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| **NUS Institutional Review Board (IRB)** |
| **nus_logo_black_4cIRB APPLICATION FORM FOR SOCIAL,**  **BEHAVIOURAL & EDUCATIONAL RESEARCH (SBER)** |
| **Please refer to the guidelines for IRB Application Form (SBER studies) before completing this.** (You can download the relevant guidelines and forms from the [NUS-IRB website](http://www.nus.edu.sg/irb/).) |
| **I. BASIC INFORMATION** |
| **Protocol Title:** |
| **Simplified Title (*if Protocol Title is too long and/or technical*):**  (for use in recruitment documents, e.g. Participant Information Sheet & Consent Form, advertisements) |
| **Principal Investigator (Applicant):** |
| |  |  |  |  | | --- | --- | --- | --- | | Title | Name | Position | Dept./Institution | |  |  |  |  |   *(please complete section III for all co-investigators)* |
| Financial Declaration: |
| Grants, Source of funding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Department Funding  Others, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No Funding  The financial benefits or other benefits derived from this study to the PI/Co-I(s)/Department/Institution are as follows (if any): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Amount of Sponsorship/Grant: $ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Status of grant:  Approved  Pending  Not applicable |
| Type of Study: |
| Archived/ Existing Database  Questionnaire/ Survey / Interview / Focus Group  Experiments  Others, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Research May Involve: |
| **Human Participants**: (Target Number: \_\_\_\_\_\_\_\_)  Healthy Adults  Children (under 21 yrs old)  Pregnant Women  Outpatients  Prisoners  Elderly Cognitively Impaired Persons |
| Research Participants Will Be: |
| Reimbursed $\_\_\_\_\_  Not reimbursed  Others – please specify: \_\_\_\_\_\_\_\_\_\_\_ |
| Has this research been rejected by any IRB / REC / DERCs? |
| No  Yes If yes, please provide details. |
| Study Site(s): |
| Site(s) of research (including PI’s Dept. & Institution): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Single-centre study  Multi-centre study - No. of local sites: \_\_\_\_\_\_\_\_\_ No. of overseas sites: \_\_\_\_\_\_\_\_ |
| This research is also submitted to or has been approved by: |
| NHG Domain-Specific Review Board (DSRB) A / B / C / D / E / F  SingHealth Centralized IRB (CIRB) A / B / C / D / E / F  **Not Applicable** |

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| **II. DECLARATION OF THE PRINCIPAL INVESTIGATOR** | |
| The information provided in this form is correct.   1. I will not initiate this research until I receive written notification of NUS-IRB approval and any other approval from relevant authorities (local/overseas) (if applicable). 2. I will not initiate any change in protocol without prior written approval from NUS-IRB except when it is necessary to reduce or eliminate risk to the subject. 3. I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that may occur in the course of this research. 4. I will maintain all relevant documents and recognize that the NUS-IRB staff and regulatory authorities may inspect these records. 5. I understand that failure to comply with all applicable regulations, institutional and NUS-IRB policies and requirements may result in the suspension or termination of this research, and other actions as stated in the NUS Code & Procedures on Research Integrity. 6. I declare that there is no existing or potential conflict of interest for any of the investigators participating in this research.   Remarks (if any): | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_ |
| Principal Investigator’s signature | Date |
| Phone: Fax  Mailing Address: | |
| Email: | |
| **\*Please state the name and email address of the person(s) to copy to in the IRB’s acknowledgement email. If no name(s) is listed, the IRB Secretariat will only correspond with the PI.**  1.  2. | |

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| **III. 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: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-investigator Date |
| Name: Email:  Position: Phone:  Department: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-investigator Date |
| Name: Email:  Position: Phone:  Department: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-investigator Date |
| Name: Email:  Position: Phone:  Department: Fax:  Institution:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Co-investigator Date |

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| **IV. DECLARATION OF THE HEAD OF DEPARTMENT\*** |
| I declare that this research is approved by the department and is in keeping with the department’s standards.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Head of Department Date  Name of Head of Department:  Title: |

\* If the PI or co-investigator is the Head of PI’s Department, this section should be completed by the Vice-Dean (Research) or Dean of the Faculty.

