**GUIDELINES FOR DERC APPLICATION FORM**

(For Social, Behavioural and Educational Research studies)

## Submission Guidelines:

1. Research studies that do not fall under the purview of the Human Biomedical Research Act (HBRA) will generally be categorised as “*Social, Behavioural and Educational Research (SBER) studies.*” for the purposes of DERC review. However, the final decision will be made by the DERC and affected PIs will be informed if further documents are required.
2. An application that does not qualify for an exemption will undergo an expedited or full review. The review type is determined by the level of risk that participants are exposed to while participating in the research study; determination of the review type will be decided by the DERC.
3. The DERC can review only **minimal risk** research.Research categorized as involving more than minimal risk will be referred to the IRB Secretariat for further consideration**.**
4. For studies undergoing expedited or full review, please submit a set of the documents that will be used for the conduct of the research study to the DERC for review. E.g. Participation Information Sheet & Consent Form, recruitment materials, etc.
5. The onus is on the Principal Investigator (PI) to ensure the study documents to be used in his/her research study comply with DERC’s guidelines for “SBER” studies.
6. In lieu of hard copies and original handwritten signatures, electronic signatures or email statements (from parties involved, e.g. PI, Co-Investigator (Co-I) or Head of Department (HOD)) are accepted for application submission. in lieu of the hardcopies of their original written signatures.

**DERC Application Form Guidelines (for “SBER” studies)**

**Section I. BASIC INFORMATION**

**Protocol title:**

* Please use a protocol title that accurately reflects the aims and objectives of the research study.

**Simplified title (if any):**

* You may wish to include a simplified title for use in recruitment documents if your protocol title is too long and/or technical.

**Principal Investigator (Applicant):**

* Please note that the DERC can only review applications where the PI is a NUS staff, NUS graduate or undergraduate student or NUS/NUHS staff.
* If the PI is a graduate or undergraduate student, please include the Thesis Advisor or Honours Thesis Advisor as the Co-investigator.
* If the PI is an adjunct staff, please include a faculty staff as a Co-investigator.
* For Visiting Fellow /Postdoctoral Fellow /Research Fellow whose remaining contract duration is one year or less at the time of submission, or is shorter than the duration of the research, please include a faculty staff as a Co-investigator for the research. Alternatively, please let the DERC have the confirmation from the HOD that he/she agrees to bear administrative responsibility for the research study.

**Financial Declaration:**

* Please provide information regarding the research study’s funding source. If the research study is funded, please provide the name of the funding agency under “Source of funding.”
* For research studies where a commercial sponsor has interest on the research results arising from this research study, a review fee of $500 (excluding GST) will be applicable if NUS has not already charged 20% indirect costs / fees for this research study.

**Type of Study:**

* Please check the appropriate box(es).

**Research May Involve:**

* Please indicate the maximum target number of participants you wish to recruit and check the appropriate box(es).

**Research Participants Will Be:**

* Please check the appropriate box(es) with regards to reimbursement of research participants.

**Has this research been rejected by any IRB / REC / DERCs?**

* Please tick the appropriate box(es).
* If you have checked “Yes”, please provide details.

**Study Site(s):**

* Please state the PI’s department as one of the site(s) of the research study.
* If this research study is conducted in only one site, please check “*Single-centre study*”.
* If this research study is conducted in more than 1 site, please check “*Multi-centre study*”. Indicate the number of local and/or overseas sites.

**This research is also submitted to or has been approved by:**

* If this research study has been reviewed or is currently being reviewed by National Healthcare Group Domain-Specific Review Board (NHG-DSRB) or Singhealth Centralized Institutional Review Board (CIRB), please tick the relevant box(es) and indicate the domain that reviewed this study.
* Please check “Not Applicable” otherwise.

**Section II. DECLARATION OF THE PRINCIPAL INVESTIGATOR**

* By signing on this section, the PI declares that the information in the application form is correct and he/she will adhere to the stated declarations (a-f).
* If you wish to copy anyone in the IRB’s acknowledgement email, please state the name and email address of the person(s). If no name(s) is listed, the DERC secretariat will only correspond with the PI.

**Section III. CO-INVESTIGATORS**

* A Co-Investigator (Co-I) is any member of the research team designated and supervised by the PI to perform study-related procedures and/or make important study-related decisions.
* The PI of a research project should decide who his/her Co-I should be and determine the role of the Co-I.
* Please submit a copy of the Co-I’s CV for our records.
* If the PI is a graduate student, the supervisor must be a Co-I in the application.

**Section IV. DECLARATION OF THE HEAD OF DEPARTMENT**

* If the PI or Co-I is the Head of PI’s Department, this section should be completed by the Vice-Dean (Research) or Dean of the Faculty.
* Anyone signing on behalf of the HOD should ensure he/she is designated by the HOD to sign on the form.

