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Research Online Administration & Management

Sample DSRB Application using the Population Health Study Application Form
Version 1.0

Disclaimer:

Please note that this sample application is intended to serve as a guide and should not be duplicated in its entirety for submission. Researchers would be required to complete their DSRB applications accordingly to suit the nature of their studies.

Acknowledgements:

Special thanks to Ms Ong Yu Han and Mr Lim Yong Hao from the Health Outcomes & Medical Education Research (HOMER) team at NHG Education Development Office who assisted in creating this sample application.

NHG Research

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CONTENT

Study Reference Number: [DRAFT]

Version Number: 0

A1. Please enter the full study title.

Assessing shared leadership in interprofessional team meetings: A validation study

A2. (Optional) Please assign Study Administrators below.* Click here for help

No.	Name	Institution	Department	Role	Email
There is nothing.					

B1. Overall Principal Investigator' (Main contact for DSRB): Yu Han Ong

B2 Study Sites under the oversight of NHG DSRB (Please click here to view complete list)

No.	Study Site	Name	Study Role	Institution	Department	Min Training
1	NHG HQ	Ms Yu Han Ong	PI	NHG HQ	NHG Education Development Office	Completed
2	NHG HQ	Mr Lim Yong Hao	Co-Investigator	NHG HQ	NHG Education Development Office	Completed

B3. External Study Sites under the supervision of the 'Overall Principal Investigator' (eg. Nursing Home, Community Hospitals, Community Centres etc). Please attach the Notice of Intent (NoI) if applicable.* Click here for help

No.	Study Site	Institution Authorisation	Engaged in research	IRB Approval	Contact Person
There is nothing.					

B4 External Study Site (for Institutions NOT under the oversight of NHG DSRB)

(a) to another IRB?

- ◉ No
- ○ Yes, please state the IRB.

(b) Has the application been previously rejected by any IRB? (Including NHG-DSRB)

- ◉ No
- ○ Yes

B5 Research Specialty

(a) Please indicate the Special / Research Expertise

No.	Primary Specialty	Primary Sub Specialty	Others
1	Geriatric Medicine	Others	All healthcare workers

(b) Please indicate/add Secondary Special / Research Expertise

No.	Primary Specialty	Primary Sub Specialty
1		

With effect from 1 January 2015, all study team members involved in the design, conduct or reporting of the research are required to complete and endorse a Conflict of Interest Declaration Form annually to the DSRB Financial Conflict of Interest (FCOI) Secretariat. This declaration includes any conflicts of interest of their immediate family members (includes parents, siblings, spouse and each dependent child).

The annual Conflict of Interest Declaration Cycle will be from 01 Jan to 31 Jan of the year and the declaration will be valid from 1 Jan to 31 Dec of the same year. The Conflict of Interest Declaration Form may still be submitted beyond the Declaration Cycle. However, the declaration will only be valid until the next Declaration Cycle.The Conflict of Interest Declaration Form can be downloaded fromhttps://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/financial+conflict+of+interest/fcoi+policy.

An updated Conflict of Interest Declaration Form must be submitted to the FCOI Secretariat as soon as possible but no later than 30 days if any of the circumstances relevant described herein change during the conduct of the research.

Ms Yu Han Ong (Principal Investigator)

- ○ Yes
- ◉ No

Mr Lim Yong Hao (Co-Investigator)

- ○ Yes
- ◉ No

Please attach the Study Team Member List if there are any study team members (study coordinators, biostatisticians etc.) involved in the design, conduct and reporting of the research, who are not listed in Section B and C of the DSRB Application Form.

D1 Please select the Nature(s) of Study that best describes your application

- ☑ Education Research
- ☐ Health Services and Outcome Research
- ☐ Prevention & Health Promotion Programme
- ☐ Epidemiological Research
- ☐ Social and Behavioral Research
- ☐ Community-based Participatory Research
- ☐ Others

D2 Please tick all research method(s) that is/are relevant to your study:* Click here for help

- ☑ Questionnaire or Survey
- ☐ Analysis of Existing Data
- ☐ Focus Group Discussion / Interview
- ☐ Clinical Research

E1. Who will be responsible for the payment and compensation of injury or illness arising from participation of research participants in the study?

