**GUIDELINES FOR IRB EXEMPTION 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 NUS-IRB review. However, the final decision will be made by the IRB and affected PIs will be informed if further documents are required.
2. The NUS does not allow investigators to self-exempt their human participant research studies. The NUS-Institutional Review Board (IRB) determines whether a study can be exempted.
3. All “SBER” studies are likely to qualify for an exemption if they fulfil the following criteria:
4. Fall into one or more of the exemption categories (please check section 4A for the exemption categories guide);
5. Are of minimal risk;
6. Do not involve a vulnerable population;
7. Do not touch on sensitive topics; **and**
8. Do not involve deception / withholding of study’s stated aims and objectives from research participants.
9. For studies that qualify for exemption, only the IRB exemption form and data collection instruments (e.g. questionnaires, interview and discussion guides) are required for review. No other documents are needed.
10. The onus is on the Principal Investigator (PI) to ensure that documents used in his/her research study comply with the various NUS-IRB’s guidelines for “SBER” studies.
11. Electronic signatures or email statements (from parties involved, e.g. PI, Co-Investigator (Co-I) or Head of Department (HOD)) are now accepted for application submission.
12. If there are co-investigators involved in the research study, please submit a copy of the “*List of PI and Co-investigators*” form that can be downloaded from the NUS-IRB website.
13. In the event that an application does not qualify for exemption, additional documents may be requested for review, e.g., Participant Information Sheet & Consent Form, recruitment materials, etc.

**Section A) Exemption Form Guidelines**

**Section 1a: Protocol title**

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

**Section 1b: 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.

**Section 2: PI and Department**

* Please note that the NUS-IRB can only review applications where the PI is an NUS staff, NUS graduate student or NUHS staff.
* If the PI is a graduate student, please include the supervisor 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 IRB have the confirmation from the HOD that he/she agrees to bear administrative responsibility for the research study.

**Section 3: Study Site**

* 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 choose “*Single-Centre*” under “Site Details.”
* If this research study is conducted in more than 1 site in Singapore, please choose “*Singapore Multi-Centred*” under “Site Details.”
* If this research study is conducted in more than 1 site in Singapore and overseas, please chose “*International Multi-Centred*” under “Site Details.”
* If this research study has been reviewed or is currently being reviewed by another ethics committee or IRB, please choose “*Yes*” for “*Previous Ethics Committee Submission*”. Please provide details. E.g. “*This application has been or is being reviewed by Domain Specific Review Board (DSRB) or Central Institutional Review Board (CIRB)*.”

**Section 4A: Exemption Category**

Please choose the exemption category from the drop-down list that best describes your research study. Please see below for the detailed definitions of the 7 categories:

1A) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. No analysis of academic grades will be involved.

1B) Educational research (with grades analysis) that fulfils all 5 criteria below:

1. The proposed usage complies with either para (h) or (l) of the NUS Student Data Protection Policy;
2. The academic staff are using personal/ academic-related data of students who are reading their modules;
3. The aim of their research project is to provide an assessment of class/program effectiveness and/or to help students to learn better;
4. The PI is not sharing the data with external parties (*publications are not considered as “sharing with external parties”*) or sharing it with external parties in an anonymous/ aggregate manner; **and**
5. Prospective consent will be obtained from all students for the use of their grades/data for the research.
6. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless: (i) information obtained is recorded in such a manner that research participants can be identified, directly or through identifiers linked to the research participants; **and** (ii) any disclosure of the research participants' responses outside the research could reasonably place the research participants at risk of criminal or civil liability or be damaging to the research participants' financial standing, employability, or reputation.
7. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviour that is not exempted under paragraph (2) of this section, if: (i) the research participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
8. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that research participants cannot be identified, directly or through identifiers linked to the research participants.
9. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
10. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the relevant agencies in Singapore or overseas.

The food item being tasted must be edible, and you should only recruit research participants who are not allergic to said food item.

1. Use of anonymous experiments or/and behavioural tasks that are already published in the literature.

**Section 4B: Type of Study**

* Please check the appropriate box(es).

**Section 5: PI’s Declaration**

* Please check only “Yes”, “No”, or “N.A.” (Not applicable).
* If you check “No” for any of the declaration, your application will not qualify for an exemption. Please fill in and submit the IRB application form (SBER studies) instead.

**Section 6: 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 the 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.

**Section 7: HOD’s Declaration**

* 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 8: PI’s Signature**

* The PI should check and ensure all information on the form are correct before signing.

**Section B) Research Protocol Guidelines**

**Section 1: Specific Aims and Objectives**

* Please state the aims and objectives of the research study, including the hypothesis to be tested, if any.

**Section 2: Characteristics of Target Research Participants/ Target Research Participants Data:**

2.1

* Please state the maximum target number of research participants you wish to recruit at each recruitment site/ institution.

2.2

* 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.

2.3

* Inclusion criteria: please state the eligibility criteria of research participants you wish to recruit.

2.4

* Exclusion criteria: please state the criteria that will exclude individuals from participating in the study.

2.5

* 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.

**Section 3: 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.

**Section 4: Recruitment Process**

* 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.

**Section 5: 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, the technical terms should be explained in layman language.
* Please include the total time required by each research participant to complete the study procedure(s).
* 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?

**Section 6: Data Storage**

6.1.1

- 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.”*

6.1.2

* Please let the IRB 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 in section 6.1.2 of the IRB application form. 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.

6.1.3

* 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 IRB 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 in section 6.1.3 of the IRB application form. Permission to re-contact research participants for participation in future related research studies should be sought from them in the consent form.

**Section 7: Application for Waiver of Documentation of Informed Consent (if applicable)**

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

1. personal data is collected and linked to the research data; **and**
2. 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.
	* Please justify how your research study meets each of the 4 criteria in section 7 of the Research Protocol. Please note that simply stating “*Yes*” is insufficient justification.
	* The application for waiver of documentation of informed consent will be subject to the IRB’s approval.

**Glossary:**

1. Anonymous

where no personal data (e.g. name, contact information etc) are 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).