Please choose one of the following options that best describe the study's funding source. **<u>No funding is required for this study to be carried out</u>** If 'No funding is required for this study to be carried out' is selected, proceed to Section E3 after the selection is made. **<u>Pharmaceutical / Industry Sponsored</u>** If 'Pharmaceutical/Industry Sponsored' is selected, please provide: • Name of the Sponsor Company, and the contact information of the Sponsor. • Name of the Clinical Research Organization (CRO), and the contact information of the CRO, if applicable Please be informed that an initial DSRB Review fee applies. Please refer to www.research.nhg.com.sg for the DSRB Review Fees. **<u>Grant / other source(s) of funding</u>** If there is a grant, please provide the name of Grant agency and Grant name, Amount, Deadline of Grant application and if the Grant application has been approved. • If the Grant application has been approved/successful, please provide the date of grant approval, expiry and the amount awarded. Please attach the grant approval letter or notification of award. However, if it is a US federally funded research, please attach the approved grant proposal and all relevant documents approved by the grant body (e.g. study protocol, consent form). • If the Grant application is pending approval, please indicate if the study's initiation is dependent on the Grant approval.

	○ If you have alternative financial source(s) to fund this study, select 'No. The study can be started without the Grant'. ○ If you do NOT have alternative financial source(s) to fund this study, select 'Yes. The study is dependent on the Grant to start'. **<u>If there are other source(s) of funding, please select 'Others' under 'Name of Grant Agency or Grant Name' and provide the relevant details on the funding.</u>** **IMPORTANT NOTE:** 1. The DSRB will only start reviewing the study when we receive a notification that the Grant Application is successful. Please contact the DSRB once you have received information on the grant results to start the DSRB review process. 2. If your grant application was not successful, please inform the DSRB as soon as possible and describe your next course of action (e.g. withdrawal of the study, look for alternative funding).
E3	**Will the funding cover all subject study-related drugs, devices, procedures, tests and visits?***
Objective	To ensure that the PI has sufficient funding available to cover all research-related costs (e.g. funding from Pharmaceutical Company, Grant, Department Funds).
Definition / Explanation	Please note that it is generally not appropriate for research participants to pay for research-related procedures.

Application Form: Section F – Research Methodology

Objective: The DSRB requires detailed information on the study methodology in order to conduct a thorough review of research studies to ensure that the rights, safety, and well-being of human research participants involved in a research study are protected.

Sect / No	Question
F1	**What are the Specific Aims of this study? ***
Definition / Explanation	Please describe the Specific Aims of the study.
F2	**What is the Hypothesis of this study? For qualitative studies, please provide the research question instead. ***
Definition / Explanation	Please describe the study hypothesis or research question.
F3	**Please state concisely the importance of the research described in this application by relating the specific aims to the long term objectives.***
Definition / Explanation	Please describe why this study is important.
F4	**Please describe the background to the current study proposal. Critically evaluate the existing knowledge and specifically identify the gap that the proposed study is intended to fill.***
Definition / Explanation	In this section, please include the following: • General introduction of the study (e.g. Describe current international and/or local standards) • Evidence or any previous literature that suggest current gaps • Rationale of study / Why are you prompted to do this study?

F5	**Please provide a list of relevant references.***
Definition / Explanation	Please list at least two relevant papers pertaining to the importance of the study.
F6	**Please submit a copy of at least two relevant papers.***
Definition / Explanation	Please attach at least two relevant publications that support the conduct of the study.
F7	**Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. If this study involves the extraction of data from existing medical records/database, please indicate the period of data that will be extracted (e.g. 1 Jan 2000 - 31 Dec 2010) and the database to be accessed. (Note: NEHR cannot be accessed for research).***
Definition / Explanation	Please provide details on the experimental design used to accomplish the specific aims of the project (e.g. two period crossover, case control, placebo controlled). The description should include, but is not limited to, information on blinding, randomization, number of study arms, phase of trial, approximate time to complete study recruitment, expected duration of subject participation, sequence and duration of all trial periods (including follow up), changes in scheduling, single or multi centre, healthy or sick population, in or outpatient etc. If this study involves **medical records review**, please specify the period of data collection in date – month- year format (e.g. 1 Jan 2000 - 31 Dec 2010). **Retrospective medical records review:** Evaluates patient data that is **existing** at the time the protocol is submitted to the IRB for initial approval. This type of chart review uses information that has usually been collected for reasons other than research, such as administrative data and medical records. Therefore, the outcome of interest has already occurred by the time the study is started. **Prospective medical records review:** Evaluates patient data that **does not yet exist** at the time the protocol is submitted to the IRB for initial review. The protocols are designed before any information is collected. Study subjects are identified and followed forward to see if the outcome of interest happens over time. Research conducted based on prospective medical records review will require informed consent from the research participants whose data will be obtained for the prospective period. If this study involves the administration of an **anonymous survey**, please also describe in detail, how the questionnaire/demographic data collection form will be distributed and collected back to ensure anonymity (e.g. the questionnaire/demographic data collection forms will be given to participants at the clinic and they can return the completed forms by dropping them into a collection box or by using the return envelope provided).
F8	**Please provide details on (i) sample size and power calculation and (ii) the means by which data will be analysed and interpreted.** **If this is a pilot study/qualitative study and no sample size calculation is performed, please provide a rationale on how the recruitment target is determined.***
Definition / Explanation	Please describe (i) how you derived with the required sample size for the study and (ii) which statistical test(s) will be used to analyse and interpret the data. Where applicable, please specify the following: • Null and alternate hypothesis • Type I error rate • Type II error rate

	The means by which data will be analysed and interpreted can come in the form of data analysis software that will be applied. (E.g. SPSS)
F9	**Please list all activities that are carried out for the purpose of research in this study and attach the data collection form (if any) under "Attachments" tab, Section "Others".***
Definition / Explanation	Please list all activities that are performed **solely** for the purpose of the research. E.g. The drawing of an extra 20ml of blood for research, or an additional biopsy taken for research purposes. If research data specific to this study is to be recorded onto any form of database such as excel worksheets, or word documents (e.g. data collection form/ case report form) please provide a copy of it for review. Please ensure that the document title, version number and version date is included on the data collection form/case report form itself. This is mandatory for approval purposes. Approved version controls will be stated in the DSRB Approval letter for proper audit trail. **IMPORTANT NOTE:** The data collection form (DCF)/ case report form (CRF) should not contain any subject identifiers (e.g. Name, NRIC, Date of Birth) or allow sticker labels containing subject identifiers to be pasted on it **unless they are to be used as source documents**. This is to ensure data confidentiality.
F10	**Please list all activities that are performed for routine diagnostic or standard medical treatment as part of the research participant's standard care.** **Research-related activities stated in F9 should be excluded from this section.***
Definition / Explanation	Please list all activities that are also carried out as part of **standard care** of the research participant. E.g. Routine blood taking of Full Blood Count and Biochemistry, biopsies taken for diagnosis and are required as part of the research participant's standard care.
F11	**Please describe the subject's visits (frequency and activities involved).** **Please attach study schedule if available. ***
Definition / Explanation	Please list all research-related participants' visits (frequency and activities involved). If multiple visits are involved, please attach a study schedule. Please ensure that the document title, version number and version date is included on the study schedule document itself. This is mandatory for approval purposes. Approved version controls will be stated in the DSRB Approval letter for audit trail.
F12	**Discuss the potential difficulties and limitations of the proposed activities and alternative approaches to achieve the aims.***
Definition / Explanation	Please list the potential difficulties and limitations of the proposed activities that may lead to failure to achieve the aims and/or failure to complete the study. In addition, list all corresponding alternative approaches to achieve the aims/overcome the difficulties and limitations.
F13	**What are the Potential Risks to Subjects?***
Definition / Explanation	Please list all potential risks to research participants (both common as well as the rare ones). **IMPORTANT NOTE:** There is always a possibility of risks to participants. Risks may include discomfort or breach of confidentiality. It is not appropriate to provide a nil response as all research procedures have some risks or side effects. For retrospective medical records review or questionnaires study, although the risks are expected to be minimal, there may be a potential risk from the breach of confidentiality.

F14	**What are the Potential Benefits (direct as well as indirect) to research participants and to the society? ***
Definition / Explanation	Please list the potential benefits to research participants (direct as well as the indirect benefits) and to the society or population beyond the research participants. Indirect benefit may refer to the medical knowledge gained from this research to the participants' disease.
F15	**Preliminary Studies/ Progress Reports. Please provide an account of the Principal Investigator's preliminary studies (if any) pertinent to this application.***
Definition / Explanation	If the PI or study team has done related studies for the current submission, please include the relevant information (e.g. short description of the previous study/studies) to support this study.
F16	**What is the estimated time needed to conduct this study? ***
Definition / Explanation	Please state the estimated time (in Year & Month format) needed to conduct this study (e.g. 2 Years 0 Months).
F17	**Does this study have a Study Protocol?** **Note: For Clinical Trials, investigators must submit a Study Protocol for review. ***
Definition / Explanation	(i) If 'Yes' is selected, you will be required to attach a copy of the Study Protocol. (ii) Click on the 'Attach' button to submit a copy of the Study Protocol. **IMPORTANT NOTE:** Investigators conducting Clinical Trials **must** submit a Study Protocol for DSRB review. You may refer to the NHG Research website for the Study Protocol template. Before submitting the Study Protocol, please ensure that the details provided in the Protocol correspond with details provided in the main DSRB Application Form to minimise queries by the DSRB. This is also important to prevent study deviations and non-compliance which could happen when Study Team Members refer to documents with differing information.
F18	**The PI is responsible for ensuring that all study research participants give informed consent before enrolling into the study.**
Definition / Explanation	Please select all the applicable consent scenarios.* **Informed Consent will be taken for study subjects.** Please note that the DSRB requires that written informed consent should be obtained from all research participants and documented prior to their participation in any research, unless the DSRB approves the waiver of consent or waiver of documentation of consent. **Waiver of Informed Consent is requested for study subjects.** If you would like to request for a waiver of consent or wavier of documentation of consent, please make the relevant selection and provide your justification/rationale in Section Q or P6 respectively. There are 3 scenarios for the waiver of informed consent. They are differentiated according to the 3 scenarios as described in the Fifth Schedule of the Human Biomedical Research Act. Please select all the scenarios that are applicable to your study. If you are conducting a human biomedical research that is regulated by the Human Biomedical Research Act, then Section Q 'Consent Process - Waiver of Consent' will display the waiver criteria relevant to the scenarios which you have selected. If you are not conducting a human biomedical research, then Section Q 'Consent Process - Waiver of Consent' will display the waiver criteria according to the DSRB policies.

