|  |
| --- |
|  |
|  |
| **nus_logo_black_4c**  **Departmental Ethics Review Committee (DERC)**  **Department of English, Linguistics and Theatre Studies** |
| **DERC APPLICATION FORM FOR SOCIAL,**  **BEHAVIOURAL & EDUCATIONAL RESEARCH (SBER)** |
| **Please refer to the guidelines for DERC Application Form (SBER studies) before completing this.** |
| **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 | |  | [DELETE this after reading] - Faculty members can use this form or the Exemption one, as the  case may be. Students should fill in the Full/Expedited form only for any project (Honours thesis, ISM, MA, PhD) that involves minimal risk Human Subject research (informant judgments, interviews, surveys etc.). Any research that is more than minimal risk should go through iRIMS-IRB. |  | English, Linguistics and Theatre Studies (ELTS) |   *(please complete section III for all co-investigators)* |
| **Purpose of Research:** |
| PhD/ MA Thesis  Honours Thesis  Qualifying Examination  Independent Study Course  Private Research  Others – please specify: \_\_\_\_\_\_\_\_\_\_\_ |
| 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  *\* Please note that DERC can review student research with no funding, is self-funded, or funded by internal NUS grant/funding. Student research that is externally funded to be sent to IRB for review.* |
| 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 (at DELTS, NUS)  Multi-centre study (if there is official collaboration with organisations outside NUS)  Overseas research (**for research involving data collection from China, Hong Kong or Macau please submit to IRB for review**) |
| 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** |

|  |  |
| --- | --- |
| **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 DERC 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 DERC 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 DERC staff and regulatory authorities may inspect these records. 5. I understand that failure to comply with all applicable regulations, institutional and DERC 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 DERC (ELT)’s acknowledgement email. If no name(s) is listed, the DERC Secretariat will only correspond with the PI.**  1.  2. | |

|  |
| --- |
| **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 |
| **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.

|  |  |  |
| --- | --- | --- |
| **V.** **Detailed Information** | | |
| **1** | **Study Introduction** | **Abstract:** Provide an abstract of this study that includes the following information (in no more than 300 words):  **Specific Aims**:  **Hypothesis:** *State N/A if not applicable.*  **Preliminary Studies:** State those studies relevant to this project. *State N/A if not applicable*.  **Study Participants:** Will this project involve the recruitment of human participants?  **Yes / No**  **If *No*:** (explain what data from human subjects will be used, in the Methodology section. You may ignore Study Participants, Recruitment, Recording and Reimbursement sections) |
| **2** | **Methodology** | 1. **Type of Study:** Select as applicable:   Archived/ Existing Data (attach supporting documents, if any);  Questionnaire/ Survey/ Interview/ Focus Group Discussion (FGD) (attach questionnaire/ survey/ interview guide/ FGD guide, if available);  Observations;  Interventions/ Experiments;  Educational Research;  Use of non-Medical Devices;  Deception: (attach debriefing statement);  Other(s), please describe.   1. **Procedures**: Describe the research procedure.   (i) What is the nature of the research? (ii) Does the research involve investigating a sensitive topic? (iii) For Internet research said to be ‘publicly available’, will login/password be required to access the site? Provide a sample analysis to show whether personal identifiers remain, i.e. can the avatar/online persona be traced to their offline/regular identity? (iv) Does the research involve subject research visits? If yes, please state frequency and duration of each session.   1. **Study Sites:** Will research procedures be conducted in non-NUS premise(s)? **Yes / No**   **If *Yes*,** please state premise(s).   1. **Anticipated Study End Date: (Please provide reasons for an end date that is longer than the candidature period).** |
