**School of Social Sciences**

Economics Programme

**HE4099 Graduation Project**

**Ethics Declaration Form**

|  |
| --- |
| **Project Title:** |
|  |
| **Name of Team members:** |
| Student (1): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email (1): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Student (2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email (2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Student (3): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email (3): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Name of Supervisor(s)** |
| Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact/Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Type of Research** |
| My research will not involve human subjects.  My research will involve human subjects and I have completed the application accordingly. |
| Declaration |
| Student:  I declare that the information that I have provided is correct; I will report any changes in my proposed  project that may require a further review of its compliance with ECON’s Ethics Guidelines.  In light of the information I provided and the details contained in Annex A, I declare that my research  proposal satisfies the condition(s) for Exemption from NTU’s Full IRB Review.  I declare that I am and shall be responsible for ensuring that my proposed Graduation Project and that my  final submitted work will comply with ECON’s Ethics Guidelines.  Signature of Student 1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Student 2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Student 3: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Supervisor:  I have discussed with the student(s) and reviewed the application and confirm that both comply with ECON’s Ethics Guidelines at the time of my signature and date. I have also reminded the student(s) that both the ECON programme and I must be informed if there are any further changes to the research design that may trigger the need for a new ethics application.  Signature of Supervisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**School of Social Sciences**

Economics Programme

**HE4099 Graduation Project**

**IRB Application Form**

**Please do not submit the IRB form if :**

1. this is a joint project with your supervisor’s research. You must submit your request to the University’s IRB. If your supervisor is planning to publish this project upon completion, the request must be submitted directly to the university.
2. your supervisor and another faculty member on the Ethics Review Committee plans to work with any of the graduation project group members on developing it into a joint research project, your request cannot be submitted to the programme’s IRB for review.
3. Finally, students need to declare whether their adviser is on the ERC or not. If so, they will need to state his name and the ethics review forms will be sent to another ERC member.

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| --- | --- | --- |
| **Project Title:** | | |
|  | | |
| **Name of Team members:** | | |
| **Student (1): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email (1): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Student (2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email (2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Student (3): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email (3): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
| **Name of Supervisor(s)** | | |
| **Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact/Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Is your supervisor on the Ethics Review Committee? Yes/No** | | |
| **Review Category**  (Please select an appropriate review category below based on the risk level of your proposed study. Note than selecting an inappropriate category could lead to delays due to re-assigning your submission) | | |
| Full Board Review (Please submit your project to the university IRB via NORA)  Expedited Review (Please submit your project to the university IRB via NORA)  Exempt Review (only applicable for the following criteria)  Research involves less than minimal risk to the study participants  Research does not involve vulnerable populations  Does not touch on sensitive topics (including but not limited to illegal conduct, criminal activities, racism, politics, sexual behaviour)  Research does not involve deception or withholding study’s stated aims and objectives from research participants  Selection of study participants is equitable  Research does not collect individually-identifiable data (Other than category 4) | | |
| **Type of Study** | | |
| Non-HBRA  HBRA  Are you collecting any human biological materials in this study?  No  Yes (Please submit your project to the university IRB via NORA)  Restricted-HBRA  Are you collecting any human biological materials in this study?  No  Yes (Please submit your project to the university IRB via NORA)  (HBRA = Human Biomedical Research Act) | | |
| **Domain of Research** | | |
| Social, Behavioural, Educational Research  Human Biomedical Research  Human Performance & Endurance Research | | |
| **Has a similar study been conducted elsewhere?** | | |
| No  Yes | | |
| **Please list the research site(s) and provide details of each site.**  (eg: Social of Social Sciences - NTU, School of Biological Sciences – NTU & etc) | | |
|  | | |
| **Has this study been submitted to or reviewed by another IRB/REC** | | |
| No  Yes, \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Proposed timeline of this study** | | |
| Start date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Research Aims**  (State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested). | | |
|  | | |
| **Procedures/Methodology** | | |
| **Describe in detail the study design and procedures to be used** | | |
|  | | |
| **Describe the protocol(s)/research methods to be used** | | |
|  | | |
| **List all subjects’ related procedures, including a step-by-step description of what the human participants will be expected to do.** (Leave this section blank for exempt application) | | |
|  | | |
| **What is the duration of subject involvement in the study?**  (Please indicate number of hours/days/weeks) | | |
|  | | |
| **Include details on how the collected data will be analysed and interpreted.** | | |
|  | | |
| **Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Please provide information on how these limitations/difficulties faced may be minimised/overcome.** | | |
|  | | |
| **Human Subjects Information** | | |
| **Study population**  (Please provide justification for using a vulnerable population and a description of the special considerations/steps/safeguards that will be taken to ensure that the vulnerable population will be adequately protected | | |
|  | | |
| **Key in the lower and upper age limits** | | |
|  | | |
| **What are the inclusion and exclusion criteria for participating in the study?** | | |
|  | | |
| **Include details on sample size calculation to support your target recruitment number (if any).** | | |
|  | | |
| **What is the maximum number of participants to be recruited per population type?** | | |
|  |  |  |
|  |  | |
|  | | |
| **Recruitment Process** | | |
| **How will you initially select and contact participants?** | | |
|  | | |