	Some studies may also use anonymised data and/or biological materials in the same study to study a specific sub-group or sub-population. Therefore there is an additional checkbox for principal investigators to indicate if it applies to their study.

Application Form: Section G – Research Details- Clinical Trials

Objective: The DSRB requires detailed information on the investigational product used in order to conduct a thorough review of the study to ensure that the rights, safety, and well-being of human research participants involved in a research study are protected.

Sect / No	Question
G1	**Please provide information on the study drug / device / surgical procedures that will be used, and describe how you plan to manage the receipt, handling, storage, utilization, and disposal of the study drug/device.***

Definition / Explanation	Information to be provided may include:
	• Background information on the trial product, the safety issues and duration of exposure.
	  ○ For drugs, please include:
	  ▪ Information on dosage. Clearly explain the rationale for the dose used during the study.
	  ▪ Describe in what form the study drug will be dispensed to the research participants.
	  ▪ Describe the drug regimen to be used. State any special precautions or warnings relevant for the study drug administration.
	  ○ For devices, please include:
	  ▪ Detailed device information from the sponsor, such as a description of the device and how it is used.
	  ▪ Diagrams and/or in situ photographs of the device are very useful.
	  ▪ Directions for use, typically provided by the sponsor or manufacturer.
	• If applicable, describe if there will be blinding, the measures that will be undertaken to blind the study participants and/or study staff from participant treatment assignments. State when un-blinding is expected and if/when participants will be told their assignments.
	• Describe product's storage needs. Include storage requirements and stability (temperature, humidity, security and container).

G2	**Please attach the Investigator's Brochure or local product information sheet/leaflet, as applicable.**
Definition / Explanation	Click on the 'Attach' button to submit a copy of the Investigator's Brochure or local product information sheet/leaflet. For clinical trials involving devices, if possible, please attach photographs of the device and how it will be used.
G3	**Describe alternative treatments used at your institution for this condition.***
Definition / Explanation	If the drug/device/procedure is the experimental aspect of the study, please indicate the standard/alternative treatment available for the condition of the participant. If this section is not applicable to your study, please indicate "NA".
G4	**Is this a placebo controlled trial?***
Definition / Explanation	If 'Yes' is selected, you will be required to answer the following questions and provide answers in the textboxes provided:

	(i) <u>Explain what 'standard of care' therapy is available for this condition.*</u> Please provide some examples of therapy used for the research participant's condition outside of research (e.g. the first line medication; second line medication; behavioural support; routine procedures already adopted by the department). **(ii) <u>Discuss the ethical implications of using placebo instead of 'standard of care' therapy in this situation.*</u>** Please discuss and explain the decision/determination made to use a placebo as a comparator on this study or if there is a standard of care therapy, why is a placebo used in place of the standard. **(iii) <u>Address the issues of safety and efficacy of other available therapies.*</u>** You may wish to include information regarding any replacement therapy available in the market, existing treatment approaches, etc. **(iv) <u>What is the total duration the research participants would be on the placebo arm of the study?*</u>** Total time in days/ months/ years that the research participants will be issued with placebo. **(v) <u>What is the greatest potential harm that the research participants might be exposed to as a result of not receiving effective therapy?*</u>** You may wish to highlight the possible implications to the research participants as a result of not receiving effective therapy (as the placebo does not contain any active ingredient) for their condition (e.g. condition of participants may deteriorated in the absence of active treatment). **(vi) <u>What are the procedures in place to safeguard research participants receiving placebo?*</u>** You may wish to include information on any additional procedures to safeguard research participants receiving placebo such as any additional therapy for those in placebo arm, or additional procedures, etc or provide a detailed exit protocol **(vii) <u>Do you have any other comments supporting the use of a placebo in your study?*</u>** Please include any other remarks concerning the administration of placebo.

Application Form: Section H – Recruitment Details

Sect / No	Question
H1	**How will potential research participants be identified?**
Objective	To determine how the research participants will be identified and approached for recruitment. Recruitment process should promote voluntary participation and not be coercive.
Definition / Explanation	• **<u>Referral by attending healthcare professional</u>** o The potential participants should first be informed about the study by their attending healthcare professionals. If the potential participants are agreeable, the attending healthcare professional can then refer them to the study team. • **<u>Persons with dependent relationship with study team (e.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)</u>** o Please describe how the study team will manage the dependent relationship to prevent coercion or undue influence. E.g. Participation is voluntary and the research participants may withdraw from the study at any time without being penalized. For participants who are patients of the

	Investigator, their decision to participate in the research study will not affect the standard of care provided to them. Where possible, the informed consent process will be conducted by a qualified study team member, delegated by the PI, who is not involved in the primary care for the research participant. • **Databases** o If 'Databases' is selected, please indicate which databases will be used ▪ If 'Standing databases/other department's databases/ Institution's clinical databases are selected, please indicate (i) whether the database is registered as an NHG Standing Database, the reference number, and (ii) if the custodian has given permission for you to use the data from this database. o If 'Medical Records' is selected, please elaborate how the names and NRIC of research participants will be obtained by you to extract the records from the Medical Records Office. o If 'Other Data Sources' is selected, please elaborate and ensure that approval for use of the data has been obtained. • **Other methods of subject identification** o Please indicate your method(s) of subject identification (e.g. Advertisement, word of mouth).
H2	**Who will make the first contact with research participant? ***
Objective	To determine the person(s) best suited to approach potential research participants.
Definition / Explanation	Please identify the person(s) who will make the first contact with the research participants. E.g. The healthcare professionals involved in the clinical care of the eligible patients will be the first to approach them to ask if they are keen to participate in the research study. **IMPORTANT NOTE:** Contact with potential research participants should be made in accordance to the Institution's Personal Data Protection Act (PDPA) policy. Please enter "NA" if there is no participant interaction in this study.
H3	**How will the research participant be contacted? ***
Objective	To determine if methods to contact potential research participants are appropriate.
Definition / Explanation	Possible methods of subject recruitment can be: (a) Face-to-face contact when they come for their prospective regular clinic visits. (b) Call back patients who have visited the hospital/clinic in the past o Permission should be obtained from the primary physician/head of the department before calling these patients (if you are not the attending physician of these patients). (c) Call back participants who had previously participated in other research studies o These participants may be re-contacted only if they have provided consent for the study team to do so. **IMPORTANT NOTE:** 1. Contact with potential research participants should be in accordance to the Institution's

	Personal Data Protection Act (PDPA) policy. 2. An invitation letter should be mailed to the potential research participants before calling them. Please submit the invitation letter and a sample telephone script under Section H4 for DSRB review. Please enter "NA" if there is no participant interaction in this study.
H4	**Will any advertising/ recruitment materials be used to recruit research participants?***
Objective	Materials to be used for recruiting potential research participants should meet DSRB requirements and should only be used after obtaining written approval from the DSRB.
Definition / Explanation	Please indicate the type of recruitment materials that will be used: **(i) Posters** Please state the location(s) where the posters will be placed (e.g. in the hospital lift, in the general waiting area in Clinic X), and attach a copy of the poster.* **IMPORTANT NOTE:** The PI / members of the research team is/are recommended to work with the Corporate Communications Office to confirm the location(s) where the poster(s) will be placed. **(ii) Brochures** Please state the location(s) where the brochures will be placed (e.g. in the general waiting area in Clinic X), and attach a copy of the brochure.* **(iii) Advertisements in Newspapers / Magazines / Publications** Please state which publications will be carrying the advertisements, how many times the advertisement will run for, and attach a copy of the advertisement.* **(iv) Advertisements on Radio / TV** Please state which radio / TV stations will be carrying the advertisements, how many times the advertisement will be aired, and attach a copy of the advertisement.* **(v) 'Letter of Invitation' to potential research participants.** Letter of Invitation' refers to email, letters or any form of documents used as part of the recruitment strategy, with the intention of inviting the research participants to participate in the study. Please attach a copy of the Letter of Invitation for DSRB Approval before use. **(vi) Letter to Doctors requesting for referrals.** DSRB review and approval is not required for letters to doctors for referring potential research participants. **(vii)Other types of materials will be used.** Please elaborate on the recruitment material(s) that will be used, and attach a copy for DSRB review. **IMPORTANT NOTE:** 1. Guidelines for preparing advertisements Any advertisement to recruit research participants should be limited to the information the prospective research participants need to determine their eligibility and interest. The following information must be included: (i) That volunteers are being recruited for research. (ii) The name and address of the institution conducting the research. (iii) The condition under study and/or the purpose of the research.