| **3** | **Study Participants** | 1. **Participant Groups:** Select participant group(s) as applicable, and specify the target number(s), lower age limit(s) and upper age limit(s) for each group:   Healthy Adults;  NUS students (including Duke-NUS & Yale-NUS) (at least 18 years old);  Children below 21 years old who are not NUS Students;  Elderly with mental capacity (state how mental capacity will be screened);  Individuals who lack mental capacity (state how lack of mental capacity is determined);  Vulnerable Populations (state type of vulnerable population).  2. **Total number of Study Participants:**  3. **Inclusion Criteria (include minimum and maximum age):**  4. **Exclusion Criteria:**  5. **Relationship with Researchers**: Are there any participants in a dependent relationship with the researchers? **Yes / No**  **If *Yes*:**   1. Explain the dependent relationship(s) in detail and the mitigating measures to prevent cases where participants agree to participate while under duress, by coercion, intimidation, deception or misrepresentation. Please note that research participants who are in a dependent relationship with the researchers should not be approached directly during recruitment, in order to prevent situations where participants consent under duress. 2. PI will prevent cases where participants agree to participate while under duress, by coercion, intimidation, deception or misrepresentation. ☐ **Yes** |
| **4** | **Recruitment** | 1. **Where will participants be recruited from?:**   General Public;  NUS  NUS students  NUS staff  Organisations/ Agencies/ Companies/ Institutions/ Schools.   * + 1. Specify Organisations/ Agencies/ Companies/ Institutions/ Schools.     2. Confirm permission will be obtained from relevant authorities for recruitment of their staff/ clients/ students or on their premises~~:~~  **Yes / Not Required**   If not required, please explain why?   * + 1. Attach correspondence of willingness, if any.  1. **Overseas Recruitment:** Will participants be recruited from overseas? **Yes / No If *Yes*:** 2. List the countries: 3. Confirm that permission will be obtained from the relevant local authorities to conduct this research study there, if necessary.  **Yes  Not Required** 4. **How will participants be recruited?** Select recruitment method(s) as applicable:   Online survey platform;  Word of mouth/ Snowballing/ Referral/ Personal Contacts;  Phone calls (state where phone numbers will be obtained from);  Email invitation/ Letters (attach a copy);   * + - State where email addresses/ addresses will be obtained from.     - State who will be sending the invitation/ letters.   Advertisements/ Flyers/ Posters (attach a copy);   * + - Confirm permission will be obtained from the relevant authorities for the posting/ distribution of recruitment materials, if necessary.   Social Media;   * + - Confirm permission will be obtained from the relevant platform administrators for recruitment on their social media, if necessary.   Door-to-door recruitment (attach Notification letter);   |  | | --- | | Notification Letter should state the following details:  - Who is conducting research?  - What is research about?  - When the visit(s) will be conducted?  - Who to contact if they do not wish to be visited. |  * + - Confirm that door-to-door recruitment notification letter will be sent to residents at least 2 weeks in advance prior to the visit.  **Yes**   Other method(s), please describe.   1. Confirm that permission, where applicable, will be/ has been obtained from potential subjects for the use for their personal data (e.g. name and contact information) for recruitment purposes.  **Yes** |
| **5** | **Recording** | 1. **Will the procedure(s) be recorded?**  **Yes**  **No**   **If *Yes*** (Fill in Q2 – 4 in this section):   1. **Select type(s) of recording:**   Audio-recording;  Video-recording;  Photography.   1. Please explain how will the recorded information be used: 2. Will information collected be published with or without identifying research participants? 3. How long will the recordings be retained for: 4. How will the recordings be disposed of: 5. **Will participants who decline recording be excluded from the study? Yes / No**   **If *No*:** Specify alternative.  **If *Yes*:** Please state in the inclusion criteria above, *“Agrees to audio-recording”*, for example.   1. Confirm that any identifiable information in the recordings (e.g. faces, recorded names, etc.) will be removed/ covered before any publication or use, unless PI has obtained prior consent from participants.  **Yes** |
| **6** | **Risks and Benefits** | 1. **Anticipated Benefits and Risks:** What are the anticipated benefits and risks to the participants in this study? If applicable, please state the mitigating factors. |