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| --- |
| **Describe your screening procedures to determine if a subject qualifies for the study.** |
|  |
| **Explain the process of recruitment in detail.** |
|  |
| **Will research subjects be reimbursed (or given extra credits for students)?** |
|  |
| **Describe your plan for voluntary and involuntary withdrawal of participants from the study.** |
|  |
| **Please state the proposed Recruitment Period** |
|  |
| **Data Collection** |
| **Does your study involve the use of archived/existing database, or any pre-existing data?** |
| No  Yes |

|  |
| --- |
| **Type(s) of data that you will be collecting** |
| Questionnaires/surveys  Interviews  Observations  Audio/video recordings  Images (photographs, x-rays & etc)  Physiological measurements  Clinical laboratory results  Biological specimens  Databases  Medical records/chart reviews  Public health records  others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **When you obtain the data, will it already be** |
| Anonymous (without any identifiers that could link the data to a specific subject)  Unlinked (collected with identifiers, but all identifiers/codes have been removed and destroyed)  Coded (linked to specific subject by a code-link rather than a direct identifier, eg. Name)  Identified (linked to a specific subject by personal identifiers sufficient to identify a specific subject) |
| **When you store the data it will be** |
| Anonymous (without any identifiers that could link the data to a specific subject)  Unlinked (collected with identifiers, but all identifiers/codes have been removed and destroyed)  Coded (linked to specific subject by a code-link rather than a direct identifier, eg. Name)  Identified (linked to a specific subject by personal identifiers sufficient to identify a specific subject) |
| **If you are collecting identifiable personal data, please check any that apply below**  (Please refer to our NTU-IRB guidelines on personal data under PDPA) |
| N/A (Anonymous study)  Name  NRIC Numbers/FIN Numbers/Passport Numbers/Driver’s License Numbers  Facial Images (in photographs or video recording)  Voice of an individual (in a voice recording)  Fingerprints/Iris images  Mailing addresses  Email addresses  Vehicle identifiers and serial numbers, including license plate numbers  Any type of Account number/Medical records numbers  Certificate/License numbers (professional licenses)  IP/MAC addresses  Device identifiers and serial numbers  Any other unique identifying number, characteristics, or code |
| **Storage and Access of Data** |
| **Where will the data be stored?** |
|  |
| **Who will have access to the data?** |
|  |
| **What will happen to the data after research completion?** |
|  |
| **Will data identifying the subjects be made available to anyone other than the Supervisor and student team members?** |
|  |
| **Please indicate if data collected in this study will be used for future research?** |
| No  Yes |