	(iv) In summary form, the criteria that will be used to determine eligibility for the study. (v) A brief list of participation benefits, if any (e.g. a no cost health examination). (vi) The time or other commitment required of the research participants. (vii) The location of the research and the person or office to contact for further information. The advertisement should not, either explicitly or implicitly: (i) State or imply a certainty of favourable outcome or other benefits beyond what is outlined in the consent document and protocol. (ii) Make claims that the drug, device or biologic is safe or effective for the purposes under investigation. (iii) Make claims that the test article is known to be equivalent or superior to any other drug, biologic or device. (iv) Use terms such as "new treatment", "new medication" or "new drug" without explaining that the test article is investigational. (v) Promise "free medical treatment" when the intent is only to say research participants will not be charged for taking part in the investigation. Advertisements may state that research participants will be paid, but should not emphasize the payment by such means as larger or bold type. Advertisements should not state the amount that will paid. (vi) Include any exculpatory language. (vii) Make claims about the drug, biologic or device under investigation that are inconsistent with currently approved labelling. 2. Please ensure that the document title, version number and version date is included on the recruitment materials submitted to DSRB. This is mandatory for approval purposes. (Approved version controls will be stated in the DSRB Approval letter for proper audit trail.)
H5	**Will any other recruitment strategies be used (e.g. talks in public places, societies etc.)?***
Definition / Explanation	If you have other method(s) to broadcast/advertise your study to recruit research participants, other than recruitment materials, please select 'Yes' and elaborate on the method(s). E.g. Event(s)/Talk(s)/Public forum(s) at hospitals, schools, and public places (such as Community Centres). Please specify where, when, how and the agenda of the event/talk/forum. PIs should ensure that this information is submitted to the DSRB as early as possible (not later than 2 weeks prior to the event) to allow sufficient time for DSRB's review and approval.
H6	**(If applicable) Please indicate the length of time of the subject's direct involvement in the study. E.g. For clinical visits, examinations etc.**
Objective	To determine if the participant's duration of involvement is reasonable.
Definition / Explanation	Please indicate the time period (e.g. 6 weeks) during which the research participants will be involved in study related activities or taking study medication. Please enter "NA" if there is no participant interaction in this study.

Application Form: Section I – Study Sites & Recruitment Targets

Sect / No	Question
I1	**Please state the target number of research subjects to be recruited for each study site in Singapore. If exact numbers are not available, please give an approximate number range in the Recruitment Target Minimum and Maximum columns.**

	Please note that recruiting subjects beyond the Max. No. without DSRB's approval would constitute a Non-Compliance. If you intend to recruit beyond the Max. No., please submit a study amendment to increase the recruitment target. **For the distribution of Males, Females and Children to be recruited onto the study, please use the Recruitment Target Max. No. to provide an approximate distribution ratio.**
Objective	To determine the adequacy of the sample size and equitable selection of research participants.
Definition / Explanation	Please indicate the estimated minimum and maximum number of research participants which will be recruited at each study site. Please use the **estimated maximum number** to provide the distribution number of adult males, adult females and children (i.e. the sum of male, female and children to be recruited should not exceed the maximum recruitment target). If no actual research participants are involved, then state the target number of medical records, biological samples etc, to be collected/reviewed for the study. **IMPORTANT NOTE:** 1. Participants who have withdrawn will also count towards the total number of research participants recruited. When determining the estimated number, please make provisions for participant withdrawals. 2. The study site(s) reflected in this section are based on the sites selected in Section B1. If you would like to include additional site(s), please add them under Section B1.
I2	**Is this study part of an international study?***
Definition / Explanation	If there is any site(s) involved in this study outside of Singapore, please select 'Yes' and state the worldwide total target enrolment number. If an exact number is not available, please give an approximate number.

Application Form: Section K - Research Participant Characteristics

Objective: To determine if the selection of subjects is equitable.

Sect / No	Question
K1	**Please list the inclusion criteria.** **Note: For global studies, please modify the criteria according to local regulations (e.g. persons below the age of 21 who are not and were never married are considered minors in Singapore and would require parental consent prior to participation).**
Definition / Explanation	Please 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). If the study involves recruitment of different participant groups with different inclusion criteria, please list the inclusion criteria of the different groups separately. (e.g. healthy volunteers vs patients with particular disease indication) Please also ensure that the symbols used are displayed accurately. Use ">=" or "<=" to represent "more than or equals to" or "less than or equals to" respectively.
K2	**Please list the exclusion criteria.**

	Please state clearly, if pregnant women will be excluded from the study.
Definition / Explanation	Please 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). Please also ensure that the symbols used are displayed accurately. Use ">=" or "<=" to represent "more than or equals to" or "less than or equals to" respectively.
K3	**Please state the age group of the research subjects. ***
Definition / Explanation	Please state the numeric age, and then select the unit (years, months or days). This section should correspond with Section K1 and K2, where applicable. **IMPORTANT NOTE:** Persons who are less than 21 years old and have never been married are considered minors and will require additional safeguards (e.g. parental consent) to protect their rights, safety and welfare in research. If minors will be included in the study, please indicate so in Section K6.
K4	**Are there any recruitment restrictions based on the gender of the research subjects? ***
Definition / Explanation	Please explain the rationale for a gender bias.
K5	**Are there any recruitment restrictions based on the race of the research subjects?***
Definition / Explanation	Please explain the rationale for a race bias.
K6	**Does the study involve any vulnerable research participants? ***
Definition / Explanation	Please select the applicable population(s) from the list of selections: • If **Pregnant Women, Foetuses and Neonates** is selected, you will be required to respond to Section L. • If **Children (persons who are less than 21 years of age)** is selected, you will be required to respond to Section M. • If **Prisoners** is selected, you will be required to respond to Section N. • If **Cognitively Impaired persons** is selected, you will be required to respond to Section O. • If '**Others**' is selected, please describe the population, explain why the research must recruit this group of research participants (as opposed to other research participants who are not vulnerable) and list the safeguards that will be in place to protect their rights and welfare.
K7	**Does the study involve any of the following?*** • **Inpatients** • **Outpatients** • **Healthy volunteers** • **Not applicable** • **Others (e.g. parents, students, residents, house owners)**
Objective	To identify the study populations involved as the recruitment and consent process should be tailored according to the individual participant group(s).
Definition / Explanation	Please select the applicable group(s).

Application Form: Section L - Research Participants – Pregnant Women, Foetuses & Neonates

Objective: The DSRB regards pregnant women, human foetuses, neonates of uncertain viability and nonviable neonates as a vulnerable population and requires additional protections to be in place when they are involved in research.

Sect / No	Question
L1	**Please indicate if your research involves:*** • **Pregnant Women and Foetuses** • **Neonates of Uncertain Viability and/or Nonviable neonates** • **Viable neonates**
Definition / Explanation	Please tick all the applicable categories. 1. **Neonates of uncertain viability** – Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met: (a) The DSRB determines that: (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate from the research. (b) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally acceptable representative is obtained, except that the consent of the father or his legally acceptable representative need not be obtained if the pregnancy resulted from rape or incest. 2. **Nonviable neonates** - After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met: (a) Vital functions of the neonate will not be artificially maintained. (b) The research will not terminate the heartbeat or respiration of the neonate. (c) There will be no added risk to the neonate resulting from the research. (d) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. (e) The legally effective informed consent of both parents of the neonate is obtained, except that the waiver and alteration provisions do not apply. (i) However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy had resulted from rape or incest. (ii) The consent of a legally acceptable representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph. 3. **Viable neonates** – A neonate that has been determined to be viable after delivery may be included in research only to the extent permitted by, and in accordance with, the requirements stated in Section M, Research involving Children. 4. Research involving (after delivery) the placenta, dead foetus, macerated fetal material, or cells/ tissue/organs excised from a dead foetus, shall be conducted only in accordance with any regulations governing such activities.
L2	**For research studies that involve pregnant women, foetuses and/or neonates, the research must**

	meet specific criteria. Please provide protocol specific information explaining how your proposed research project meets ALL of the following criteria. **Describe if appropriate 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 fetus.***
Objective	Where scientifically appropriate, preclinical studies should be conducted and the results from these studies would provide data for assessing the potential risks to pregnant women and fetuses.
Definition / Explanation	Information regarding the potential risk of fetal toxicity should be submitted to the DSRB to do a risk-benefit assessment. If animal reproductive toxicity studies are complete, the results should be presented, with some explanation of their significance in humans. If these studies have not been completed, other pertinent information should be provided, such as general assessment of fetal toxicity in drugs with related structures or pharmacological effects. If no relevant information is available, the informed consent should explicitly note the potential for fetal risk.
L3	**Describe how the risk to the foetus will be minimized.**
Definition / Explanation	Explain how you would minimize the risk to the foetus to attain the research objectives.
L4	**Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable subjects.***
Definition / Explanation	Kindly state all additional steps that will be taken to minimize coercion and to protect the rights, safety and wellbeing of study participants.
L5	**Special Informed Consent Requirements (Check all that apply)***
Definition / Explanation	You may obtain informed consent from ONLY the pregnant women if your study meet any of the following: • 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. You must obtain informed consent from the pregnant women AND the father of the foetus if your study meet the following: • Research holds out the prospect of direct benefit solely to the foetus. The Informed Consent Form(s) must provide information regarding the reasonably foreseeable impact of the research on the foetus or neonate.
L6	**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.***
Definition /	Please select a response 'Yes' or 'No' in reference to the Assurances as listed.

Explanation	

Application Form: Section M - Research Participants – Children

Objective: The DSRB regards children as a vulnerable population and requires additional protections to be in place when they are involved in research.