**Section V. DETAILED INFORMATION**

**Study Introduction**

* Give an abstract of the research protocol in no more than 300 words.
* Please state the aims and objectives of the research study, including the hypothesis to be tested, if any.
* Provide a brief account of the PI’s preliminary/pilot studies (if any) pertinent to the application.

**Methodology**

* Please state your research methodology.
* The information contained in this section must be self-explanatory so that it can serve as a succinct and accurate description of the study when it is read by itself. As far as possible, explain technical terms in layman language.
* Please include the total time required by each research participant to complete the study procedure(s).
* Please state how the sample size is calculated and how research data will be analysed and interpreted.

- If it is possible that the PI may discover adverse / incidental findings during the conduct of the research study, please state the action the PI will take upon discovering them.

- Discuss the potential difficulties and limitations of the proposed procedures that may lead to failure to achieve the aims or complete the study. In addition, please list the corresponding alternative approaches to achieve the aims/overcome the difficulties and limitations.

- If any part of the procedure(s) will be placed on audio-recordings, film/video, or other electronic media, please explain how the recorded information will be used. How long will the recordings, etc, be retained and how will they be disposed of?

- If those who decline recording will be excluded from participating in the study, please state this as an exclusion criteria in section 6.5 of the DERC application form, in the Participant Information Sheet (PIS) and recruitment materials (if any).

- If those who decline recording will not be excluded from participating in the study, please specify the alternative. E.g. field notes will be taken instead.

**Study Participants**

* Please state the maximum target number of research participants you wish to recruit at each recruitment site/ institution, with a breakdown of the number of adults / children to be recruited.
* Please indicate the lower and upper age limit of each group of research participants. If there is no upper age limit, this field can be left blank.
* If there are any participant recruitment restrictions based on race or gender, please elaborate. If not, please state “Not Applicable”.
* Inclusion criteria: please state the eligibility criteria of research participants you wish to recruit.
* Exclusion criteria: please state the criteria that will exclude individuals from participating in the study.
* If research participants are in a dependent relationship with the researchers, please provide more details, e.g., teacher-student relationship, etc.
* 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 research participants consent under duress. The IRB recommends the use of an open invitation instead, e.g., class announcement.
* Research Studies Involving Data from China to be Reviewed by the NUS-IRB

Due to the enactment of China Personal Information Protection Law (PIPL) in November 2021, there are potential legal issues or complications associated for any study conducted in China and this applies to the processing of personal information of natural persons within the territory of the People’s Republic of China. This Law also applies to activities, carried out outside of the territory, to process personal information of natural persons within the territory under circumstances described in Article 3 of the PIPL.

Hence, until further notice, all research studies involving data from China should be reviewed by the NUS-IRB.

**Recruitment**

* Please explain how potential research participants will be recruited, e.g. using advertisements, email invitations, etc.
* Please state where personal data of potential research participants will be obtained from. If said personal data is not obtained from publicly available sources, please confirm that potential research participants have given their consent for the use of their personal data for recruitment.

**Timelines**

* Please note that recruitment of participants should only begin after obtaining IRB’s approval.

**Recording**

* Even if an obtained recording (audio, video, photography) is coded anonymously, please elaborate on how the original recording will be protected for the participant’s assurance regarding confidentiality.

**Risks and Benefits**

* Please state the anticipated benefits (direct and/or indirect) for participants in this research study, if any. Note that the DERC does not view reimbursement as a form of benefit.
* Please state and elaborate on the risks to participants in this research study, if any. E.g. physical harm, psychological harm, economic harm etc.
* Please state the measures that will be taken to mitigate the possible risks, if any
* If there is no benefit and/or risk to the research participants, please state so.

**Reimbursement**

* If research participants are to be given reimbursement or student course credits for their participation, please provide details. If there is no reimbursement, please state “*no reimbursement*”.
* If participants are required to attend more than 1 session, please state if reimbursement or student course credits will be pro-rated for those who are unable to complete all the sessions.

**Consent**

* Please fill in the PISCF (Participant Information and Consent Form) - This is an information sheet to provide information to research participants about the research study, e.g. participation in research is voluntary, the contact information of the PI and the DERC.
* A copy of the Participant Form should be given to the research participant even if the PI is applying for a waiver of documentation of informed consent.

- Please specify how informed consent will be obtained and who will obtain consent. Ensure that the person who is obtaining informed consent is trained to do so.

- The application for any type(s) of waiver will be subject to the DERC’s approval.Please justify how your research study meets each of the 4 criteria in section 7.3 of the Research Protocol. Please note that simply stating “*Yes*” is insufficient justification.

* Please ensure that your stated justifications sufficiently cover the different types of waivers that you are applying for.