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| **V. ABSTRACT OF RESEARCH PROTOCOL** |
| ***In no more than 300 words****, describe concisely the specific aims, hypotheses, methodology and approach of the application, indicating where appropriate it’s importance to science, existing knowledge and relevant applications. The abstract must be self-explanatory so that it can serve as a succinct and accurate description of the research study. Please use layman terms. If this is not possible, the technical terms should be explained in simple language.* |
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| **VI. RESEARCH PROTOCOL** |
| Organise details of the research protocol under the following headings (in no more than 7 pages). |
| **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. Introduction:** |
| *2.1 Briefly describe the background and the importance of the research.* |
| *2.2 Relevant references* |
| **3. Preliminary Studies:** |
| *3.1 Provide a brief account of the Principal Investigator’s preliminary/pilot studies (if any) pertinent to the application.* |
| **4. Methodology:** |
| * 1. *Describe in detail the (i) experimental design and research procedures, (ii) subject research visits (frequency and duration of procedures involved) and (iii) period of recruitment to accomplish the aims of this research.* |
| * 1. *Include details on sample size calculation and the means by which data will be analysed and interpreted.* |
| * 1. *What are the anticipated benefits and risks to human participants participating in this research?* |
| * 1. *Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.* |
| * 1. *Will any part of the procedures be audio-recorded, video-recorded, or placed on other electronic media?*  *Yes*  *No*   *If Yes, explain how the recorded information will be used? Will information collected be published with or without identifying research participants? How long will the recordings be retained and how will they be disposed of?*  *Will participants who decline recording be excluded from the study?*  *Yes*  *No*  *Please specify alternative:* |
| **5. Data Storage:** |
| *5.1 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?      * + 1. Who will have access to the data, and what are the data protection measures put in place for this study? What will happen to the research data after research completion?      * + 1. 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 personal data will be protected. What will happen to the personal data collected after completion of the research study?      * + 1. Any other remarks? |
| **6. Characteristics of Target Research Participants/ Target Research Participants Data:** |
| * 1. What is the number of participants to be enrolled? Give a breakdown by site of recruitment for multi-centred studies.  |  |  |  |  | | --- | --- | --- | --- | | Institution(s)/Site(s) of Recruitment | Total | Adults (at least 21 years old) | Children | |  |  |  |  |  * 1. Lower Age Limit:       Upper Age Limit (if any):   2. Are there any recruitment restrictions based on race or gender of the participant? If yes, please elaborate. If no, please state “Not Applicable”.      * 1. Inclusion criteria      * 1. Exclusion criteria      * 1. Are the 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. |
| **7. Participant Information Sheet and Informed Consent Form:** |
| * 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://nus.edu.sg/irb/guidelines.html*](http://nus.edu.sg/irb/guidelines.html)*)*  ***Note:******A Consent Form is NOT required where data collected is anonymous****, e.g. anonymous surveys.* |
| * 1. *Summarise the consent procedure. Please specify how informed consent will be obtained and who will obtain consent.* |
| * 1. ***I require a waiver of:***   ***Informed Consent as my research involves deception***  ***Parental Consent*  *Not applicable***  ***Documentation of Informed Consent (i.e. no documented consent)***  ***Documentation of Parental Consent (i.e. no documented parental consent)***  *If applying for waiver, please justify how your research meets each of the following criteria:*   * + 1. *The research involves no more than minimal risk to the participants.*      * + 1. *The waiver or alteration will not adversely affect the rights and welfare of the participants.*      * + 1. *Whenever appropriate, the participants will be provided with additional pertinent information after participation.*      * + 1. *The research could not practicably be carried out without the waiver or alteration.* |
| **8. Recruitment Process:** |
| * 1. *Explain the process of recruitment in detail, for example, state where and how potential research participants will be recruited/contacted. Please submit a copy of any advertisements/posters that will be used.* |
| **9. Timelines:** |
| * 1. *What are the estimated start and end dates of the research? Please note that you should not commence your research prior to IRB approval.*   *Start Date:*       *End Date:* |
| **10. Financial Aspects/Reimbursement:** |
| * 1. *Who will be responsible for research related costs? For sponsored research, list the costs that will be borne by the sponsor.* |
| * 1. *Will research participants receive payment/ student course credits for participation? If yes, please elaborate. If no, please state “No reimbursement”.* |

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