Sect / No	Question
M1	**Describe if appropriate studies have been conducted on animals and adults first, and data is available to assess risks to children participating in the research.**
Definition / Explanation	If such studies have been published, please provide a copy of the paper.
M2	**Please justify the need to involve children and if the research question can be answered through alternative means (e.g. involving adults only).**
Definition / Explanation	Kindly explain why the research has to be conducted in children e.g. research question is related to disease or treatment in children. **IMPORTANT NOTE:** Research involving children will be classified into one of the following three categories: a. **CATEGORY 1** – Research that does not involve more than minimal risk. b. **CATEGORY 2 –** Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant and the relation of the anticipated benefit to the risk is at least as favourable to the participant as that presented by alternative approaches. c. **CATEGORY 3** – Research involving greater than minimal risk and no prospect of benefit to the individual participant. In order to approve research in this category, the DSRB must determine that: i. The risk of the research presents no more than a minor increase over minimal risk. ii. The intervention or procedure presents experiences to the participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations. iii. The intervention or procedure is likely to yield generalisable knowledge about the participant's disorder or condition which is of vital importance for the understanding or the amelioration of the disorder or condition.
M3	**Describe how the relation of potential benefits to risks is at least as favourable as that presented by alternative approaches.**
Definition / Explanation	If your study involves greater than minimal risk but offers the prospect of direct benefit to the individual participant, then please justify how the anticipated benefits relative to the risks is at least comparable to the treatment options available (or the absence of any clinically available treatment).
M4	**Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable subjects.**
Definition / Explanation	Please state if additional steps will be taken to minimize risks and to protect rights, safety and wellbeing of research participants.
M5	**What are the provisions for obtaining the child's assent/consent and parent's/legally acceptable representative's permission? * (Check all that apply)** **- Assent/consent will be obtained from all children above 6 years old and parent's/legally acceptable representative's permission will be obtained.**

	- Assent/consent will not be obtained from the children. Only parent's/legally acceptable representative's permission will be obtained. **- Parent's/legally acceptable representative's will not be obtained. Only assent/consent will be obtained.** **- Neither the children's assent/consent nor parent's/legally acceptable representative's will be obtained.**

Definition / Explanation	Please check all sections which are applicable for this study.
	
	• Assent/consent will be obtained from all children above 6 years old and parent's/legally acceptable representative's permission will be obtained.
	  o Please provide a separate Assent Form to document assent for children aged 6-12 years old.
	  o Please provide provision for Signature of Child on Parental Consent Form for children age 13-20 years old.
	
	• Assent/consent will not be obtained from the children. Only parent's/legally acceptable representative's permission will be obtained.
	  o Please provide a rationale on why assent/consent will not be obtained from the children and only parent's/legally acceptable representative's permission will be obtained (e.g. only children below 6 years old will be recruited).
	
	• Parent's/legally acceptable representative's permission will not be obtained from the parents. Only assent/consent will be obtained.
	  o Please provide a rationale on why parent's/legally acceptable representative's permission will not be obtained from the parent/ legally acceptable representative and only assent/consent will be obtained (e.g. the research is on sensitive topics and the children may not want their parents to be informed).
	
	• Neither the child's assent/consent nor parent's/legally acceptable representative's permission will be obtained.
	  o Please provide a rationale on why neither the child's assent/consent nor parent's/legally acceptable representative's permission will be obtained.
	
	IMPORTANT NOTE:
	PARENTAL PERMISSION – DSRB 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 M2), permission from at least one parent or legal guardian must be obtained.
	(c) For research approved under Category 3 (See Section M2), 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.
	
	ASSENT BY THE CHILD – While a child may not have sufficient understanding and intelligence to understand what is proposed in the research, he/she may possess the ability to assent to or dissent from participation. In general, the DSRB recommends that assent be obtained from children who are over six years old. The DSRB will determine whether all or some of the children are capable of assent by considering the following:
	(a) Nature of research
	(b) The age, status, condition of the proposed subjects, and/or
	(c) Maturity and psychological state of proposed subjects.
	
	Primary school aged children (6–12 yrs old) should be provided with a short Assent Form in simple language that clearly explains discomforts and inconveniences that the child may experience if he or

	she agrees to participate. The document should also emphasize the voluntary nature of the research and that the child may refuse to participate without any consequences. For research involving children of secondary school age and older children (13-20 yrs old), provision may be made in the same Informed Consent Form that will be signed by the parents for the signature of the child. If they are assessed to be of sufficient understanding and intelligence to understand what is proposed in the research, then their informed consent should be obtained. The DSRB must review and approve the Assent Form and Informed Consent Form prior to initiation of the study. A template of the Assent Form and Informed Consent Form can be downloaded from NHG Research Website.

Application Form: Section N - Research Participants – Prisoners

Objective: The DSRB regards prisoners as a vulnerable population and requires additional protections to be in place when they are involved in research.

Sect / No	Question
N1	**Research involving Prisoners - Please provide protocol specific information explaining how your proposed research project meets the following criteria.** **Does the research purpose justify enrolling prisoners? ***
Definition / Explanation	Kindly justify the reason(s) for including prisoners in this study (e.g. particular research question can only be addressed by involving prisoners). **IMPORTANT NOTE:** Only certain kinds of research may involve prisoners as research participants: (a) Studies (involving no more than minimal risk or inconvenience) of the possible causes, effects, and processes of incarceration and criminal behaviour; (b) Studies (involving no more than minimal risk or inconvenience) of prisons as institutional structures or of prisoners as incarcerated persons; (c) Research on particular conditions affecting prisoners as a class; and (d) Research involving a therapy likely to benefit the prisoners who are involved as research participants
N2	**Is there any evidence of duress, coercion, or undue influence in the particular prison(s) from which research participants will be recruited? ***
Definition / Explanation	Please state if there will be any duress, coercion, or undue influence in the particular prison(s) from which participants will be recruited and provide the justification.
N3	**Are potential research related risks to prisoners comparable to risks that would be accepted by non-prisoner volunteers? ***
Definition / Explanation	Please justify if the risks of participating in a study to prisoners will be acceptable by non-prisoner research volunteers.
N4	**Describe the systems in place to ensure subject and data confidentiality.**
Definition / Explanation	Kindly explain all steps which will be taken to ensure the privacy of research participants and confidentiality of data (e.g. where and how consent will be taken, where the data will be stored, if the data is coded, who will have access to the data).
N5	**Describe any additional safeguards that will be provided to protect the rights, safety and welfare**

	of these vulnerable participants? *
Definition / Explanation	Kindly indicate if any additional steps are taken to ensure the rights, safety and well-being of research participants.

Section O - Research Participant – Cognitively Impaired Persons

Objective: The DSRB regards cognitively impaired persons as a vulnerable population and requires additional protections to be in place when they are involved in research.

Sect / No	Question
O1	**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).**
Definition / Explanation	Please provide your justification for including cognitively-impaired persons in this study including why the research cannot be carried out without their involvement (e.g. particular research question can only be addressed in cognitively-impaired persons).
O2	**Are adequate procedures for evaluating the mental status of prospective research participants employed to determine if they are capable of providing consent?**
Definition / Explanation	If 'Yes' is selected, please provide details on the procedures for evaluating the mental status of prospective research participants (e.g. with validated assessment such as Mini-Mental State Examination (MMSE)). If 'No' is selected, please justify the reason for not evaluating the mental status of prospective participants. **IMPORTANT NOTE:** All adults, regardless of their diagnosis or condition, should be presumed to be competent to consent unless there is evidence of a serious mental disability that would impair reasoning or judgment. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent. **DOCUMENTING CAPACITY** – For all research, regardless of study population, the person who obtains the subjects' consent must determine that the person has sufficient capacity to give consent. This is documented by the signature in the consent form of the person obtaining consent. In research studies that involve cognitively impaired persons, the DSRB may require the Investigator to conduct an independent assessment of capacity depending on the study design. For clinical trials regulated by HSA, it is required to have an independent assessment of capacity by a doctor. The DSRB may set qualifications for the person making assessment such as requiring a psychiatrist or geriatrician to make this assessment. The independent assessment should be documented by a formal note that is dated and signed. A template of the sample language for Documentation of Capacity can be obtained from NHG Research Website.
O3	**Will legally acceptable representatives (LARs) be approached to give consent on behalf of the individuals judged incapable of providing consent?**
Definition / Explanation	If 'No' is selected, please elaborate why a Legally Acceptable Representative (LAR) would not be approached to give consent on behalf of the individuals judged incapable of providing consent.
O4	**Will a separate Assent Form be used for cognitively impaired persons?**

Definition / Explanation	If 'Yes' is selected, please attach a copy of the separate Assent Form. It should be written in simple words which is appropriate to the level of understanding for the proposed population of cognitively impaired persons. If 'No' is selected, please justify the reason for not obtaining assent from the research participants.
O5	**If a research participant is incapable of giving valid consent, will his/her objection to participation be overridden?***
Definition / Explanation	The research participant's objection should be respected. However, if you propose to do otherwise, please provide justification for overriding the research participants' objection to participate.
O6	**Will the patient's physician or other health care provider be consulted before any individual is invited to participate in the research?***
Definition / Explanation	If 'No' is selected, please justify the reason for not consulting the patient's physician or other health care provider (e.g. the subject's participation in the research study does not interfere with his/her routine clinical care).
O7	**Is there a possibility that the request to participate may provoke anxiety, stress or any other serious negative response?**
Definition / Explanation	If 'Yes' is selected, please provide details on the additional measures that will be taken to manage this (e.g. a psychiatrist will be present during the consent taking process to monitor the signs and symptoms displayed by the potential research participants, and the consent taking process will be stopped if potential participants show any signs of distress).
O8	**Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.**
Definition / Explanation	Kindly indicate if any additional steps are taken to ensure the rights, safety and wellbeing of research participants.

Application Form: Section P - Consent Process - Consent obtained

Objective: Informed consent is a necessary process to ensure that potential research participants are fully informed before deciding to volunteer in research studies of any type. The DSRB requires that informed consent should be obtained from all potential research participants prior to their participation in any research unless the process, or any part thereof, has been waived by the DSRB.