**Economics Program IRB Submission Guidelines**

1. If your study involves any vulnerable population such as children, prisoners, individuals with health- related issues, individuals with who have financial issues etc., your adviser will need to submit your project to the university IRB via NORA. You should not submit your application to the economics program’s IRB.
2. If your study requires a government agency’s approval to execute, your adviser will need to submit your project to the university IRB via NORA. For example, if your study requires the participants to consume fresh food in the lab (NEA approval required) or you want to sell actual financial products to the respondents (MAS approval required), your adviser will need to submit your project to the university IRB via NORA. You should not submit your application to the economics program’s IRB.
3. If your study contravenes any laws in Singapore, your adviser will need to submit your project to the university IRB via NORA. For example, if your study is going to falsely inform participants that meat products in Singapore are tainted by a virus, your adviser will need to submit your project to the university IRB via NORA. You should not submit your application to the economics program’s IRB.
4. If the study is not one of the two items stated below, your study may pose significant risk to the participants. As such, your adviser will need to submit your project to the university IRB via NORA. You should not submit your application to the economics program’s IRB. The only items that can/should be submitted to the economics program’s IRB are restricted to these two items.
5. A lab experiment that only requires students to play standard economics games in a lab. The only incentives that will be given out in the study are monetary incentives and nothing more.
6. Surveys that only include standard economic questions from any branch of the economic literature done on paper or an electronic device. The only incentives that will be given out in the study are monetary incentives and nothing more.

**Declaration**

Graduation Project Team members:

I understand the information provided in this document. I certify that our group’s Graduation Project does not fall into any of the above. I understand that I am responsible for any ethics breaches or legal consequences for this project.

Signature of Student 1: Date:

Signature of Student 2: Date:

Signature of Student 3: Date:

Graduation Project Supervisor:

By signing the following, I am acknowledging that the student has set out reasonable guidelines for conducting her/his GP research in an ethical manner.

I agree to take responsibility for ensuring the student’s compliance with ethics guidelines as set out in this form. Should the student fail to comply by the ethical guidelines, or change the direction of their project significantly, I shall ensure that they re-apply for approval.

Signature: Date:

This undergraduate study has been reviewed by the Economics Programme’s Ethics Committee/representatives and is determined to be suitable for exemption from NTU IRB review.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Signature of Chair of Ethics Committee/HoD/HoD’s designate)

Economics Programme

**SAMPLE PARTICIPANT INFORMATION SHEET AND CONSENT FORM FOR RESEARCH SUBJECTS**

<**Instructions to Principal Investigators:** When using this template, kindly amend the appropriate portions, and delete any irrelevant wordings and the instructions to PI noted in parenthesis. Please do not delete compulsory sections required under HBRA (refer to Annex). Purple sections are specific for Human Tissue Framework.>

