National Healthcare Group

Adding years of healthy life

NHG ROAM

Research Online Administration & Management

Online DSRB Application Form Guidebook for Population Health Study
Version 4.0

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	**<u>Submission Criteria for Population Health Study (Domain F)</u>** Population Health is defined as the health outcomes of a group of individuals, including the distribution (e.g. due to race, socioeconomic, gender) of the outcomes within the group. Examples of types of research that can be submitted to Domain F include: o Community-based Participatory Research o Health Services and Outcome Research o Epidemiological Research o Social and Behavioural research o Research on Prevention & Health Promotion Programme o Education Research Research proposals submitted to Domain F should **<u>NOT</u>**: o Involve prospective use of drug, device, surgical and/or invasive procedure (regardless of whether it is investigational or standard care) except for blood draw. o Be subjected to Singapore HSA, US FDA and/or other US Federal regulations. o Be a Quality Improvement / Quality Assurance Project Hybrid studies (research proposals that also involve biomedical research activities) should be submitted using the Biomedical Study Form (Domain A – E) If the application does not fulfil the above, the Biomedical Study Form (Domain A – E) has to be submitted. If the application does not fulfil the above and is submitted using the Population Health Study Form, the application will have to be **<u>re-submitted</u>** using the Biomedical Study Form when it reaches DSRB. The determination of whether a research study meets the criteria for Population Health Study (Domain F) review is made by the DSRB. The DSRB secretariat may request for you to re-submit 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.

Application Form: Section A - Protocol Title & Study Administrators

Sect / No	Question
A	**Please declare if the study falls under the purview of the Human Biomedical Research Act.**
Definition /	Please declare if your study falls under the purview of the Human Biomedical Research Act (HBRA) (Yes/No).

Explanation	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.
A1	**Please enter the Full Study Title.***
Definition /	

Explanation	Please enter your full protocol title 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 completing the various online forms and reports, however, only the PI may 'submit' these online forms and reports to the DSRB. This section is optional but PIs are encouraged to nominate at least one Study Administrator.

Application Form: Section B - Study Team

Sect / No	Question
B1. (a) **B1. (b)** **B2**	**(Optional) Overall Principal Investigator** **Submitting Principal Investigator (Main contact for DSRB):** **Study Sites under the oversight of NHG DSRB**
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 Submiting 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). **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.
B3 **B4**	**External Study Sites under the supervision of the 'Submitting Principal Investigator (Main contact for DSRB)' (eg. Nursing Home, Community Hospitals, Community Centres etc). Please attach the Notice of Intent (NoI) if applicable.** **Study Sites not under the oversight of NHG DSRB and not under the supervision of the 'Submitting Principal Investigator'** **(a) Has this study been submitted to another IRB?*** **(b) Has the application been previously rejected by any IRB? (Including NHG-DSRB)***
Definition / Explanation	**(a) For External Study Sites under the supervision of the 'SubmittingPrincipal 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. **For external Study Sites (NOT under the oversight of NHG DSRB)** Please apply for IRB approval from the respective site's IRB. (b) 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.
B5	**Research Specialty**
Definition / Explanation	**(a) Please indicate the Special / Research Expertise** Please select the Primary Specialty, and then choose the relevant Subspecialty 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. **(b) Please indicate/add Secondary Special / Research Expertise** Please add Secondary Specialty, and then choose the relevant Subspecialty 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.

Application Form: Section C - Conflict of Interest Declaration

Sect / No	Question
C1	**Does the Principal Investigator or any study team members have any potential conflict of interest? *** **a. Please tick all the applicable boxes.** **b. Please provide details of all of the above Conflict of Interest** **c. Please describe the plan to manage all of the above Conflict of Interest**
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 the Nature(s) of Study that best describes your application***
Definition / Explanation	Please select the category that best describes your research activities. If you are unable to decide, please contact the DSRB for assistance. **<u>Education Research</u>** Choose this if your research involves - Teacher or students as Research Participants. - Research conducted in established or commonly accepted educational setting, involving normal educational practice. - Research on different aspects of education including but not limited to: student learning, teaching methods, teacher training, and classroom dynamics. **<u>Health Services Research</u>** Choose this if your research involves - Analysis of how social factors, financing systems, organizational structures and processes, medical technology and/or personal behaviors, etc affect access to health care, the quality and cost of health care, and quantity and quality of life. **<u>Prevention & Health Promotion Programme</u>** Choose this if your research involves - Identifying and assessing risk, and developing interventions to prevent the occurrence, recurrence, or progression of illness, symptoms, risk factors, of health problems or diseases. - Evaluating disease prevention and health promotion recommendations and/or public health programs.