Sect / No	Question
P	**Will you be obtaining consent from donors for any oocyte or embryo for the purpose of restricted research?**
Definition / Explanation	If the study protocol requires oocytes or embryos from donors for the purpose of restricted research, then researchers must ensure that they comply with the special requirements in consent-taking for oocyte and embryo donors as stipulated in Part 3 of the Human Biomedical Research (Restricted Research) Regulations 2017. You will need to declare that: (a) appropriate consent shall be obtained from the donor in person and only if the donor has capacity to give consent (b) appropriate consent shall not be obtained from any other person (c) appropriate consent shall be obtained separately and independently from any consent for assisted reproduction treatment or any other therapeutic purpose

	(d) all investigators shall ensure that the donors have been informed of the full implications of the donation and that they do not require oocyte for future reproductive use (e) only surplus embryos obtained from assisted reproduction treatment shall be used for the research, the donors and their husbands have been informed of the full implications of the donation and they do not require the embryo for future reproductive use (f) appropriate consent shall be obtained only after a period of 8 days after the day all the relevant information necessary for the informed consent has been given to the donor However, these requirements will not apply to you if you are using oocytes and embryos imported from a place outside Singapore where there is documentary evidence that consent has been given in accordance with the legal and ethical requirements of that place.
P1	**Describe when the consent process will take place with the potential research participant/legally acceptable representative, including the time provided for him/her to consider his/her participation in the study.**
Definition / Explanation	Informed consent should be obtained from the participants prior to completing any activities that are being performed solely for research. Research participants should be given adequate time to consider before making a decision whether or not to participate. They should be encouraged to discuss participation with their family members. It is not appropriate to approach a participant immediately before a procedure or surgery, while in labour, while under sedation and any other situation where a participant might feel compromised.
P2	**Where will consent be taken (e.g. in room ward, outpatient clinic etc.)? How will privacy, freedom from intrusion and comfort be ensured?***
Definition / Explanation	Research participants should be approached in a quiet and conducive environment to allow the participant to be in the right frame of mind to consider participation. It would not be appropriate to approach a participant in an Operating Theatre for a study when he/she is getting ready for a procedure, even though the study is not related to the procedure. The PI should also protect the privacy of the research participant when approaching the patients to participate in research (e.g. researchers who are conducting the consent process in the Waiting Area of a General Clinic may violate the participant's privacy). Informed consent discussion should take place in person, whenever possible.
P3	**Who will take consent from potential research participants/legally acceptable representative (e.g. PI, Co-Investigators etc)?**
Definition / Explanation	Kindly indicate who will be involved in taking informed consent from potential participants (e.g. PI, co-investigators). **IMPORTANT NOTE:** Informed consent discussion should be conducted by the Principal Investigator, Co-investigator or a member of the study staff who is listed in this section as the designated person for conducting the informed consent discussion. Any change of Principal Investigator(s) or Co-Investigator(s) should be submitted to DSRB for review and approval. Only study team members who have been properly trained (e.g. completed CITI, GCP, PCR course) to obtain consent and designated by the PI with the responsibility of taking informed consent from research participants can obtain consent. Delegation of responsibility should also be documented in the Study Responsibility Log. It is the PI's responsibility to ensure that the study staff who are delegated to obtain consent have received proper training.

	The delegated study team member should also be appropriately qualified to adequately answer questions from the potential research participants. For clinical trials regulated by HSA, where a medical opinion is required, a medically trained staff should conduct the informed consent discussion so that the participant can have his/her questions adequately answered. Informed consent must be presented in a language that is understandable to the research participant.
P4	**Besides the Informed Consent Form, will any other materials or documents be used to explain the study to potential Research Participants/legally acceptable representatives (e.g. scripts, handouts, brochures, videos, logs etc.)? ***
Definition / Explanation	If 'Yes' is selected, please attach the document(s) for DSRB review.
P5	**Will research participants receive any monetary payments (including transportation allowances) or gifts for their participation in the study?***
Objective	To assure there is no undue influence on the research participants when agreeing to his/ her participation in the research study.
Definition / Explanation	If 'Yes' is selected, kindly state the reimbursement amount (per participant visit) for travel, meal or other expenses incurred due to participation in the research and its mode of payment (e.g. participants will be reimbursed $50 for transportation fare for each study visit or participants will be reimbursed $50 supermarket vouchers at each visit as a token of appreciation for participation). Payment to research participants should be pro-rated and participants should not be paid only at the end of the study to minimise coercion/inducement to complete the study. **IMPORTANT NOTE:** 1. Payment to research participants is not considered a benefit, but a reimbursement for the participant's time and expenses incurred. 2. The amount and proposed method and timing of payment should not present any undue influence. 3. Payment of a small proportion as an incentive for completion is acceptable, providing the incentive is not coercive. 4. Compensation for participation should not include coupons for discount on the price of the study material after the product is approved for marketing.
P6	**Will consent be documented in the form of a written and signed Informed Consent Form? ***
Definition / Explanation	If 'Yes' is selected, please attach a copy of the Informed Consent Form. If consent will not be documented, you must justify that the study meets the conditions for the waiver of documentation of consent. Please select the appropriate category (Category A or B) that describes your study. **<u>Category A</u>** • The only record linking the research participant and the research would be the consent document. Please explain why your study fulfils this criterion.* • The principal risk would be potential harm resulting from a breach of confidentiality.

	Please explain why your study fulfils this criterion.*
	• The research is not subjected to FDA regulations.*
	  ○ Kindly select appropriate answer
	  ▪ No. The research is subjected to FDA regulations. If this response is chosen, your study do not qualify for waiver of documentation of consent under Category A.
	  ▪ Yes. The research is not subjected to FDA regulations.
	• Each research participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.*
	  ○ Kindly select appropriate answer
	  ▪ No. The research participant will not be asked. If this response is chosen, your study do not qualify for waiver of documentation of consent under Category A
	  ▪ Yes. The research participant will be asked.
	
	Category B
	• The research presents no more than minimal risk of harm to research participants.
	Please explain why your study fulfils this criterion.*
	• The research involves no procedures for which written consent is normally required outside of the research context.
	Please explain why your study fulfils this criterion.*
	
	IMPORTANT NOTE:
	Guidelines for research studies requesting for a waiver of documentation of consent:
	
	If you propose to obtain informed consent for the research activity without obtaining the subject's signature on a consent form, then you are requesting for a waiver of documentation of consent. Waiving the requirement for a written form does not eliminate the requirement for informed consent. Subjects must be informed of the nature of the research, and their consent (or the consent of their legally acceptable representatives) must be obtained whenever appropriate. This type of waiver would be acceptable for some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the participant.
	
	Examples where a waiver of documentation of consent may be approved:
	a. When there is a possible legal, social or economic risk to the subject entailed in signing the consent form (e.g. for illegal immigrants, for HIV antibody-positive individuals who might be identified as such by signing the consent form.)
	b. When the study involves only a telephone interview

P7	**Will the study enrol non English speaking research participants/legally acceptable representatives?***
Objective	Selection of research participants should be equitable. It is generally not acceptable to exclude potential research participants based on their inability to speak and understand English. For non-English speaking participants, it is recommended that they are consented using a translated Informed Consent Form that is written in the language that is understandable to them. All Informed Consent Forms (including translated copies) must be submitted to DSRB for approval/acknowledgement prior to their use.
Definition / Explanation	If 'No', please explain why. E.g. The study will only involve a single focus group session that is conducted in English. The DSRB would also consider genuine reasons where it is not feasible due to logistical/ resource

	constraints. However, this should not be used as a convenient excuse to exclude this population. If 'Yes', please respond to the following questions: **(a) <u>What are the languages that will be used to communicate with the prospective participant or the legally acceptable representative? *</u>** Please select the appropriate language(s). **<u>(b) How will the Non-English consent be documented?*.</u>** Please select the appropriate type of consent document(s) that will be used. (i) Consent Document (Full) translated to the language understood by the prospective participant or the legally acceptable representative. You may attach the translated consent document, if available. Otherwise, please submit the translated document after the English version has been approved by DSRB. Submission of the translated consent forms to DSRB should be accompanied by a Certification of Translation from the translator or translation service. A template of Certificate of Translation can be downloaded from the NHG Research Website. (ii) Informed Consent Form (English) with DSRB Short Consent Form Template (Translated). The Short Consent Form is required to be appended to the Main English Language Informed Consent Form (ICF) as a single set of document. A document footer (mentioning the document version number and version date) and page number (i.e. Page X of Y) must be provided to link the English language ICF to each translated Short Consent Form. E.g. Informed Consent Form Version XX with Short Consent Form (Translated language), dated DD-MMM-YYYY The templates of DSRB Short Consent Forms (Translated) in Simplified Chinese, Malay and Tamil languages can be downloaded from the NHG Research Website. Please note that separate sets of documents should be submitted for each translated language. You may submit the set(s) of documents, if available. Otherwise, please submit them after the English language ICF has been approved by DSRB. (iii) Informed Consent Form (English) with Other Short Consent Form (Translated) Please refer to the above (ii) for the requirements for submitting Informed Consent Form (English) with Other Short Consent Form (Translated). **IMPORTANT NOTE:** Use of short form consent document: a. Appended to the DSRB-approved English language informed consent form serving as the written summary of the information to be orally translated and presented to the research participant b. The short form consent document should state the elements of informed consent which would have been presented orally to the participant or the participant's LAR.
P8	**Will the study be recruiting research participants under emergency situations, when prior consent of the research participant is not possible?***