- ◉ National Clinical Trial (CT) Insurance Policy (Contact your institution research office for more information)
- ○ Sponsor
- ○ Others

E2 Please give information regarding the study's Funding source or Sponsor information.

- ○ No funding is required for this study to be carried out
- ○ Pharmaceutical / Industry Sponsored
- ◉ Grant

i. Name of Grant Agency and Grant Name Others

Please specify: HOMER Grant

ii. Grant amount applied for 5000

iii. Date of Grant application deadline 18-Feb-2013

iv. Has the Grant application been approved?

- ○ Yes. Grant application successful.
- ◉ No. Grant application is pending approval.

Is the study's initiation dependent on Grant approval?

- ◉ No. The study can be started without the Grant.
- ○ Yes. The study is dependent on the Grant to start.

- ○ Financing/Sponsorship from Community Based Agency

◉ Non- Exempt (Expedited / Full Board)
○ Exempt. Please note that if your study does not qualify as exempt, the application for Non-Exempt review must be completed.Please click on "Exempt" to find out more on the list

G1 What are the specific aims of this study?

To develop and validate a shared leadership scale in the context of interprofessional geriatrics care.

G2 What is the Hypothesis of this study? For qualitative studies, please provide the research question instead.

There is no hypothesis because this is an exploratory study. We aim to explore whether the modified Carson's(2007) scale can be used in interprofessional teams meetings.

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.

Traditionally, the study of leadership in the healthcare context has focused on the characteristics of individual leaders (Bass, 1992). In recent years, interprofessional collaborative work is increasingly required of healthcare professionals to render effective patient care. This is especially so in specialties like Geriatric Medicine, where the professional expertise of different healthcare professionals are needed to effectively and efficiently manage the increasingly complex medical, functional, and social issues of elderly patients (Tan et al., 2012). In view of this, there is a concomitant shift in leadership trends from a top-down approach to a dynamic collaborative decision-making approach. Shared leadership, a well-developed concept in business and organizational literature (Pearce, Hoch, Jeppesen, amp; Wegge, 2009), is thus salient in enhancing our understanding of the leadership dynamics that occur in interprofessional teams. Although several studies (Hiller, Day and Vance, 2006; Hoch, Dulebohn and Pearce, 2010a; Grille amp; Kauffeld, 2015) have reported validated scales to assess shared leadership, none of these scales have been validated in the healthcare setting.Despite the emerging importance of shared leadership and related concepts in the healthcare literature (Dow et al., 2013; Leasure et al., 2013; Lingard et al., 2012; Rogers, 2012; Kunzle et al., 2010; Klein et al, 2006; Steinert, Goebel, amp; Rieger, 2006), there is currently no validated instrument to assess shared leadership in interprofessional healthcare teams. There is also a significant gap in the understanding of what constitutes shared leadership in the healthcare setting, and its role in bringing about effective interprofessional collaboration. Hence, we aim to validate an instrument,to assess shared leadership as a measure of interprofessional collaborative practice in shared decision-making. Our aim is to validate a shared leadership scale by determining its internal consistency, factor structure, as well as convergent, discriminant, concurrent and predictive validity in interprofessional team meetings in geriatrics care.

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.

Power calculations will not be done as the study is exploratory in nature. We are also looking at recruiting all healthcare professionals working in geriatric subacute wards in Tan Tock Seng Hospital who have attended interprofessional team meetings in the preceding year. The estimated number that we will be recruiting is 115 health professionals. They are selected because of the multidisciplinary nature of the work in geriatric subacute wards. The focus of the analysis will be on examining the psychometric properties of the adapted scale. The properties that we will be looking at are internal consistency using Cronbach's Alpha, construct validity using exploratory factor analysis (EFA), and concurrent and predictive validity using logistic regression.