Type of waivers:

The PI should apply for a waiver of informed consent when:

* The research study involves deception / withholding of study’s stated aims and objectives from research participants.
* It is advisable to conduct a debrief at the end of the session to let participants know the true aims and objectives of this research study since they were not aware of them at the point of recruitment. In this way, they will be able to decide if they still permit their data to be used for this study or to withdraw their participation after the debrief.
* Please submit a copy of the debriefing sheet that will be distributed to participants at the end of their session.
* Please include the following information in the de-briefing material provided to participants:
* (i) The full title of the research proposal;
* (ii) An explanation of what information was withheld or what the deception consisted of (if any) and clarifying any mistaken impressions the research participant may have gotten from not knowing this initially;
* (iii) who the participant could contact if s/he has concerns/ queries regarding the research or the de-briefing materials;
* (iv) a statement that the participant is free to withdraw his/her data after being debriefed; (v) a statement that participants will still be awarded their RP credit/reimbursement (if this is available) if they withdrew their data from the research study after the debriefing.

The PI should apply for a waiver of documentation of informed consent when:

* personal data is collected and linked to the research data; **and**
* the PI does not intend to obtain documented consent.
* The PI does not need to apply for a waiver of documentation of informed consent if research data is collected anonymously.
* The PI does not need to apply for a waiver of documentation of informed consent if personal data is collected for the sole purposes of scheduling the study procedure(s) and/or for reimbursement, and will be deleted when the procedure(s) and/or reimbursement is completed.
* If the PI is collecting personal data and only wishes to obtain verbal consent, please apply for a waiver of documentation of informed consent.
* The PI should apply for a waiver of documentation of parental consent when(i) The PI does not intend to obtain documented parental consent for research participants who are below 21 years old (or below 18 for NUS students). Only verbal consent will be sought. Note that parental consent must be sought for participants below 21 years old (or below 18 for NUS students) regardless of whether personal data will be collected from the participants.
* The PI should apply for a waiver of parental consent when:the PI does not intend to obtain parental consent for research participants who are below 21 years old (or below 18 for NUS students).

**Research and Personal Data Protection Storage**

- Please state where the research data will be stored.

- The NUS’ Research Data Management Policy states: *“Records of a research project carried out by NUS staff or students are the property of NUS. Individual researchers should be able to hold copies of appropriate materials for their own use, but in order to protect NUS and the individual against loss or allegations of research misconduct, one copy of primary data in original format, (e.g. in a laboratory notebook or in secure electronic form) should be kept securely within the Dept/Research Institutes and Centres while back-up copies can be outside. Formats of retention should be adequately documented, secure and, as far as possible, immune to subsequent alteration.”*

* Please let the DERC know who will have access to the research data, what will happen to the research data after research completion and what are the data protection measures put in place e.g. all identifiable research data will be coded (i.e. only identified with a code number) at the earliest possible stage of the research.
* If you intend to use collected research data for future research studies that will be subject to an institutional review board’s approval, please include this information.. Permission for future use of research participants’ data should be sought from them in the consent form.
* All research data used in publication/presentation should be kept for a minimum period of 10 years in accordance with NUS’ Research Data Management Policy.
* Please state the personal data (e.g., name, contact information, etc) that will be collected and how research participants’ privacy and the confidentiality of their personal data will be protected (e.g., coding at the earliest possible stage of the research). Please also state what will happen to the personal data that you have collected after completion of the research study.
* You may wish to note that research data not used in publication/presentation does not have to be retained for the minimum period of 10 years. e.g. personal data.
* In general, due to the Personal Data Protection Act (PDPA), the DERC does not encourage personal data to be kept for longer than necessary. If you do not intend to discard personal data at the end of the study, please state your retention period and reason(s).
* If you intend to use collected personal data to re-contact research participants for participation in future research studies that will be subject to an institutional review board’s approval, please include this information. Permission to re-contact research participants for participation in future related research studies should be sought from them in the consent form.

**Glossary:**

1. Anonymous

where no personal data (e.g. name, contact information etc) is collected or where personal data are collected for the sole purpose of scheduling the session or for reimbursement but will not be linked to the data collected.

Deception

when (i) a researcher deliberately gives research participants false information about some aspects of the research study; or (ii) knowingly withholds information about the real purpose or nature of the research (i.e. incomplete disclosure or concealment).

Documented Consent

Consent that is documented through a document that is provided by the researcher and signed/acknowledged by the research participant. Such consent is traceable to the individual participant, e.g. wet-ink signature on consent form, instructing participants to click “Yes” on an electronic consent form, and written consent via email.

1. Minimal risk

where the probability and magnitude of harm or discomfort anticipated in the research study are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. NUS’ Research Data Management Policy

Please refer to NUS’ Research Data Management Policy issued by the Office of the Deputy President (Research & Technology).

Vulnerable Population

People who may be unduly coerced or influenced to participate (e.g. children, prisoners, pregnant women, cognitively impaired persons, or educationally disadvantaged persons who require special consideration to protect their welfare.)

Personal data

Personal data refers to data, whether true or not, about an individual who can be identified from that data (e.g. name, contact information etc.); or from that data and other information to which the organisation has or is likely to have access. Personal data in Singapore is protected under the Personal Data Protection Act 2012 (PDPA).