Definition / Explanation	If you selected "Yes. This is a clinical trial regulated by HSA.", then you would need to justify that your study meets the following criteria to conduct an emergency research under the Health Products (Clinical Trials) Regulations/Medicines (Clinical Trials): a. the trial needs to be conducted on potential subjects who are facing a life-threatening situation to determine the safety or efficacy of an investigational product b. available treatments or procedures are unproven or unsatisfactory c. there is a reasonable prospect that participation in the trial will directly benefit the potential subjects because — i. the potential subjects 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 subjects; and iii. the risks associated with the trial are reasonable in relation to what is known about — A. the medical condition of the potential subjects; B. the risks and benefits of standard therapy, if any; and C. the risks and benefits of the proposed use of the therapeutic product; d. the potential subjects are unable to consent to being subjects as a result of their medical condition e. it is not feasible to obtain consent from the legal representatives of the potential subjects within the window period f. there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the trial g. the trial cannot practicably be carried out if the consent must be obtained from the subjects or their legal representatives You would also need to attach the documentation from 2 independent specialists to certify that the study meets the criteria. Please attach the documents under 'Attachments' tab, Section 'Others'. You are also required to declare that: i. provision will be made to re-consent the subject at the earliest feasible opportunity; ii. if consent cannot be obtained from the prospective subject or prospective subject's legal representative, and no family member has objected to the prospective subject's trial participation (if feasible), provision will be made for an Investigator (who is a specialist) and 1 independent specialist to certify, prior to the enrolment of the subject that: (a) the person is facing a life-threatening situation which necessitates intervention; (b) the person is unable to consent as a result of the person's medical condition; (c) it is not feasible to obtain consent from the legal representative of the person within the window period; and (d) neither the person nor the legal representative of the person nor any member of the person's family has informed the principal investigator of any objection to the person being a subject in the clinical trial. If you selected "Yes. This is a human biomedical research governed by HBRA.", then you would need to justify that your study meets the following criteria to conduct an emergency research that requires a waiver of consent under Part 3 of the Fifth Schedule Part of the HBRA: a. the research subjects are in a life-threatening situation b. there is no professionally accepted standard of treatment or the available treatments are unproven; c. the collection of valid scientific evidence is necessary to determine the safety and effectiveness of a particular intervention or treatment; d. participation in the proposed research holds out the prospect of direct benefit to the research subjects; e. obtaining appropriate consent is not feasible because –

	i. the subjects will not have capacity within the time available to give their appropriate consent as a result of their medical condition or situation; and, ii. the subject's Legal Representative is not available; f. the human biomedical research may not practicably be carried out unless there is a waiver You are also required to declare that: (a) provision is made for one of the following, whichever occurs first: i. the subject 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; or ii. the subject's legal representative to be informed as soon as is practicable of the subject's participation in the research and to be given an opportunity to request that the subject be withdrawn from further participation in the research; and (b) provision is made for a specialist in the specialty relating to the research and who is not involved in the research as a researcher or supervisor to certify, prior to the enrolment of the subject to the best of the specialist's knowledge that paragraphs a to e above have been complied with.
P9	**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.**
Definition / Explanation	If your study is a human biomedical research under the purview of HBRA, then according to the Human Biomedical Research Regulations 2017, appropriate consent must be taken in the presence of a witness: (*a*) who is 21 years of age or older; (*b*) who has mental capacity; and (*c*) who must not be the same individual taking the appropriate consent. The witness may be a member of the study team. The witness must take reasonable steps to ascertain the identity the identity of the individual giving the appropriate consent and that the consent was given voluntarily without any coercion or intimidation. The requirement for witness may be exempted if the research is (a) not invasive; (b) not interventional; and (c) not restricted human biomedical research. For all studies, an impartial witness (an individual who is not a member of the study team) will be required if the research participant/legally acceptable representative is: (i) illiterate or unable to read English or any of the fully translated Informed Consent Forms due to visual impairment, or (ii) unable to personally sign and date the Informed Consent Form due to a physical disability.
P10	**Do you have any additional comments regarding the Informed Consent process? ***
Definition / Explanation	Please elaborate if you have additional comments regarding the informed consent process.

Application Form: Section Q - Consent Process - Waiver of Consent

Objective: The DSRB will use the information provided under this section to determine if it can waive the requirement to obtain informed consent.

Sect / No	Question
Q	**The DSRB may waive the requirement to obtain informed consent if the DSRB finds that the study meets the following criteria:**

Q1	**The study poses no more than minimal risk to research participants.**
Definition / Explanation	You must ensure all of the following are met: • The harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life of the potential participant(s); • The information collected is not sensitive in nature; and • The data has been collected and are derived from standard clinically indicated procedures. E.g. The study involves minimal to no risk to subjects because it only involves data collection. The only known risk to patients is the possible loss of confidentiality, which has been minimized by limited access to only the study team members.
Q2	**Waiver of informed consent will not adversely affect the rights and welfare of research participants.**
Definition / Explanation	You must provide assurance that regardless of being part of the research or not, the information will still be collected as part of patients' clinically indicated procedures or as part of the normal running of business operations. None of the information collected would affect the clinical decisions about the individual's care, and patients are not being deprived of clinical care to which they would normally be entitled to. E.g. As the data had been collected as part of routine clinical care, the waiver of informed consent would not affect the rights and welfare of the research participants.
Q3	**The study cannot be practically conducted without the waiver of informed consent. (E.g. the participants are no longer on follow-up, lost to follow-up or deceased).**
Definition / Explanation	This criterion means that it would not be practical to conduct the research if consent is required to be taken. Practicability should not be determined solely by considerations of convenience, cost, or speed. Practicable means possible; it does not mean convenient. If the study team has access to the contact details of the participant, then it is usually possible to obtain their consent. There may be situations where the study team has access to the prospective participants but getting consent would make it impossible to actually conduct the study or would threaten the scientific validity of the research results. E.g. Studies involving behavioural observations where results will be affected should informed consent be taken prior to the observations.
Q3Ai	**The research cannot reasonably be carried out without the use of human biological material or health information in an individually-identifiable form.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable data and/or biological material that was/were obtained or compiled on/after 1 November 2017. Where possible, every attempt should be made to use only de-identified health information/human biological material (e.g. from an independent third party) for the research as a safeguard. If that is not possible, then you would need to explain why you are not able to do so and why it is essential and important for you to use individually-identifiable health information/human biological material for your research.

Q3Aii	**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.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable data and/or biological material that was/were obtained or compiled on/after 1 November 2017. You will need to justify why obtaining consent from the research participants/legally acceptable representatives will involve a disproportionate amount of effort and resources (e.g. manpower, funding available etc.) in comparison to what is required to achieve the desired research outcomes (e.g. the study only requires the use of patients' clinical data that already exists in the medical records).
Q3Bi	**The research cannot be reasonably carried out without the use of the health information in an individually-identifiable form.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable data that was obtained or compiled before 1 November 2017. Where possible, every attempt should be made to use only de-identified health information (e.g. from an independent third party) for the research as a safeguard. If that is not possible, then you would need to explain why you are not able to do so and why it is essential and important for you to use individually-identifiable health information for your research.
Q3Bii	**The process of obtaining consent from the person, to which the individually-identifiable health information relates, will involve a disproportionate amount of effort resources relative to the study requirements.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable data that was obtained or compiled before 1 November 2017. You will need to justify why obtaining consent from the research participants/legally acceptable representatives will involve a disproportionate amount of effort and resources (e.g. manpower, funding available etc.) in comparison to what is required to achieve the desired research outcomes (e.g. the study only requires the use of patients' clinical data that already exists in the medical records).
Q3Ci	**The research cannot be reasonably carried out without the use of the human biological material in an individually-identifiable form.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable biological material that was obtained or compiled before 1 November 2017. Where possible, every attempt should be made to use only de-identified human biological material (e.g. from an independent third party) for the research as a safeguard. If that is not possible, then you would need to explain why you are not able to do so and why it is essential and important for you to use individually-identifiable human biological material for your research.
Q3Cii	**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.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable biological material that was obtained or compiled before 1 November 2017. You would need to demonstrate that had made reasonable efforts to re-contact the individuals to

	obtain their consent to use their individually-identifiable biological material. Please describe what you had done.
Q4	**Whenever appropriate, will the research participants be provided with additional pertinent information after participation?**
Definition / Explanation	Please state if the research participants will be provided with additional pertinent information after participation. E.g.: • This study is non-interventional and thus it is not likely to provide any information that would be directly useful to the research participants. However, if there is information that needs to be provided to the research participant, the DSRB will be informed on how the participants will be contacted. • This study only involves medical records review and no recording of identifiers. Information collected cannot be linked back to the research participants and therefore it is not possible to provide additional information.
Q5	**The study would reasonably be considered to contribute to the greater public good.**
Definition / Explanation	This criterion only applies to human biomedical research that use individually-identifiable data and/or biological material that was/were obtained or compiled on/after 1 November 2017. At the 12 June 2018 Point of Contact meeting, MOH had explained that human biomedical research that may fulfil the "greater public good" criterion would pertain to situations where the research is beneficial to the greater public but obtaining consent may not be practicable, for example, in population-wide studies where information would be drawn from a national or disease registry (including linkages from multiple databases). MOH also emphasised that Institutional Review Boards should allow such requests on an exceptional basis only. You would need to justify how your research would be beneficial to the greater public.
Q5/Q6	**Do you have any additional comments supporting the waiver of informed consent? ***
Definition / Explanation	You may provide any other comments to justify the wavier of informed consent.

Application Form: Section R - Research Data Confidentiality

Objective: The Principal Investigator/custodian of the research data should put in place adequate policies and procedures to maintain data confidentiality.