G5 Please provide a list of relevant references

Carson, J. B., Tesluk, P. E., amp; Marrone, J. A. (2007). Shared leadership in teams: An investigation of antecedent conditions and performance. Academy of Management Journal, 50(5), 1217–1234.D'Innocenzo, L., Mathieu, J. E., amp; Kukenberger, M. R. (2014). A meta-analysis of different forms of shared leadership–team performance relations. Journal Of Management.Daiker, B. L. (2009). Shared Leadership in a Medical Practice: Keys to Success. The Journal of medical practice management: MPM, 25(2), 111.Dow, A. W., DiazGranados, D., Mazmanian, P. E., amp; Retchin, S. M. (2013). Applying Organizational Science to Health Care: A Framework for Collaborative Practice. Academic Medicine, 88(7), 952–957. Faraj, S., amp; Sproull, L. (2000). Coordinating expertise in software development teams. Management science, 46(12), 1554-1568.Grille, A., amp; Kauffeld, S. (2015). Development and Preliminary Validation of the Shared Professional Leadership Inventory for Teams (SPLIT). Psychology, 06(01), 75–92. Hoch, J. E., Dulebohn, J. H., amp; Pearce, C. L. (2010a). Shared Leadership Questionnaire (SLQ): Developing a Short Scale to Measure Shared and Vertical Leadership in Teams. Visual Presentation at the Society for Industrial and Organizational Psychology

(SIOP) Conference 2010, Atlanta.Klein, K. J., Ziegert, J. C., Knight, A. P., amp; Xiao, Y. (2006). Dynamic delegation: Shared, hierarchical, and deindividualized leadership in extreme action teams. Administrative Science Quarterly, 51(4), 590-621.Klimoski, R., amp; Mohammed, S. (1994). Team mental model: construct or metaphor? Journal of management, 20(2), 403-437.Künzle, B., Zala-Mezö, E., Wacker, J., Kolbe, M., Spahn, D. R., amp; Grote, G. (2010). Leadership in anaesthesia teams: the most effective leadership is shared. Quality and Safety in Health Care, qshc-2008.Leasure, E. L., Jones, R. R., Meade, L. B., Sanger, M. I., Thomas, K. G., Tilden, V. P.,Bowen, J.L., Warm, E. J. (2013). There Is No "I" in Teamwork in the Patient-Centered Medical Home: Defining Teamwork Competencies for Academic Practice. Academic Medicine, 88(5), 585–592. Lingard, L., Vanstone, M., Durrant, M., Fleming-Carroll, B., Lowe, M., Rashotte, J., Sinclair L. amp; Tallett, S. (2012). Conflicting messages: examining the dynamics of leadership on interprofessional teams. Academic Medicine, 87(12), 1762-1767.Mayo, M., Meindl, J. R., amp; Pastor, J. C. (2003). Shared leadership in work teams: A social network approach. In C. L. Pearce amp; J. A. Conger (Eds.). Shared leadership: Reframing the hows and whys of leadership (pp.193–214). Thousand Oaks, CA: Sage.Pearce, C. L. (2004). The future of leadership: Combining vertical and shared leadership to transform knowledge work. The Academy of Management Executive, 18(1), 47-57.Pearce, C. L., amp; Conger, J. A. (2003). Shared leadership: Reframing the hows and whys of leadership. Sage Publications.Pearce, C. L., Hoch, J. E., Jeppesen, H. J., amp; Wegge, J. (2009). New forms of management: Shared and distributed leadership in organizations. European Journal of Psychological Assessment, 25(4), 285–286.Pearce, C. L., amp; Manz, C. C. (2005). The New Silver Bullets of Leadership: Organizational Dynamics, 34(2), 130–140. Pearce, C. L., amp; Sims, H. P., Jr. (2002). Vertical versus shared leadership as predictors of the effectiveness of change management teams: An examination of aversive, directive, transactional, transformational, and empowering leader behaviors. Group Dynamics: Theory, Research, and Practice, 6(2), 172–197. Pethybridge, J. (2004). How team working influences discharge planning from hospital: a study of four multi-disciplinary teams in an acute hospital in England. Journal of Interprofessional Care, 18(1), 29–41.Podsakoff, P. M., amp; MacKenzie, S. B., (1994). An examination of the psychometric properties and nomological validity of some revised and reduced substitutes for leadership scales. Journal of Applied Psychology, 79, 702-713.Steinert, T., Goebel, R., amp; Rieger, W. (2006). A nurse–physician co-leadership model in psychiatric hospitals: Results of a survey among leading staff members in three sites. International Journal of Mental Health Nursing, 15(4), 251-257. Tan, K. T., Adzhahar, F. B. B., Lim, I., Chan, M., amp; Lim, W. S. (2014). Transactive memory system as a measure of collaborative practice in a geriatrics team: implications for continuing interprofessional education. Journal of interprofessional care, 28(3), 239-245.Wegner, D.M. (1986). Transactive memory: A contemporary analysis of the group mind. In B. Mullen amp; G.R. Goethals (Eds.), Theories of group behaviour (pp. 185–208). New York, NY, USA: Springer-Verlag.Wetzel, A.P. (2012). Factor analysis methods and validity evidence: A review of instrument development across the medical education continuum. Academic Medicine: Journal of the Association of American Medical Colleges, 87, 1060–1069.Wood, M. S. (2005). Determinants of shared leadership in management teams. International Journal of Leadership Studies, 1(1), 64–85.