| **7** | **Reimburse-ment** | 1. **Will participants be reimbursed for their participation? Yes / No**   **If *Yes*** (Fill in Q2 – 4 in this section):  Indicate Type(s) of Reimbursement:  Cash/ Voucher (please elaborate):  Course Credit (please elaborate):  Please note that reimbursement using course credits should adhere to NUS-IRB’s guidelines (IRB-Guide-023)  Lucky Draw (please describe):  Please note that use of lucky should adhere to NUS-IRB guidelines (*SBER Guidelines-Lucky Draw V1*):  Other(s) (please describe).   1. Will participants be entitled to reimbursement if they withdraw after their participation?  **Yes  No**   If ***No*:** please explain.   1. Will reimbursement be pro-rated if participants withdraw from the study mid-way?  **Yes  No**   If ***No***: please explain. |
| **8** | **Consent** | 1. **Will documented informed consent be taken?** Select as applicable:   Yes (attach PIS&CF);  No (attach PIS and request for a waiver of documentation of informed consent);  N.A (for studies conducted anonymously only)   1. **For individuals who lack mental capacity:** Confirm that documented consent will be obtained from the deputy or the subject's next-of-kin (attach PIS&CF from deputy or next-of- kin) 2. If recruiting non-NUS students below 21 years old, or NUS students below 18 years old, please confirm that documented parental consent will be obtained.  **Yes**   Please attach parental ISCF.   1. **Consent Procedures:** Please specify how informed consent will be obtained and who will obtain consent. 2. **Request for Waiver:** Request for Waiver: Select as applicable:   Not Applicable.  Documentation of Informed Consent;  Informed Consent (for research under SBER Exemption categories 1C and 4B);  Informed Consent as my research involves Deception;  **Please justify how your research meets each of the following criteria:**   1. The research involves no more than minimal risk to the participants. 2. The waiver or alteration will not adversely affect the rights and welfare of the participants. 3. Whenever appropriate, the participants will be provided with additional pertinent information after participation. 4. The research cannot be carried out without the waiver or alteration.   **Confirm that participation is voluntary and non-participation or withdrawal from the study will not have any negative impact on the participants.**  **Yes** |

|  |  |  |
| --- | --- | --- |
| 1. **9** | 1. **Research and personal data protection storage** | 1. **Will personal data be collected in this research?** Yes / No   **If Yes** (Fill in Q2 – 7 in this section):   1. **What personal data is collected**: e.g. name, contact number, etc.? 2. **Linkage of personal data to research data**: Will personal data be linked to research data? **Yes / No**    1. **If *Yes*,** confirm that personal data and research data will be coded at the earliest possible stage of the research.       1. Code Key Holder: Who will be holding onto the key to the code?       2. Code Key Location: At which secure/ password-protected platform will the key to the code be kept?       3. Code Key Destruction: When will the key to the code be discarded?    2. **If *No*,** select reason(s) for collecting personal data:   for reimbursement and/or scheduling reasons only;  to re-contact participants for future research opportunities;  other reason(s), please specify.   1. **Location of Personal data:** Where will personal data be kept?   nBox;  Encrypted thumbdrive and/or devices;  Other(s), please describe.   1. **Access:** Who will have access to the personal data?   NUS research team;  Other(s), please describe.   1. **Discarding Personal Data:** When will personal data be discarded?   Before/ Upon completion of study;  Kept beyond research period (justify the retention of personal data for DERC’s assessment).   1. **What will happen to the personal data if subjects withdraw from research?**   All of their personal data will be discarded at the earliest possible time;  Other(s), please explain.   1. **Where will research material/ research data be kept?**   nBox;  Encrypted thumbdrive, laptop or PC/Mac desktop.  Other(s), please describe.   1. **How long will research data be kept after completion of study?**   Research data will be kept for at least 10 years, password/encrypted, in accordance with NUS Research Data Management Policy;  Other(s), please explain.   1. **Who will have access to the research material/ research data?**   The P.I. and Co-I (if applicable) only;  Other(s), please describe.   1. **What will happen to the research data if subjects withdraw from research?**   All of their research data will be discarded at the earliest possible time;  Only research data which is individually-identifiable will be discarded;  Others, please elaborate. |
| **10** | **Attachments** | **Other Relevant Documents/Information:** Please elaborate on and/or attach any other relevant documents for this Research Protocol submission that may be important to reviewers and that were not included in the application. |