Sect / No	Question
R	**In general, to protect the Research Participant's confidentiality, research data should be coded, and the links between the Participants' identifiers and the codes should be stored separately from the research data.**
R1	**Will coded / anonymous research data be sent to the pharmaceutical sponsor?** **Radio-button to select option** • **No, the study team would store all research data within the institution** • **Yes, the study team would send research data to the study sponsor**
Definition /	If 'Yes' is selected, this would mean that research data will be sent to the study sponsor, and

Explanation	therefore no research database will be created and stored in NHG. There will be no further questions for Section R1. If 'No' is selected, this would mean that the research database is created and stored in NHG. Please continue to answer the questions that follow.
	(i) **<u>Please state how the research data will be protected to ensure confidentiality and security.*</u>** (Please tick the checkboxes where applicable) • For hardcopy data, they will be stored in designated locked cabinet(s) or room(s) that are accessible to authorized study personnel only. • For electronic data, they will be stored in a secured computer that is password-protected. The databases used for analysis should not contain subject identifiers. The data linking subject identifiers and the subject identification codes should be stored separately. When portable media (e.g. CD, USB drives etc.) are used to store the data, subject identifiers are stored separately. Only documents used as source documents can contain subject identifiers. **(ii)** **<u>Describe who will have access to the research data. (Please state the personnel who will have access to the study data e.g. PI, Co-investigator, study coordinator.)*</u>** Please list all personnel(s) who have access to the study data. There should be limited access to the study data in order to maintain the confidentiality of the research data and participant identities. **(iii)** **<u>Will research data be released and shared with individuals or entities outside the institution?</u>** • No • Yes, please ensure that only coded data is shared to protect data confidentiality. If research data is to be released and shared with individuals or entities outside the institution, it is the PI's responsibility to ensure that only coded data is shared. There should also be a proper research agreement in place for such collaboration. You may contact your institutional research office / clinical research unit for help with the research agreements. **(iv)** **<u>Will the research data be used for future research after the study is completed?*</u>** **(Radio-button to select option)** • No, the research data will be destroyed after it has been stored for 6 years or minimum duration of retention period as specified by your institutional policy, whichever is longer. • Yes, the research data will be used for future research. Please register a standing database with DSRB when the study has completed. For clinical trials regulated by HSA, according to **GCP**, the essential documents should be retained until • at least 2 years after the last approval of a marketing application and until there are no pending or contemplated; or • at least 2 years after **formal discontinuation of clinical development of the investigational product; or** • **6 years after the completion of the clinical trial** For other types of research, the NHG research policy recommends a minimum storage

	period of 6 years. The length of time for which essential documents should be retained depends on the type of research and institutional policy. **IMPORTANT NOTE:** A Standing Database should be registered with the DSRB if there is a possibility of using the data stored for future research. Consent from research participants would be required for storing and using the data for future research, unless waived by the DSRB. A separate DSRB new study application will be required before using the stored data for research even though the Standing Database has been registered with DSRB.
R2	**Will any part of the study activities be recorded on audiotape, film/video, or other electronic medium (excluding non-identifiable images such as MRI/ X-Ray/ CT)?***
Definition / Explanation	If 'No' is selected, this would mean that no data will be recorded on audiotape, film/video, or other electronic medium. There will be no further questions for Section R2. If 'Yes' is selected, this would mean that data will be recorded on audiotape, film/video, or other electronic medium. Please continue to answer the questions that follow.
	(i) Please describe what will be recorded.* Please describe the contents of the recording (e.g. audio-recording of interview/focus group discussion, images of facial features). **(ii) What is the medium (audio tape / video etc) used for recording?*** State the option/choice of recording medium. **(iii) Explain how the recorded information will be used in the study.*** Please explain how the recorded information will be used (e.g. photographs will be taken to assess/compare the disease condition, interviews with the participant will be audio-taped and later transcribed). **(iv) For how long and where will the recording medium be stored? Who will have access, and how will access be controlled and monitored?*** • Please state location of storage of medium and ensure that it is a secured location. • Please state how long the recording medium will be stored and ensure that it complies with the minimum storage period. • If copies are made, who will have access to them, and what are the procedures for accessing and using the data in the recording medium. **(v) How will the recording medium be disposed?*** Please describe how the recording medium will be destroyed. **IMPORTANT NOTE:** Research data should be destroyed after it has been stored for 6 years or minimum duration of retention period as specified by your institutional policy, whichever is longer.

Application Form: Section S - Biological Materials Usage & Storage

Sect / No	Question
S1	**Will any biological materials (such as blood or tissue) be used as part of the study?***
Definition /	If 'No' is selected, there is no further question in Section S that will require your response.

Explanation	If 'Yes' is selected, you will be required to answer all the questions in this section.
S1 – (i)	**(For prospective biological materials only). Please state the type of biological materials used and describe how they will be obtained. Please include the frequency of collection, the amount collected each time and the total amount collected for the research study.***
Objective	This section is used as a general measure to identify if the amount of samples collected will pose excessive risks to the participants.
Definition / Explanation	Biological materials include, but are not limited to: - Blood - Skin cells/cheek cells - Leftover tissue from routine surgery/procedure - Urine Some examples of how samples are obtained: - Additional blood to be drawn during a routine blood taking by venepuncture - Skin/buccal scrapings - Foetus of patients undergoing elective/medically indicated termination of pregnancy which will be discarded otherwise. **The frequency of collection, the amount collected each time and the total amount collected for the research study must be stated.** E.g. Frequency of collection: a) During screening b) 1 hour after stent placement c) 24 hours after stent placement d) 48 hours after stent placement 5mls of blood will be taken each time. The total amount of blood drawn from each subject would be 20mls.
S1 – (ii)	**(For existing biological materials only). Please state the type of biological materials used and the source, i.e. tissue repository, left over/ bio-banked samples from a previous/ on-going DSRB approved studies (Please provide the relevant DSRB study reference number).***
Objective	The existing biological materials should be obtained from a legitimate source.
Definition / Explanation	Please state the type of biological materials used and the source, i.e. tissue repository, left over/ bio-banked samples from a previous/ on-going DSRB approved studies (Please provide the DSRB study reference number).* The PI should ensure relevant approvals have been sought for the use of the biological samples for the study.
S1 – (iia)	**I declare that:** **[ ] Only surplus embryos created in assisted reproduction treatment will be used for the research.** **[ ] The research does not involve a human embryo which is more than 14 days old from the time of creation of the embryo (excluding any period when the development of the embryo is suspended).**
Definition / Explanation	If the study uses human embryos, then you must ensure that you comply with the special requirements regarding their usage as stipulated in Part 3 of the Human Biomedical Research

	(Restricted Research) Regulations 2017. Part 3 of the Human Biomedical Research (Restricted Research) Regulations 2017 "Section 10. Every research institution and every researcher conducting restricted research must ensure that restricted research carried out does not involve a human embryo which is more than 14 days old from the time of creation of the embryo (excluding any period when the development of the embryo is suspended)." "Section 12(6). The research institution and the researcher must ensure that –– (*a*) only surplus embryos created in assisted reproduction treatment may be used for research"
S1 – (iii)	**What tests will be performed on these biological materials?***
Definition / Explanation	The tests may include the following but are not limited to: - Genetics testing - Cytokines testing - Confirmation of diseases - Pharmacokinetic testing
S1 – (iv)	**Will results from the tests be communicated to the research participants? If not, please explain.***
Objective	To assess if there is adequate plan to inform participants if the results may affect their health, clinical management and/or decision to continue participation.
Definition / Explanation	Please indicate if results will be conveyed to the research participants. If not, please indicate the reason(s) for not divulging the information to the participants (e.g. the information would not affect the clinical decisions about the individual's care).
S1 – (v)	**How are the biological materials identified? Please tick all the applicable boxes.*** • No Identifiers. • Biological materials are coded and the code is maintained at source. • Identifiers present. • Other methods. Please elaborate more in the textboxes provided.
Definition / Explanation	It is recommended that the biological materials be anonymised or coded to protect the identities of the participants. In addition, the identities of the participants should not be disclosed to unauthorized parties.
S1 – (vi)	**Will any cell lines be created from the biological materials?***
Objective	This is to protect the identities of the research participants and that the cell lines cannot be traced back to the individual participant.
Definition / Explanation	If 'No' is selected, there will be no further questions from S1 (vi). If 'Yes' is selected, please indicate if the cell lines will have any identifiers linking to the particulars of the participants/donors. Cell lines may be coded or stripped of identifiers or by other methods to be specified. Please choose an option: • The cell lines are stripped of any identifiers and cannot be linked or traced back to its donor. • The cell lines are coded. If this option is selected, please indicate who will maintain the codes linking the cell lines and its donor. • By other methods. If this option is selected, please elaborate the method that will be used.

S1 – (vii)	**Will the biological materials be destroyed at the completion of the study, or will they be stored for future use?**
Objective	To assess if the biological samples collected will be stored for future use. If stored, there should be adequate measures to protect subject confidentiality and the participant should also have consented to have their samples stored for future research.
Definition / Explanation	If 'Yes' is selected, this would mean that the biological materials will be destroyed at the completion of the study. If 'No' is selected, this would mean that the biological materials will be stored. You will need to respond to the following questions: **(a) Please indicate the location, duration and purpose of storage. *** E.g. Biological materials will be stored in XYZ lab. The samples will be stored for 15 years and thereafter destroyed. These biological materials will be used for further genetic testing/future related research. **(b) How will these stored biological materials be identified?*** • The stored biological materials are stripped of any identifiers and cannot be linked or traced back to its donor. • The stored biological materials are coded. If this option is selected, please indicate who will maintain the codes linking the biological materials and its donor. • By other methods. If this option is selected, please elaborate the method that will be used. A Tissue Bank should be registered with the DSRB if there is a possibility of using the samples stored for future research. Consent from research participants would be required for storing and using the samples for future research, unless waived by the DSRB. A separate DSRB new study application will be required before using the stored samples for research even though the Tissue Bank has been registered with DSRB.