G6 Please submit a copy of at least two relevant papers

woods (2005) - determinants of shared leadership in management teams.pdf

carson et al (2007) - shared leadership in teams_an investigation of antecedent conditions and performance.pdf

G7 Does this study have a Study Protocol?

- ○ Yes
- ◉ No

G8 What is the estimated time needed to conduct this study?

No. of Years 1 **No. of Months 0**

G9 The PI is responsible for ensuring that all Research Participants give informed consent before enrolling into the study.* Click here for help

Please select all the applicable consent scenarios. For combinations of consent, please tick more than one

- ☑ Informed Consent will be taken from individual Research Participant
- ☐ Waiver of Informed Consent is requested for individual Research Participant
- ☐ Community Consent will be taken.

H1. Identify all categories or groups, primary or secondary target, age range and total number to be enrolled (consented).* Click here for help 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).

No.	Study Site (s)	Group / Population (e.g. Parents, Students, Residents, House Owners, Patients)	Primary or Secondary Target	Age Range (e.g. 6-12, 13 -21, 21-99)	Minimum Total Enrolment Target	Maximum Total Enrolment Target
1	NHG HQ	Healthcare workers	Primary	21-70	115	130
				Total	**115**	**130**

H2 Please provide justification for selection of all the group/population indicated in Section H1

The research involves studying perceptions of shared leadership among healthcare professionals in IPTMs at the Department of Geriatric Medicine.All healthcare professionals who have attended IPTM will be invited. The Department of Geriatrics Medicine is selected because the departments consist of multidisciplinary healthcare professionals.

H3 Please list the inclusion criteria.* Click here for help

We will invite healthcare professionals who attended IPTM in the preceding year to participate in the survey.

H4 Please list the exclusion criteria. Please state clearly, if pregnant women will be excluded from the study.* Click here for help

Healthcare workers who have not attended IPTM in the Department of Geriatric Medicine. Since this is an educational research study and does not cause any risk to pregnant women (they only need to complete survey), pregnant women are included in the study.

H5 Are there any recruitment restrictions based on the gender of the research participants?

- ◉ No
- ○ Yes

H6 Are there any recruitment restrictions based on the race of the research participants?

- ◉ No
- ○ Yes

H7 Does the study involve any of the vulnerable Research Participants ?

- ◉ No
- ○ Yes

H8 Is this study part of an international study?

- ◉ No
- ○ Yes

H9 Does the study involve any of the following?

☐ Inpatient
☐ Outpatient
☐ Healthy Volunteers
☑ Not applicable
☐ Others (e.g. parents, students, residents, house owners)

I1

Please list all procedures, measures and analyses that will be performed in this study. If you are extracting data from existing record, please indicate the period of data that will be extracted (E.g. 1 Jan 2000 ï¿½31 Dec 2010)

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).

Procedure:We will invite healthcare professionals who attended IPTM in the preceding year to participate in the survey. Using pre-defined categories from an earlier study (Tan et al., 2014), we will collect demographic details on age, gender, and clinical roles (doctors, nurses, therapists, social workers/care coordinators, and others). We will explain the study to participants and administer the survey using hardcopy questionnaire. Measure:We adapt the Shared Leadership Perception Survey (Wood, 2005), which originally measured the occurrence of shared leadership by pastors within church management teams. We select this scale because it assesses shared leadership at the team level with respect to: 1) team behaviour, 2) team structure, and 3) team members' tendency to share leadership. Due to inappropriateness of three items under the "emotional support" subscale (Wood, 2005) in the healthcare setting, we substituted with questions from the "social support" subscale of Carson's (2007) work on management teams. Analysis:Descriptive and analytical statistics will be performed using STATA version 12. To validate the shared leadership scale, we will perform the following analysis for both total and factor scores: (1) construct, convergent, discriminant, concurrent, and predictive validity; and (2) internal consistency using Cronbach's a.

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)* Click here for help

Questionnaire_v1.0_5 Oct 2016.docx

I3 Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

Low participation rate. The PI will do presentations at department meeting to generate interests among healthcare workers, so that they are encouraged to participate in the study.

- ◉ No
- ○ Yes

J1 How will potential Research Participants be identified? (Please tick all the applicable boxes)

- ☑ Referral by attending healthcare professional
- ☐ Persons with dependent relationship with study team (e.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)
- ☐ Databases
- ☐ Other methods of identifying potential research participants

J2 Will there be direct contact with Research Participants?

- ○ No
- ◉ Yes

(i) Who will make the first contact with Research Participants ?

The PI, Ong Yu Han

(ii) How will the Research Participants be contacted ?* Click here for help

The participants will be recruited face-to-face

(iii) Will any advertising / recruitment materials (for e.g. posters/brochures/advertisements/ telephone/email script) be used to recruit Research Participants?* Click here for help

- ◉ No
- ○ Yes

(iv) Will any other recruitment strategies be used? (Eg. Talks in public places, societies etc.)

- ○ No
- ◉ Yes

Please elaborate.

Presentation of the study proposal at Geriatrics department meeting.

(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)

15 minutes for completion of surveys

K1 Describe when the consent process will take place with the potential research participant, including the time provided for him/her to consider his/her participation in the study.* Click here for help

For the survey, implied consent will be taken. Completing the survey means that the person is willing to take part in the study. Before conducting the survey, the purpose, risk and benefit will be explained. They will be given 10 minutes to ask questions and to consider whether to take part in the study.

K2 Where will consent be taken (e.g. room, ward, outpatient clinic etc)? How will privacy, freedom from intrusion and comfort be ensured?* Click here for help

The surveys will be conducted in a quiet and conducive room in TTSH Annex.

K3 Who will take consent from potential research participants (e.g. PI, Co-Investigators etc)?* Click here for help

The PI

K4 Besides the Informed Consent Form, will any other materials or documents be used to explain the study to potential Research Participants?

- ◉ No
- ○ Yes

K5 Will Research Participants receive any monetary payments (including transportation allowances) or gifts for their participation in the study?* Click here for help

- ◉ No
- ○ Yes

K6 Will consent be documented in the form of a written and signed Informed Consent Form?

- ○ Yes, all Research Participants will be given a copy of the Research Participant Information Sheet and Consent Form.
- ◉ No, Consent will not be documented. (E.g. verbal consent).

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

- ○ Category A
- ◉ Category B

The research presents no more than minimal risk of harm to Research Participants.

Please explain why your study fulfils this criterion.

The study has minimal risk. Before conducting the survey, research participants will be informed thatparticipation in this study is voluntary. Withdrawal from the study will not affect their job or any benefits towhich they are entitled. The survey will be carried out in a quiet and conducive room in TTSH Annex.To protect participants' identity and privacy, all collected data will be stored in a secured computer with passwords and the computer will be kept in the PI's office at Level 3,TTSH Annex 2. Participatory of the study is anonymous. Participants' real names will not be identified as pseudonyms will be used.

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.

By completing the survey, it means that the individual is willing to take part in the study. Implied consent will be taken.

K7 Will the study enroll non-English speaking research participants?

- ◉ No

Please explain why.

All potential participants are proficient in English. Hence, we do not foresee enrolling any non-English speaking participants.

○ Yes

K8 Do you have any additional comments regarding the Informed Consent process?

◉ No

○ Yes

K9 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.

Not applicable

Identify the risk(s) to individual subject 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).* Click here for help

- ☐ M1 Economic / Financial Risk
- ☐ M2 Legal Risk
- ☐ M3 Physical Risk
- ☑ M4 Psychological Risk

Section

Group	Identify the risk & steps to overcome / minimise the risk	Probability (High /Low)	Magnitude (High / Low)
Individual Research Participant	The study has minimal risk as they only need to complete a questionnaire. No identifier will be collected in the questionnaire. During the consent process, research participants will be informed that participation in this study is voluntary. Withdrawal from the study will not affect their job or any benefits to which they are entitled. The consent process will be carried out in a quiet and conducive room in TTSH Annex. All data collected	Low	Low

	will be stored in a password protected computer which will be locked in the PI's office at Level 3,TTSH Annex 2.		
Group / Population	NA	**Not applicable**	**Not applicable**

☐ M5 Social Risk

M6 Discuss any potential benefits to the individual Research Participants and/or the population of Research Participants that justify involvement of Research Participants in this study.

There is currently no validated instrument to assess shared leadership in interprofessional healthcare teams. There is also a significant gap in the understanding of what constitutes shared leadership in the healthcare setting, and its role in bringing about effective interprofessional collaboration. By developing and validating a shared leadership scale, the tool can be used to assess shared leadership in interprofessional collaborative practice in shared decision-making.

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)* Click here for help

◉ No
○ Yes

N1 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.

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

- ☑ 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.

N2 Describe who will have access to the research data.* Click here for help

The research team members and the Research Assistant. The RA will sign a confidentiality form before his/ her data entry job commences.All data will be coded to an identifier, and to be kept in a password secured computer.

N3 Will research data be released and shared with individuals or entities outside the institution? If yes, please ensure that there is an agreement in place to protect data confidentiality.

- ◉ No
- ○ Yes

N4 Will the research data be used for future research after the study is completed?* Click here for help

- ○ No, the research data will be destroyed after it has been stored for 6 years or minimum duration of retention period as specific 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.

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)?

- ◉ No
- ○ Yes

O1 Will any biological materials (such as blood or tissue) be used as part of the study?

- ◉ No
- ○ Yes

P1 Will research results be disseminated to the community?

○ No
◉ Yes

Please explain how results be disseminated:

Results will be presented at conferences and internal symposium. The PI will communicate the results with anyhealthcare professionals who are interested in this study.

P2 Will research results raise any community concern?

◉ No
○ Yes

Please ensure that the Curriculum Vitae is accurate and up to date.* Click here for help

No.	Study Site	Name	Study Role	CV
1	NHG HQ	Ms Yu Han Ong	PI	
2	NHG HQ	Mr Lim Yong Hao	Co-Investigator	

Your DSRB Application is now complete and ready for submission.

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

☐ **I have read and agree to the above declaration.**

Principal Investigator: Yu Han Ong