	Epidemiological Research Choose this if your research involves - Research on health-event, health-characteristic, or health-determinant patterns in a population. **Social and Behavioural Research** Choose this if your research involves - Research involving the identification and understanding of behavioral and social risk and protective factors associated with the onset and course of illness, and/or health conditions. - Research on the effects of illness or physical condition on behavioral and social functioning. **Community-based Participatory Research** Choose this if your research involves - Research conducted in communities in which community members, persons affected by condition or issue under study and/or other key stakeholders in the community participate as partners in the development, implementation and dissemination of the research. **Others** Choose this if your research involves - any other population health research categories Please select the methodology that best describes your application. **Questionnaire or Survey** Choose this if your research involves: - Administering questionnaires/surveys/interviews. This type of research may also include a medical records review component. - Online questionnaire involves collection of data via the internet, e.g. E-mail communications, online surveys, online chat rooms, and interactive website programs. **Analysis of Existing Data** Choose this if your research involves: - Collection of data for a specific research project by review of medical records including results of routine diagnostic tests performed for standard clinical purposes. - Prospective and/or retrospective data collection. - Collection of data for a specific research project by review of existing research data or publication, e.g. literature review. **Focus Group Discussion / Interview** Choose this if your research involves: - Administration of questions whereby a group of people are asked about their perceptions, opinions, beliefs, and attitudes towards a particular topic. **Clinical Research** Choose this if your research involves: - Collection of blood by venepuncture, finger stick, etc. - Prospective collection of biological specimen by non-invasive means (e.g. hair, nail clipping, saliva, etc) - Collection of data through non-invasive procedures (e.g. MRI, ultrasound, ECG, EEG, etc) - Any other research methodology

Application Form: Section E - Study Funding

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.
	As a guide, both sponsored and investigator-initiated research studies which are approved by the 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.
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.

	Grant/ other source(s) of funding
	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.
	  o If you have alternative financial source(s) to fund this study, select 'No. The study can be started without the Grant'.
	  o If you do NOT have alternative financial source(s) to fund this study, select 'Yes. The study is dependent on the Grant to start'.
	
	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.
	
	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).
	
	Financing/Sponsorship from Community Based Agency
	If selection is 'Financing/Sponsorship from Community Based Agency', please provide the name of Community Based Agency, Grant Amount, Date of Approval and Expiry.
	
	Please briefly describe the terms of funding and provide a copy of the approved contract or proposal.

Application Form: Section F – DSRB Review Category

Sect / No	Question
F1	**Please select the type of DSRB review you are applying for this study** *
Definition/ Explanation	**Non Exempt Review category** Principal Investigators should select "Non-Exempt" if their research activity does not qualify under the Exempt Category. Submissions will be routed for a Full Board or Expedited Review. **Exempt Review category** Research activities in which the only involvement of human Research Participant will be in **one or more of the following categories** may be able to qualify for the Exempt Review category. **IMPORTANT: The criteria for the Exempt category do not apply when the research activity:-** i. involves more than minimal risks to individual Research Participants and population ii. selection of Research Participants and population is not equitable iii. identifiable information is recorded iv. involves prisoners v. 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

vi. is a US FDA-regulated research activity.

Category 1 – Normal Educational Practices and Settings
Research conducted in established or commonly accepted educational settings, involving normal educations practices, such as: Research on regular and special education instructional strategies; or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Research will qualify for exemption under this category if **all** the following are met:

i. All of the research is conducted in a commonly accepted educational setting (e.g., a private or public school).

ii. The research involves normal educational practices (e.g. comparison of instructional techniques).

iii. The study procedures do not entail a significant deviation in time or effort from those educational practices already existent at the study site.

iv. The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices, including physical education.

v. The study procedures do not involve deception or withholding of information.

vi. The study procedures do not involve sensitive topics, such as sexual behavior of individual subjects or population. A sensitive survey is one that deals with socially questionable or highly personal issues or alcohol and/or drug abuse.

vii. Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.

viii. The school or other agency grants written approval for the research to be conducted.

ix. Educational tests of (i) knowledge, (ii) mastery, or (iii) skills.