Application Form: Section T - Data & Safety Monitoring

Objective: To ensure that the study has adequate provisions for monitoring the data collected for scientific validity and safety of research participants.

Sect / No	Question
T1	**Who performs the data and safety monitoring?*** **Radio-button to select option** • **Principal Investigator and/or Study Team** • **Data Safety Monitoring Board (DSMB)(Please submit the DSMB charter)** • **Others**
Definition / Explanation	All research proposals should include provisions for monitoring of data collected for scientific validity and safety of research participants. The person(s) who performs the data and safety monitoring will depend on the type and risk of the research study. For minimal risk studies, it may be appropriate for the Principal Investigator and/or Study Team to manage the data and safety monitoring. For minimal risk studies involving multiple sites, this function could be managed by the Principal Investigator and/or Study Team at each site, or the lead Principal Investigator for the entire study.

	For moderate risk studies or an investigator-initiated clinical trial, it is recommended that data safety monitoring be performed by an expert or group of experts in the disease who are familiar with the agent being investigated. Using an independent expert or team of experts is particularly helpful in monitoring the unblinded data for double-blind research studies as this will help ensure a meaningful review by the independent experts while maintaining study blinding amongst research staff. A Data Safety Monitoring Board (DSMB) may be established specifically to monitor data throughout the course of a research study to determine if it is appropriate, from both scientific and ethical standpoints, to continue the research study as planned. For high risk studies and for large sponsor-initiated, blinded studies involving multiple sites, it is recommended that a formal DSMB be appointed.
T2	**Please state the Safety Monitoring plan, i.e. frequency of review (e.g. daily, weekly, quarterly) and type of data (e.g. adverse events/serious adverse events) that will be monitored.**
Definition / Explanation	Please elaborate on the Safety Monitoring plan. The monitoring plan for a particular research study would depend on the complexity of the research study and the possibility of potential harm to subjects. The monitoring may be planned to occur at specific points in time, such as quarterly, or every six months or annually or after a specific number of participants have been enrolled, or upon recognition of harm. The safety monitoring plan should include (where applicable): • Details of the assessments (laboratory tests, physical examinations, etc) used to monitor for adverse events and the schedule of these evaluations; • Description of anticipated events including character and expected incidence; • Plan for grading the seriousness of events; • Plan for assessing the causal relationship of events to the study and/or agent(s) being investigated; • Person(s) responsible for assessing events; • Person(s) responsible for managing events; • Person(s) responsible for reporting events according to DSRB guidelines.
T3	**Please state the Data Monitoring plan, i.e. frequency of review (e.g. daily, weekly, quarterly), how data integrity is assured.**
Definition / Explanation	Please elaborate on the Data Monitoring plan. For investigator-initiated minimal risks studies, monitoring for data accuracy and compliance would entail checking for completeness of the Investigator File and verifying data collection forms. For investigator-initiated trials and more than minimal risks studies, data monitoring should be in accordance with ICH GCP. Sponsor-initiated clinical trials should have a monitoring plan in place that is consistent with the requirements laid out in the ICH GCP.
T4	**Please describe the stopping criteria for the research study based on efficacy, futility and safety criteria.** **Checkbox for selection** ▪ **Efficacy - With high certainty, the study question has been answered.** ▪ **Futility - The study question will not be answered when the study is completed.** ▪ **Safety - Risks to patients are too high.**

	Please elaborate where applicable.
Definition / Explanation	Most interventional studies may be stopped for one of the following reasons:- **1. <u>Efficacy</u>** E.g. The objective of the study may have been met; one group is doing better than the others, or no group is likely to do better than the other. **2. <u>Futility</u>** E.g. Too many participants have been lost to follow up or stopped the intervention such that it is difficult to obtain conclusive data. **3. <u>Safety</u>** E.g. The risk to continuing participation to subjects is too high. However, for non-interventional studies that involve no more than minimal risk, (e.g. medical records review studies, questionnaire studies) the above may not be applicable. In such cases, it is acceptable to enter 'NA'.
T5	**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. ***
Objective	To ensure that there is a clear chain of communication to disseminate important information promptly especially in the case of multi-site studies.
Definition / Explanation	This pertains only to multi-centre studies. Please enter 'NA' if this is a single-site study.

Application Form: Section J - Exempt Review Application

Sect / No	Question
J1	**Please describe and state the source of your samples/data.**
Definition / Explanation	Please describe where and how you obtain the samples/data. **IMPORTANT NOTE:** For the study to qualify for Exempt Category 2 and/or 4, the source of the samples/data must fulfil one of the following criteria:- • Information must be recorded by the investigator in such a manner that research participants cannot be identified, directly or through identifiers linked to the participant (**i.e. the existence of a one-way identifier, such as a code that can be used to identify a participant, disqualifies the research as Exempt**) OR • Sources are publicly available (accessible to general public such as library literature or internet). Medical records are not publicly available because they are restricted to designated doctors and healthcare professionals only.
J2	**Criteria to qualify for Exemption from DSRB review**
Definition / Explanation	Category 1 – Normal Educational Practices

	Category 2 – Anonymous Educational Test, Surveys, Interviews, or Observations Category 3 – Identifiable Subjects in Special Circumstances Category 4 – Collection of Existing Data Category 5 – Public Benefit or Service Program Category 6 – Taste and Food Evaluation and Consumer Acceptance Studies The study is NOT any of the following: • Research involving prisoners • Research involving children when the research involves survey or interview procedures or observations of public behaviour, except when the investigator (s) do not participate in the activities being observed • FDA-regulated research
J2 - (i)	**The research involves no more than minimal risks to the study participants.***
Definition / Explanation	If 'Yes' is selected, no further question in J2 (i) will require your response. If 'No' is selected, your study does not qualify for Exempt review. Kindly amend the form on the "Main Page" to a **Non-Exempt Form**.
J2 - (ii)	**The selection of study participants is equitable.***
Definition / Explanation	If 'Yes' is selected, no further question in J2 (ii) will require your response. If 'No' is selected, please provide a reason why the selection of study participants is not equitable (e.g. the disease only affect the x population).
J2 - (iii)	**Recording of identifiable information:***
Definition / Explanation	Please select whether there will be recording of identifiable information. Please choose one of the following options: • No recording of identifiable information. If this option is selected, no further question in J2 (iii) will require your response. • Identifiable information is recorded and there are adequate provisions to maintain the confidentiality of the data. If this option is chosen, please describe the plan to maintain the confidentiality of the data. The plan should include where the data will be stored, whether the data/computer will be password-protected, and whether the data and identifiers will be stored separately. **IMPORTANT NOTE:** If you have selected Exempt categories 2 or 4, identifiable information **cannot** be recorded. If identifiable information is recorded for categories 2 or 4, kindly amend the form to a **Non-Exempt Form**.
J2 - (iv)	**Privacy interests of the study participants:***
Definition / Explanation	Please select how privacy interest of the study participants will be protected. Please choose one of the following options:

	• It is not applicable as there are no interactions with study participants. If this option is selected, no further question in J2 (iv) will require your response. • There are interactions with study participants and there are adequate provisions to maintain the privacy interests of the study participants. If this option is selected, please describe the plan to maintain the privacy interest of the study participant (e.g. consent will be obtained in a separate quiet room). The manner in which the research participants are identified and approached for participation in research may constitute an invasion of privacy. The investigator should take precaution that in the process of obtaining consent from a research participant, it is preferable that consent be conducted in a private consultation room to ensure and protect the privacy of the participant from others' intrusion. The wishes of the participant must also be respected if they choose not to participate in the research.
J2 - (v)	**Informed consent:***
Definition / Explanation	This is an additional question which will appear only if the option 'There are interactions with study participants and there are adequate provisions to maintain the privacy interests of the study participants' is selected in Section J2 (iv). Please select whether informed consent will be taken or waiver of informed consent is requested. Please choose one of the following options: • Informed Consent will be taken for all study participants. If this option is selected, please describe the consent process (when, where, who will perform informed consent) and attach the informed consent form. **IMPORTANT NOTE:** If you have selected Exempt categories 2 or 4, identifiable information **cannot** be recorded. As such, written consent should not be taken as the participants' name (i.e. identifiers) will be recorded. If the study involves only an anonymous survey/interview under Category 2, the return of a completed questionnaire/data collection form would indicate the participant's consent to participate (i.e. implied consent). • Waiver of Informed Consent is requested for all study participants. If this option is selected, please note that Section Q (Consent Process - Waiver of Consent) will require your response.

Application Form: Section U - Principal Investigator's Curriculum Vitae

This section shows the Principal Investigator's as well as Study Team Members' Curriculum Vitae.

Please ensure that the information shown here is **accurate and up to date**, including his/her current appointment/position under the institution and department added under Section B1(ii).

If the PI or Study Team Member needs to upload or update his/her CV, it should be done through his/her ROAM profile.

The DSRB will use the information contained here to assess the qualifications of the Principal Investigator and study team members to carry out the study as described in this Application.

Application Form: Section V - Declaration of Principal Investigator

This is the Principal Investigator's Declaration.

I will not initiate this study until I have received approval notification from the DSRB and all applicable regulatory authorities.

I will not initiate any change in the study protocol without prior written approval from the DSRB, except when it is necessary to reduce or eliminate any immediate risks to the research participants. Thereafter, I will submit the proposed amendment to the DSRB and all applicable regulatory authorities for approval.

I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that may occur in the course of this study.

I will maintain all relevant documents and recognise that the DSRB staff and applicable regulatory authorities may inspect these records.

I understand that failure to comply with all applicable regulations, institutional and DSRB policies and requirements may result in the suspension or termination of this study.

I declare that there are no existing or potential conflicts of interest for any of the investigators participating in this study and their immediate family members. If there are, I have declared them in the relevant section of this application form.

By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration