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NUSMed Medical Sciences Department Ethics Review Committee (MSDERC)

**MSDERC EXEMPTION FORM FOR SOCIAL,**

**BEHAVIOURAL & EDUCATIONAL RESEARCH (SBER)**

**Section A:**

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| **Please refer to the list of SBER exemption categories and guidelines before completing this.** (You can download the relevant guidelines and forms from the [NUS-IRB website](http://www.nus.edu.sg/irb/) under SBER guidelines) |
| **1. Protocol Title** |  |
| 1. **PI and Department**
 | Name of Principal Investigator (PI): Position/Designation: Telephone number: Email address: Dept. and Institution: \* If there is a Co-Investigator(s) (Co-I), please indicate in the “List of PI and Co-Investigators” form in the next section. |
| 1. **Study Site(s)**
 | Site(s) of Research (Dept. and Institution):[ ]  Single-centre [ ]  Singapore Multicentered [ ]  International MulticenteredIf single-centred, has a similar study been conducted elsewhere? If Yes, state where: Previous Ethics Committee Submission? If Yes, please provide details:  |
| **4a. Exemption Category** | (please refer to the application guidelines on which types of research can be exempted from IRB review)Choose your exemption category |
| **4b. Type of Study** | [ ]  Archived/ Existing Database [ ]  Experiments[ ]  Survey / Interview / Focus Group [ ]  Others, please specify:  |
| 1. **PI’s Declaration**
 | **I hereby declare that my research study:** |
| (Please check with the IRB secretariat if unsure) | **Yes** | **No** | **Risks:** |
| [ ]  | [ ]  | 1. Is of minimal risk.
 |
| [ ]  | [ ]  | 1. Does not place the research participants at risk of criminal or civil liability and is not damaging to the research participants' financial standing, employability, or reputation if their responses are disclosed outside the research study.
 |
|  | [ ]  | [ ]  | 1. Has no physical, psychological or economic harm to research participants.
 |
|  | [ ]  | [ ]  | 1. Does not involve vulnerable populations (e.g. children, prisoners, pregnant women, non-healthy volunteers, cognitively impaired etc).
 |
|  | [ ]  | [ ]  | 1. Does not touch on sensitive topics (including but not limited to illegal conduct, criminal activities, racism, politics, sexual behaviour).
 |
|  | **Yes** | **No** | **Ethics:** |
|  | [ ]  | [ ]  | 1. Does not involve deception or withholding study’s stated aims and objectives from research participants.
 |
|  | [ ]  | [ ]  | 1. Is ethically sound in terms of the protection of research participants.
 |
|  | [ ]  | [ ]  | 1. Has no ethical concerns that should be declared for this review.
 |
|  | [ ]  | [ ]  | 1. Only involves investigators with relevant experience and training in the field of the research study.
 |
|  | **Yes** | **No** | **Privacy and Confidentiality:** |
|  | [ ]  | [ ]  | 1. Research data will be retained in accordance to NUS’ Research Data Management Policy.
 |
|  | [ ]  | [ ]  | 1. The PI will protect research participants’ privacy and the confidentiality of their personal data, and comply with the NUS Data Protection Policy.
 |
|  | **Yes** | **No** | **Consent:** |
|  | [ ]  | [ ]  | 1. Uses PIS&CF(s) that complies with NUS-IRB’s Guidelines on Participant Information Sheet and Consent Form for “SBER” studies (IRB-GUIDE-S03).
 |
|  | **Yes** | **N.A.** | **Additional Declarations, if applicable:** |
|  | [ ]  | [ ]  | 1. If there is use of research participants’ photographs/ video-recordings/ quotes in publications/ presentations (with or without their personal data), express consent will be sought from research participants.
 |
|  | [ ]  | [ ]  | 1. If posters/ advertisements/recruitment emails will be used, contents of recruitment materials are in accordance with NUS-IRB’s guidelines on advertisement for “SBER” studies (IRB-Guide-S04).
 |
|  | **Yes** | **No** | **Final Declarations:** |
|  | [ ]  | [ ]  | 1. I will not initiate this research until I receive notification of NUS-IRB’s approval and any other approval from relevant authorities (local/overseas).
 |
|  | [ ]  | [ ]  | 1. I will promptly report any unexpected or serious adverse events, unanticipated problems and incidents that may occur in the course of this research.
 |
|  | [ ]  | [ ]  | 1. I will maintain all relevant study documents and recognize that the NUS-IRB staff and regulatory authorities may inspect these records.
 |
|  | [ ]  | [ ]  | 1. I understand that failure to comply with all applicable regulations, institutional and NUS-IRB’s policies and requirements may result in the suspension or termination of approval for this research, and other actions as stated in the NUS Code & Procedures on Research Integrity.
 |
|  | [ ]  | [ ]  | 1. I declare that there is no existing or potential conflict of interest for any of the investigators participating in this research.
 |
|  | [ ]  | [ ]  | 1. I will promptly report any change in the conduct of the research study that deviates from the IRB application form.
 |
| 1. **Financial Declaration**
 | Source of funding for study: Amount of Sponsorship / Grant : Status of grant: The financial benefits or other benefits derived from this study to PI / Co-I(s) / Department / Institution are as follows:  |
| 1. **HOD’s Declaration**
 | I declare that this research is approved by the department and is in keeping with the department’s standards. |
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|  | Signature of Head of Department Date |
|  | Name of Head of Department:  |
| 1. **PI’s Signature**
 | I hereby declare the information in this application form is correct. |
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|  | Signature of Principal Investigator Date |

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| **CO-INVESTIGATORS** |
| *All co-investigators who have a responsibility for the consent process or direct data collection for this research should be listed below. Multiple copies of this form may be submitted as necessary. All co–investigators need not sign on the same form.*  |
| Name:       Email:      Position:       Phone:      Department:       Institution:       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Co-investigator Date  |
| Name:       Email:      Position:       Phone:      Department:       Institution:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Co-investigator Date  |
| Name:       Email:      Position:       Phone:      Department:       Institution:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Co-investigator Date  |
| Name:       Email:      Position:       Phone:      Department:       Institution:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Co-investigator Date |

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| **Section B:** |
| **1. Specific Aims and Objectives:** |
| *1.1 State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested.* |
| 2**. Characteristics of Target Research Participants / Target Research Participants Data:** |
| * 1. *What is the target number of research participants? Give a breakdown by site of recruitment for multi-centre studies (if applicable).*

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| *Institution(s)/Site(s) of Recruitment* | *Total* |
|  |  |

* 1. *Lower Age Limit: Upper Age Limit (if any):*
	2. *Inclusion criteria:*
	3. *Exclusion criteria:*
	4. *Are the research participants vulnerable or in a dependent relationship with the researchers?*

 [ ]  *YES* [ ]  *NO* *If Yes, please provide details. Please note that research participants who are in a dependent relationship with the researchers should not be approached directly during recruitment, so as to prevent situations where participants consent under duress.*  |
| **3. Reimbursement:** |
| *3.1 Will research participants receive payment/ student course credits for participation? If yes, please elaborate. If no, please state “No reimbursement”.*  |
| **4. Recruitment Process:** |
| * 1. *Explain the process of recruitment in detail, for example, state where and how potential research participants will be recruited/ contacted.*
 |
| **5. Methodology:** |
| * 1. *Discuss in detail the (i) experimental design and research procedures, (ii) subject research visits (frequency and duration of procedures involved), (iii) period of recruitment to accomplish the aims of this research and (iv) attach the survey templates or interview questions used, if applicable.*
 |
| **6. Data Storage:** |
| *6.1 Please complete the following questions on measures you will take to protect research data and personal data collected. In addition, if your research involves making use of archived/ existing databases, please furnish the necessary documentation, e.g. permissions to use those databases, if applicable.** + 1. *Where will the research data be stored?*
		2. *Who will have access to the research data, and what are the data protection measures put in place for this study? What will happen to the research data after research completion?*

*6.1.3 Please state the personal data that will be collected (e.g., names and contact information, etc) and how research participants’ privacy and the confidentiality of their research data will be protected. What will happen to the personal data collected after completion of the research study?** + 1. *Any other remarks?*

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| **7. Application for Waiver of Documentation of Informed Consent (if applicable):** |
| * 1. *The PI is responsible for ensuring that all research participants give informed consent before enrolling into the research. Please submit a copy of the Participant Information Sheet and Consent Form.*

*(A sample of Participant Information Sheet and Consent Form is available on the IRB website at* <http://www.nus.edu.sg/research/irb/guidelines/sber-guidelines>*)****Note:******A Consent Form is NOT required where data collected is anonymous****, e.g. anonymous surveys.* |
| * 1. ***If waiver of documented consent is required (i.e. only verbal consent will be obtained)****, please justify how your research meets the 4 criteria. Please note that stating “Yes” is not a sufficient justification.*

*(The NUS-IRB may waive the requirement to obtain documented informed consent if the NUS-IRB finds that the research meets the following 4 criteria.)** + 1. *The research involves no more than minimal risk to the research participants.*
		2. *The waiver or alteration will not adversely affect the rights and welfare of the research participants.*
		3. *Whenever appropriate, the research participants will be provided with additional pertinent information after participation.*
		4. *The research could not practicably be carried out without the waiver or alteration.*

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\* Please go to the [NUS-IRB website](http://www.nus.edu.sg/irb/) to download the relevant guidelines and forms under “SBER guidelines”.