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 behavior that meet the following criteria.

Research will qualify for exempt under this category if **all** the following are met:

i. Information obtained will not be recorded in a manner that human Research Participants can be identified, directly or through identifiers linked to the subjects.

ii. Any disclosure of the human Research Participants' responses outside of the research could reasonably place Research Participants at risk of criminal or civil liability or be damaging to the Research Participants' 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 behavior that is not exempt under Exemption Category 2

Research will qualify for exemption under this category if **all** the following are met:

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 these sources are publicly available or if the information is recorded by the investigator in such a manner that Research Participants cannot be identified, directly or through identifiers linked to the Research Participants. The reviewed material should be in existence at the time the research is proposed and should not be prospectively collected. Research will qualify for exemption under this category if **all** the following are met: i. The data, documents, records, pathological specimens, or diagnostic specimens existing as of the day when application is being submitted ii. Sources are publicly available or information is recorded by the investigator in such a manner that Research Participants cannot be identified, directly or through identifiers linked to the subjects. If information is not publicly available and you wish to collect identifiers, your study will not qualify for Exemption. Please choose the Non Exempt Review Category. **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: public benefit or service programs; procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. Research will qualify for exemption under this category if **all** the following are met: i. The research or demonstration project is conducted pursuant to specific federal statutory authority. ii. There is no statutory requirement for IRB review of the project. iii. The project does not involve significant physical invasions or intrusions upon the privacy of participants. iv. The exemption is authorized by the federal funding agency. v. The program under study delivers public benefit or service (e.g., financial or medical benefits) or service (e.g., social, supportive, or nutritional services) **Category 6 – Taste and Food Evaluation and Acceptance Studies** Taste and food quality evaluation and consumer acceptance studies. Research will qualify for exemption under this category if **one of** the following is met: i. wholesome foods without additives are consumed; or ii. 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.
F1 (b)(i)	**The research involves no more than minimal risks to the study participants.***
Definition / Explanation	This section will appear if **Exempt** review category is selected. If 'Yes' is selected, no further question in F1 (b)(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**.
F1 (b)(ii)	**The selection of study participants is equitable.***

Definition / Explanation	This section will appear if **Exempt** review category is selected. If 'Yes' is selected, no further question in F1 (b)(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).
F1 (b)(iii)	**Recording of identifiable information:***
Definition / Explanation	This section will appear if **Exempt** review category is selected. 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 F1 (b)(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**.
F1 (b)(iv)	**Privacy interests of the study participants:***
Definition / Explanation	This section will appear if **Exempt** review category is selected. 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 F1 (b)(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.
F1 (b)(v)	**Informed consent:***
Definition / Explanation	This section will appear if **Exempt** review category is selected. 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 F1 (b)(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 L (Consent Process - Waiver of Consent) will require your response.

Application Form: Section G – Study Information

The information contained in this section must be self-contained so that it can serve as a succinct and accurate description of the study when it is read by itself. As far as possible, the technical and medical terms should be explained in simple layman language

Important: Do not use terms such as "Refer to attached document" or similar

Sect / No	Question
G1	**What are the Specific Aims of this study?***
Definition / Explanation	In this section, please concisely describe the Specific Aims of the study.
G2	**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.
G3	**Please describe the background to the current study proposal. Critically evaluate the existing knowledge and specifically identify the gaps 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?
G4	**Please provide details on (i) sample size and power calculation and (ii) the means by which data will be analyzed 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 /	Please describe (i) how you derived with the required sample size for the study and (ii) which

Explanation	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) If this is a pilot/qualitative study, please provide a rationale on how the recruitment target is determined instead.
G5	**Please provide a list of relevant references.***
Definition / Explanation	Please list at least two relevant papers pertaining to the importance of the study
G6	**Please submit a copy of at least two relevant papers ***
Definition / Explanation	Please attach at least two relevant publications.
G7	**Does this study have a Study Protocol?***
Definition / Explanation	(i) If selection is 'Yes"; user will be required to attach a copy of Study Protocol. (ii) Click on the 'Attach' button to submit a copy of the Study Protocol. **Note:** You may refer to the NHG Research website for Study Protocol template. http://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/dsrb+forms+and+templates 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.
G8	**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).
G9	**The PI is responsible for ensuring that all research participants give informed consent before enrolling into the study.** **Please select all the applicable consent scenarios.***
Definition / Explanation	Please select all the applicable consent scenarios **Informed Consent will be taken for study subjects.** In general, informed consent must be obtained from all individual Research Participant prior to their participation in any research. **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 L or K6

	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 L '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 L 'Consent Process - Waiver of Consent' will display the waiver criteria according to the DSRB policies. **Community Consent will be taken.** In general, community consent will only be applicable when the research is conducted in a small/ specific community (i.e. a local tribe, an uncommon religious group etc.), and the results obtained from this research study may impact or be applicable to everyone in the community; even though not all individual from the affected community is involved in the research study. Community Consent will usually be provided by the leader(s) or an individual who represents the community. IMPT: Community consent does not preclude the individual consent if DSRB deem necessary. 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 H – Research Population

Sect / No	Question
H1	**Identify all categories or groups, primary or secondary target, age range and total number to be enrolled (consented).** **Please state the target number of research subjects to be recruited for each study site, taking into account subject dropouts under the 'Maximum Total Enrolment Target'.** **Primary targets are those who either give consent or those who can only provide assent (e.g., minors). Secondary targets are those who provide data to supplement the primary target data (e.g., parents completing a questionnaire, teachers who supply information and data).**
Definition / Explanation	Primary targets are those who either give consent or those who can only provide assent (e.g. minors) Secondary targets are those who either provide data to supplement the primary target data (e.g. parents completing a questionnaire, teachers who supply information and data) Please indicate the estimated number (minimum and maximum number) of participants which will be recruited at each study site. If no actual participants are involved, then state the target number of medical records to be collected/ reviewed for the study. 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 B2. If you would like to include additional site(s), please add them under Section B2. Please note that a study amendment must be submitted and approved by the DSRB if you would like to recruit additional participants over the estimated maximum number indicated here.
H2	**Please provide justification for selection of all the group/population indicated in Section H1 ***
Definition / Explanation	Kindly justify the reason for including the specific groups/populations in this study e.g. particular research question can only be addressed in these groups/populations.
H3	**Please list the inclusion criteria. (Note: 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.
H4	**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.
H5	**Are there any recruitment restrictions based on the gender of the research participants?***
Definition / Explanation	Please explain the rationale for a gender bias.
H6	**Are there any recruitment restrictions based on the race of the research participants?***
Definition / Explanation	Please explain the rationale for a race bias.
H7	**Does the study involve any of the vulnerable Research participants?** • **Pregnant Women, Foetuses and Neonates** • **Children** • **Prisoners** • **Cognitively Impaired persons** • **Ethnic minorities** • **Low Income Persons** • **Students** • **HIV/AIDS individuals** • **National Servicemen**

	• **Others; Please specify the population if this option is selected**
Definition / Explanation	If selections is 'Yes'; please select the applicable categories from the list of selections • If **Pregnant Women, Foetuses and Neonates** is selected, you will be required to respond to Section R • If **Children (person who are less than 21 years of age)** is selected, you will be required to respond to Section S • If **Prisoners** is selected, you will be required to respond to Section T • If **Cognitively Impaired persons** is selected, you will be required to respond to Section U • If 'Others' is selected; please describe the population, explain why the research must recruit the mentioned research participant (as opposed to other research participant that are not vulnerable) and list the safeguards that will be in place to protect their rights and welfare.
H8	**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'. Then, please state the worldwide total target enrolment number. If an exact number is not available, please give an approximate number.
H9	**Does the study involve any of the following?*** - **Inpatient** - **Outpatient** - **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	If 'Yes' is selected, please select the applicable group(s).

Application Form: Section I – Research Procedure

Sect / No	Question
I1	• **Please list all procedures, measures and means by which data will be collected, analyzed and interpreted in this study. If you are extracting data from existing records, 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)** • **In your list, indicate the procedures that are being done for non-research purposes (i.e Procedures that are performed as part of curriculum / is performed for diagnostic/standard clinical purposes).**
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).
I2	**Please attach the Data Collection Form (if applicable), Questionnaire Form (if applicable), Interview/Focus Group Discussion Guide (if applicable) and/or List of Variables that will be extracted from medical record/database (if applicable)**
Definition / Explanation	Please attach the Data Collection Form, Questionnaire Form, Interview/Focus Group Discussion Guide and/or List of Variables. 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.
I3	**Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.***
Definition / Explanation	Please list the potential difficulties and limitations of the proposed procedures that may lead to failure to achieve the aims and/or failure to complete the study. In addition, list the corresponding alternative approaches to achieve the aims/overcome the difficulties and limitations.
I4	**Does the study involve incomplete disclosure of research purpose or deception of the Research Participants?**
Definition / Explanation	Please select "Yes" if the study involve incomplete disclosure of research purpose or deception of the research participants Definition of Deception When false information about some aspect of the research is given. Examples: • Research participants complete a quiz, and are falsely told that they did very poorly, regardless of their performance.

	• In a study of anxiety, research participants are told to expect mild pain during the course of the study, but no painful procedures are administered. Definition of Incomplete Disclosure When some information about the real purpose of the study, or the nature of the research procedures is withheld. Examples: • Research participants are asked to complete a quiz for research, but not told that the research question involves how background noise affects their performance. • Research participants are told they are completing study questionnaires to evaluate their satisfaction, when the true purpose of the study is to correlate psychiatric symptoms with patient satisfaction. If "Yes" is selected, 3 additional questions will appear, please provide responses to these questions. **a. Explain why the incomplete disclosure/deception is necessary to accomplish the goals of research.** Please describe why the incomplete disclosure/deception is necessary to accomplish the goals of research (e.g. to improve the internal validity of a research study, other effective, non-deceptive approaches are not feasible, no alternative to address the scientific question in a valid manner except to use deception/incomplete disclosure.) **b. Are any of the undisclosed risks to research participants more than minimal?** Please indicate if any of the undisclosed risks to research participants more than minimal. Potential risks include: • Feel coerced to have acted against one's will • Might not have chosen to participate if fully informed • If observed, subject may feel invasion of privacy • Damage to self-esteem; feeling ashamed, guilty, stressed, embarrassed • Forced to have knowledge about self that otherwise might not want to know • Feel loss of control, may be distrustful/suspicious **c. Describe your debriefing procedures for research participants.** Please provide in details • who will debrief research participants (the person should be a member of the research team and is knowledgeable about the research and the deception) • when research participants will be debriefed (e.g. immediately after the study is completed. Any delay in debriefing must be explained and justified) • Provide a rationale for any elements of the deception that will not be revealed to research participants. • Provide a full explanation of the hypothesis being tested, procedures to deceive research participants and the reason(s) why it was necessary to deceive them. It should also include other relevant background information pertaining to the study. If the study involves use of audio or videotaping an individual participant, the research participant should be given an opportunity to withdraw his/her consent for use of the tapes and, potentially, withdraw from the study all together, after the true purpose of the study is revealed.

Application Form: Section J – Recruitment Method

Sect / No	Question
J1	**How will potential research participants be identified? (Please tick all the applicable boxes)***
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	Please indicate how the potential research participants will be identified. Please select one of the options:
	
	• Referral by attending healthcare professional
	  ○ 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.
	
	• Persons with dependent relationship with study team (e.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)
	  ○ 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.)
	• Patients of study team
	• Databases
	  ○ 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.
	  ○ 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.
	• Other methods of research participant identification
	  ○ If 'Other methods of research participant identification' is selected, please indicate your method(s) of subject identification (E.g. Advertisement, word of mouth etc).

J2	**Will there be direct contact with Research Participants?**
Definition / Explanation	Please select "No" if there is no research participant interaction in this study (e.g. Medical record review). Please select "Yes" if there is research participant interaction in this study (e.g. face-to-face interview). If "Yes" is selected, six additional questions will appear, please provide responses to these questions.
J2(i)	**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.
J2(ii)	**How will the research participants be contacted?**
Objective	To determine if methods to contact potential research participants are appropriate.
Definition / Explanation	Possible methods of participant 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.
J2(iii)	**Will any advertising / recruitment materials (for e.g. posters/brochures/advertisements/telephone/email script) 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) <u>Posters</u>** 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) <u>Brochures</u>** 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) <u>Advertisements in Newspapers / Magazines / Publications</u>** Please state which publications will be carrying the advertisements, how many times the advertisement will run for, <u>and</u> attach a copy of the advertisement.***** **(iv) <u>Advertisements on Radio / TV</u>** Please state which radio / TV stations will be carrying the advertisements, how many times the advertisement will be aired, <u>and</u> attach a copy of the advertisement.***** **(v) <u>'Letter of Invitation' to potential research participants.</u>**

	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) <u>Letter to Doctors requesting for referrals.</u>** DSRB review and approval is not required for letters to doctors for referring potential research participants. **(vii)<u>Other types of materials will be used.</u>** Please elaborate on the recruitment material(s) that will be used, and attach a copy for DSRB review. **IMPORTANT NOTE:** 1. <u>Guidelines for preparing advertisements</u> 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. 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.)
J2(iv)	**Will any other recruitment strategies be used? (e.g. Talks in public places, societies etc.)**
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	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.
J2(v)	**Please indicate the length of time of the Research Participant's direct involvement in the study.E.g For completion of surveys, focus group discussion, taste evaluation, clinical visits, examinations etc. (If applicable)**
Objective	To determine if the participant's duration of involvement is reasonable.
Definition / Explanation	Kindly indicate the time period (E.g. 6 weeks) during which the research participants will be involved in study related procedures Please enter "NA" if there is no participant interaction in this study

Application Form: Section K – Consent

Sect / No	Question
	YES. Informed consent will be obtained from potential Research Participants before enrolment into the study. **The PI is responsible for ensuring that all Research Participants give informed consent before enrolling into the study. Please describe the consent process below.**
K1	**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.
K2	**Where will consent be taken (e.g. 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.
K3	**Who will take consent from potential research participants/legally acceptable representatives (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.
K4	**Besides the Informed Consent Form, will any other materials or documents be used to explain the study to potential research participants/legally acceptable representatives? (eg. scripts, handouts, brochures, videos, logs, etc).***
Definition / Explanation	If 'Yes' is selected, please attach the document(s) for DSRB review.
K5	**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. Compensation for participation should not include coupons for discount on the price of the study material after the product is approved for marketing.
K6	**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.* o 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.* o 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. **<u>Category B</u>** • 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
K7	**Consent Language** **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 possible languages that will be understood by the prospective Research Participant or the legally acceptable representative?*</u>** Please select the appropriate language(s). **<u>(b) Will the consent be communicated in a language that is understood by the prospective Research Participant or the legally acceptable representative?*</u>** **<u>(c) 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.
K8	**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
K9	**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.
K10	**If community consent is required for this study, please describe how it will be obtained. Please attach copies of documents to be used in this community consent process.**
Definition / Explanation	Please provide in details • how individuals who could be considered legitimate representatives of the community are identified • how community consent is obtained (e.g. through a process of dialogue with the community leadership or written agreement) IMPT: Community consent does not preclude the individual consent if DSRB deem necessary.

Application Form: Section L - Waiver of Consent

Sect / No	Question

L	**The DSRB may waive the requirement to obtain informed consent if the DSRB finds that the study meets the following criteria:**
L1	**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.
L2	**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.
L3	**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.
L3Ai	**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.
L3Aii	**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).
L3Bi	**The research cannot reasonably be 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.
L3Bii	**The process of obtaining consent from the person, to which the individually-identifiable health information relates, will involve a disproportionate amount of effort and 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).
L3Ci	**The study 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.
L3Cii	**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.
L4	**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.
L5	**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.
L6	**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 M – Risk & Benefit Assessment

Sect / No	Question
	Identify the risk(s) to individual research participant and group/population according to the respective categories. Then provide details on the steps that will be taken to overcome or minimize the risk (if any).
M1	**Economic / Financial Risk**
Definition / Explanation	Please identify if there is any economic / financial risk(s) to individual research participant and group/population (e.g. risk of employment termination) and propose steps to overcome or minimize the risk. Please indicate the probability and magnitude of the risks (e.g. high/low). Select "Not Applicable" if not applicable
M2	**Legal Risk**

Definition / Explanation	Please identify if there is any legal risk(s) to individual research participant and group/population (e.g. risk of getting arrested or charged when research involves population engaging in illegal behaviours) and propose steps to overcome or minimize the risk. Please indicate the probability and magnitude of the risks (e.g. high/low). Select "Not Applicable" if not applicable **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.
M3	**Physical Risk**
Definition / Explanation	Please identify if there is any physical risk(s) to individual research participant and group/population (e.g. bruising in blood taking) and propose steps to overcome or minimize the risk. Please indicate the probability and magnitude of the risks (e.g. high/low). Select "Not Applicable" if not applicable
M4	**Psychological Risk**
Definition / Explanation	Please identify if there is any psychological risk(s) to individual research participant and group/population (e.g. physiological stress during administration of questionnaires with sensitive questions or neurological testing) and propose steps to overcome or minimize the risk. Please indicate the probability and magnitude of the risks (e.g. high/low). Select "Not Applicable" if not applicable
M5	**Social Risk**
Definition / Explanation	Please identify if there is any social risk(s) to individual research participant and group/population (e.g. loss of reputation) and propose steps to overcome or minimize the risk. Please indicate the probability and magnitude of the risks (e.g. high/low). Select "Not Applicable" if not applicable
M6	**Discuss any potential benefits to the individual Research Participants and/or the population of Research Participants and/or to the society that justify involvement of Research Participants in this study.***
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 knowledge gained from this research to the study's population.
M7	**Is it appropriate for your research to have a monitoring plan to periodically assess the data to ensure the safety of Research Participants or to ensure negative outcomes do not occur (e.g. physiological stress, employment termination etc)**
Definition / Explanation	Please advise if there is a monitoring plan to periodically assess the data to ensure the safety of research participants or to ensure negative outcomes do not occur.
M7(a)	**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.
M7(b)	**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.
M7(c)	**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.

Application Form: Section N – Privacy and Confidentiality

Sect / No	Question
	In general, to protect the Research Participant's confidentiality, research data should be coded, and the links between the Research Participant's identifiers and the codes should be stored separately from the research data.
N1	**Please state how the research data will be protected to ensure confidentiality and security.*** (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 on in a secured computer that is password-protected. The databases will not contain subject identifiers and the data linking subject identifiers and the subject identification codes will be stored separately. When portable media (e.g. CD, USB drives etc.) are used to store the data, subject identifiers are stored separately.
Definition / Explanation	Please select where the data will be stored accordingly.
N2	**Describe who will have access to the research data.**
Definition / Explanation	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.
N3	**Will research data be released and shared with individuals or entities outside the institution? If yes, please ensure that only coded data is shared to protect data confidentiality.***
Definition / Explanation	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.
N4	**Will the research data be used for future research after the study is completed?** **• 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 that is longer.** **• Yes, the research data will be used for future research. Please register a standing database with DSRB only once the study has completed.**
Definition / Explanation	Please select if the research data will be used for future research after the study is completed. For other types of research (except clinical trials), 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.
N5	**Will any part of the study procedures 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 question for Section N5. If 'Yes' is selected, this would mean that data will be recorded on audiotape, film/video, or other electronic medium. Please continue to respond to the following questions.
	(a) Please describe the contents of the recording (e.g. audio-recording of interview/focus group discussion, images of facial features, etc.).* Please describe the contents of the recording (e.g. audio-recording of interview/focus group discussion, images of facial features). **(b) What is the medium (audio tape / video etc) used for recording?*** State the option/ choice of recording medium **(c) 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 subject will be audio-taped and later transcribed.) **(d) 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 assessing and using the data in the recording medium. **(e) 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 O - Biological Sample

Sect / No	Question
O1	**Will any biological materials (such as blood or tissue) be used as part of the study?***
Definition / Explanation	If 'No' is selected, there is no further question in Section O that will require your response. If 'Yes' is selected, you will be required to answer all the questions in this section.

O1 – (a)	**(For prospective biological materials only). Please state the type of biological materials used and describe how they are 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.
O1 – (b)	**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 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.
O1 – (c)	**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
O1 – (d)	**Will results from the tests be communicated to the 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).
O1 – (e)	**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
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.
O1 – (f)	**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, no cell lines will be created from the biological materials and no further question from O1 (f) will require your response. If 'Yes' is selected, please indicate if the cell lines will have any identifiers linking to the particulars of the research 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. This is to ensure that investigators protect the confidentiality of the research participants and the cell lines cannot be traced back to the individual research participant.
O1 – (g)	**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 P – Results and Outcome of Research

Sect / No	Question
P1	**Will research results be disseminated to the community? * (For community-based participatory research, the researchers should consider if the results should be disseminated to the community)***
Definition / Explanation	Please indicate if results will be conveyed to the community, especially for community-based participatory research or studies involving sensitive topics/ minority populations where it might be beneficial or important to the community. This question is not intended to ask about the presentation or sharing of research results with other clinicians, scientists etc. If yes, please indicate the reason/s for sharing the information to the community and describe how the results be disseminated (e.g. through reports, brochures or mass media).
P2	**Will research results raise any community concern?***
Definition / Explanation	Please describe the measures to evaluate the impact and if research results should be published (e.g. vetting publication etc) If yes, please provide details.

Application Form: Section R - Research Participants – Pregnant Women, Fetuses & Neonates

Sect / No	Question
R1	**Please indicate if your research involves:*** • **Pregnant Women and Foetuses** • **Neonates of Uncertain Viability and/or Nonviable neonates** • **Viable neonates** **Please ensure that your research does not involve maintaining the vital functions of the neonate artificially or terminating the heartbeat or respiration of the neonate.**
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.
R2	**Enrolling Pregnant Women, Foetuses and/or Neonates in research requires that the research meet specific criteria. Please provide protocol specific information explaining how your proposed research project meets ALL of the following criteria.** **Please list the exclusion criteria. For studies with potential risk to the foetus (e.g. use of investigational drugs, invasive medical device, X-rays, MRI scans with contrast), please state clearly, if pregnant women will be excluded from the study.***
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.
R3	**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.
R4	**Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants***
Definition / Explanation	Kindly state all additional steps that will be taken to minimize coercion and to protect the rights, safety and well-being of research participants.
R5	**Special Inform Consent Requirements (Check all that apply)***
Definition / Explanation	I will obtain consent from the pregnant women because: • 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 fetus. • Risk to the fetus 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. I will also obtain consent from the father because the research holds out the prospect of direct benefit solely to the fetus. • Research holds out the prospect of direct benefit solely to the foetus. The Informed Consent document(s) will provide information regarding the reasonably foreseeable impact of the research on the fetus or neonate.
R6	**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 / Explanation	Please select a response "Yes" or "No" in reference to the Assurances as listed.

Application Form: Section S - Research Participants – Children

Sect / No	Question
S1	**Research involving Children (Persons under the age of 21 years who are not and were never married) - Please provide protocol specific information explaining how your proposed research project meets the following criteria.** **Describe whether appropriate studies have been conducted on animals and adults first and the data available from such studies is available to assess risks to children participating in the research.***

Definition / Explanation	Describe whether appropriate studies have been conducted on animals and adults first and the data available from such studies is available to assess risks to children participating in the research. If such studies have been published please state the publication details.
S2	**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.
S3	**Describe how the relation of potential benefits to risks is at least as favourable to the participants 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).
S4	**Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.***
Definition / Explanation	Please state if additional steps will be taken to minimize risks and to protect rights, safety and wellbeing of research participants.
S5	**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 permission will not be obtained. Only assent/consent will be obtained.** **- Neither the children's assent/consent nor parent's/legally acceptable representative's permission 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. 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 children'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 T - Research Participants – Prisoners

Sect / No	Question
T1	**Research involving Prisoners - Please provide protocol specific information explaining how your proposed research project meets the following criteria.** **Does your 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
T2	**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.
T3	**Do potential research related risks commensurate with 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.
T4	**Are there adequate systems in place to ensure confidentiality of participation and of data?***
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 etc.
T5	**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 safety and well being of research participants.

Section U - Research Participant - Cognitively-Impaired Persons

Sect / No	Question
U1	**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).
U2	**Are there adequate procedures for evaluating the mental status of prospective subjects to determine whether they are capable of consenting?***
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.
U3	**Is it possible to identify persons authorized to give legally valid consent on behalf of any individuals judged incapable of consenting on their own behalf?***
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

U4	**Will the subject's assent be obtained?***
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.
U5	**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 objection to participate.
U6	**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).
U7	**Is there a possibility that the request to participate itself, 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).
U8	**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 V - 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.

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.

If any one of the study team member's curriculum vitae does not appear on this list, the CV must be uploaded through the User's ROAM Profile.

Application Form: Section W - 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.

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