|  |
| --- |
| **1. Study Information** |
| **Protocol Title:** |
| (Use the full protocol title as used in the IRB Application) |
| **Principal Investigator & Contact Details:** |
| (Please include full name, School/Institution, email address and phone number\*) *(\*For all studies, please include minimally your School’s/Institution’s mainline. For more than minimal risk studies, please also include the mobile number of PI / Co-I / study coordinator / study team member.)* |
| **Study Sponsor:** |
| *(Delete this section if this is an investigator-initiated study without specific grant funding.)* |
| **2. Purpose of the Research Study** |
| You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign the accompanying Consent Form. You will be given a copy of this Consent Form to take home with you.  You are invited because (e*xplain why participant is being approached for recruitment)*  This investigational study is carried out to find out (*insert purpose of study and explanation here)*  This study will recruit *(insert number of participants)* participants from *(state whether from the PI’s institution, or multiple institutions)* over a period of *(state recruitment and/or study period).*  **3. Inclusion/Exclusion Criteria**  This study will be undertaken with *(upper and lower age limit or gender specific)* who are *(selection criteria).* Participants who do not fall within category will be excluded from this study.   |  | | --- | | **Waiver for HBRA Section 37(3) Requirement**  *(If the proposed area of research* ***involves*** *the removal of tissues from (a) an adult who lacks mental capacity; (b) a minor who lacks mental capacity; or (c) a minor who lacks sufficient understanding and intelligence to give consent, please include the following:)*  This study **involves** the removal of tissues from <(a) an adult who lacks mental capacity; (b) a minor who lacks mental capacity; or (c) a minor who lacks sufficient understanding and intelligence to give consent> for research purposes. This study has been approved by the NTU-IRB and the IRB has waived the requirement that the removal of the tissue from the above groups is primarily for a therapeutic or diagnostic purpose under Section 37(3) of HBRA.  *(If the proposed area of research* ***does not involve*** *the removal of tissues from (a) an adult who lacks mental capacity; (b) a minor who lacks mental capacity; or (c) a minor who lacks sufficient understanding and intelligence to give consent, please include the following:)*  This study **does not involve** the removal of tissues from <(a) an adult who lacks mental capacity; (b) a minor who lacks mental capacity; or (c) a minor who lacks sufficient understanding and intelligence to give consent> for research purposes.  **Important Information for Women Participants** (Delete or modify as necessary)  The effect of *(intervention / investigation)* on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. It is your responsibility to inform the Principal Investigator if you become pregnant during the course of this study. The Principal Investigator will advise you to continue or stop participating in the study based on the complexity of the study. | | **4. What Procedures will be Followed in this Study?** | | If you take part in this study, you will be randomized to receive *(delete or expand as necessary)*. Randomization means assigning you to one of *(insert number of study groups)* groups by chance, like tossing a coin or rolling dice.  If you take part in this study, you will be asked to (*insert brief explanation of study procedures here))*.  Your participation in the study will last for *(insert length of time participant will be required for the study)*. You will *(use the study device / undergo intervention)* for about *(Insert number of times study intervention will be performed)* and be followed up for *(state length of time of follow-up within the study)*. The study will consist of *(state number of times)* visitsin the course of the study.  If you agree to take part in this study, the following procedures will be carried out:  *(Insert detailed schedule of visits and procedures, assessments, questionnaires as relevant. For multiple visits and procedures, insert tables and/or pictures for participant’s ease of understanding)*  **Schedule of Visits and Procedures:**  Visit 1 (Week 0)  Visit 2 (Week \_\_\_\_)  Final Visit (Week \_\_\_\_)  Follow-up (State the number of contacts)  *(For e.g, please state the frequency and amount of human tissues / blood / biological materials that will be collected at each visit.)* In total, *[insert amount in volume and in teaspoons; eg. 5 ml (1 teaspoon)]* of blood will be taken as part of this study.]  When your participation in the study ends, you will no longer have access to *(device / intervention)*, unless special additional arrangements are made by the Principal Investigator.  **Incidental Findings:**  *(****Compulsory section****: If the proposed biomedical research expressly provides for re-identification in the case of an* ***Incidental Finding****, please indicate this and inform the participant that he/she has a choice whether he/she would wish to be re-identified and notified in the case of incidental findings. The study should also list the types of anticipated incidental findings (if applicable) that may be discovered in the course of the study. Please refer to the sample language below. You may delete or modify the information according to your study design.)*  During the course of the current study (and future studies), there is a possibility that we might unintentionally come to know of new information about you/your child/your ward’s health condition from (insert reasons e.g. the imaging scans, the genetic testing, etc.) that is/are conducted as part of the study. These are called “incidental findings” derived from experimental tests/scans that are not of clinical grade. These findings might be expected or unexpected, and might cause you to feel anxious and could potentially have serious implications for your/your child/your ward’s well-being and/or health insurance coverage.  “Incidental findings” are findings that have potential health or reproductive importance to research participants like you/your child/your ward and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.  You will be asked to indicate whether you wish to be re-identified and notified in the event of incidental finding that is related to you/your child/your ward. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (insert list of anticipated incidental findings, if applicable).  If you agree to be re-identified and notified, the Principal Investigator (or a qualified healthcare professional or trained personnel) will explain the incidental finding to you/your child/your ward and discuss and advise you on the next steps to follow, including referral to registered medical professionals for further consultations. For this purpose, please inform the study team members listed in this document whenever there are changes in your/your next of kin contact details. You may wish to do more tests and seek advice to confirm this incidental finding.  The costs for any care that will be needed to diagnose or treat an incidental finding **would not be paid** for by this research study. These costs would be your responsibility.  ***OR***  *(If the proposed biomedical research does not provide for re-identification in the case of an incidental finding, please refer to the sample language below. You may modify the information according to your study design.)*  In the case of an “incidental finding” (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study), we will not re-identify and give you any results from the research.  ***OR***  *(If there will not be any incidental findings for the study, whether anticipated or unanticipated, please include the following sample language below.)*  “Incidental findings” are findings that have potential health or reproductive importance to research participants like you/your child/your ward and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of current and future studies. There will not be any incidental findings arising from this research; hence you will not be re-identified for this purpose. | | **5. Your Responsibilities in this Study** | | If you agree to participate in this study, you should follow the advice given to you by the study team and be prepared to undergo all the procedures that are outlined above. You should also inform the Principal Investigator as soon as possible about any side effects that you may have encountered. | | **6. What is Experimental in this Study?** | | The study is being conducted because *(the intervention or device)* is not yet proven to be a standard *(investigation, treatment, etc.)* in participants with *(condition under investigation in this study)*. We hope that your participation will help us to determine whether *(investigation / treatment)* is equal or superior to existing *(investigation / treatment).*  Use of a placebo (inactive agent), blinding (one or more parties unaware of the treatment assignment), and randomization (study drug selection by chance) are only done for research studies. *(Modify as relevant for your study.)*  Although *(investigation or treatment)* may be part of standard medical care, in this study this/these procedure(s) are only being performed for the purposes of the research, and are not part of your routine care. | | **7. Possible Risks and Side Effects**  (This section should describe all the reasonably **foreseeable risks, discomforts, or inconveniences** to the participants arising from the procedures / interventions done (i.e., venipuncture, concomitant medications, exposure to radiation, etc.) and/or medications, and/or from removal of the human tissues / blood / human biological materials. It may be best to list them in detail.) | | (PIs are reminded that virtually all research procedures have some risks or side effects, which must be explained in some detail to the participant. It is **NOT** satisfactory to make statements like “This is a well-established drug/test/procedure which has no significant side effects”. The risk of choosing not to participate in the research study or not having the intervention / investigation should be clearly stated and explained, as well as risks of any ALTERNATIVE intervention / drug / investigation. Modify the following section as relevant to your study.)  *(Insert Intervention or Procedure)* may have the following side effects or risks:  Allergic reactions can occur with any drug. Common symptoms may include: rash, itching etc. Rarely, a severe and possibly life-threatening allergic reaction can occur. Symptoms of a severe reaction include: swelling of the face, difficulty in breathing, or a sudden drop in blood pressure that may cause dizziness. If you have any of these symptoms, call your doctor or Principal Investigator at once.  *(Intervention or investigation)* is still being tested; therefore, you may experience other side effects that have not yet been reported. However, you will be kept informed of any significant new findings that may relate to your willingness to continue to take part in this study. If you experience any new symptoms, you should contact your doctor or the Principal Investigator as soon as possible.  Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs.  In addition, as you cannot (take any other medication) to treat your *(insert condition here)* while you are (receiving the study medicine), there is a possibility your condition may worsen. If this occurs, your doctor will *(explain rescue / crossover / alternative therapy).* | | **8. Possible Benefits from Participating in the Study** | | (Compulsory section)  If you participate in this study you may reasonably expect to benefit from the study *(investigation / intervention / drug)* in the following way: *(explain how participant might benefit)*  **OR**  There is no known benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of this *(medication / device / intervention / investigation)*. | | **9. Alternatives to Participation** | | (Delete or modify as necessary. This is a mandatory element of ICH-GCP. PI must explain to participants the **alternatives** to the study intervention / drug / investigation and the **benefits** and **risks** of the alternatives. This is so that the participants can make a truly informed choice about participation.)  If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be (investigation / treatment / procedure / none).  The benefits are:  (Insert list of possible benefits of the alternatives, which may be the standard care)  and the risks are:  (Insert list of possible risks from the alternatives)  *(While the standard care is mentioned in this section as the “alternative”, the investigators should explain to the participant in such a way that the participant understands that the research intervention / procedures / tests is the alternative to the standard care that is being offered to the participant.)*  *(If there is* ***no alternative treatment available****, please indicate ‘Not applicable’.)* | | **10. Costs & Payments if Participating in the Study** | | (Compulsory section)  If you take part in this study, the following will be performed **at no charge** to you: *(Insert list of procedures / drugs / tests for which the participant will NOT pay). There will not be any extra charges or expenses as a consequence of donating tissue.* These costs will be borne by *(Insert sponsor name or research grant).*  **OR**  If you take part in this study, you will have to pay for the following: *(Insert list of procedures / drugs / tests for which the participant WILL be required to pay; Any anticipated expenses the participant is likely to incur as a consequence of donating human tissues / blood / human biological materials.)*  You will be reimbursed for your time, inconvenience and transportation costs as follows:   * If you complete the study, you will be paid *(Insert payment amount)*. * If you do not complete the study for any reason, you will be paid *(Insert payment amount)* for each visit you complete.   **OR**  You **will not be reimbursed** for your time, inconvenience and transportation costs.  Please note that the institution is being paid by the sponsor for the time spent by doctors in conducting this study. (*delete this statement if not relevant)* | | **11. Voluntary Participation and Participant’s Rights** | | Your participation in this study is entirely voluntary. You are free to withdraw from the study at any time without any obligation or need to explain to your decision. Your decision not to take part in this study or withdrawal will not affect your <*medical care or any benefits*> to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator that you like to withdraw from the study. However, the data / research information that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.  If you withdraw from the study, you will be required to (*Insert consequences of participant withdrawal and procedures for orderly termination. PIs are to note that any penalty or damages imposed solely by reason of the withdrawal of consent is void and unenforceable*).  The Principal Investigator may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the Principal Investigator will decide if you may continue in the research study. *(PI should also include any other foreseeable events which might lead to the PI or the sponsoring company terminating the study before completion).*  In the event of any new information becoming available (including but not limited to occurrences of serious adverse events, and changes in proposed research) that may be relevant to your willingness to continue in this study, you (or your legally acceptable representative, if relevant) will be informed in a timely manner by the Principal Investigator (or his/her representative) and will be contacted for further consent if required.  *(Delete only if there is no recruitment of minors).* In the event of changes to the development of capacity by minors to make decisions (i.e. the participant reaches the age of 21 years old), the participant would be contacted for further consent. | | **12. Compensation for Injury** | | *(Compulsory section: PI to note that NTU has a campus-wide insurance coverage for HBR studies to compensate for bodily injuries. This does not cover SBER studies.)*  If you follow the directions of the investigators in charge of this study and you are physically injured due to the procedures carried out for this study, without prejudice or any admission of liability, will compensate you for the injuries arising from your participation in the study without you having to prove (Nanyang Technological University) is at fault. There are however, conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator.  By signing the accompanying Consent Form, you will not waive any of your legal rights or release the parties involved in this study from any liability for negligence. | | **13. Confidentiality of Data** | | *(Compulsory section: PI is to state whether or not the participation of the research participant involves information in individually-identifiable form.)*  Your participation in this study will <will not> involve the collection, use and disclosure of data / human tissues / human biological materials in an individually-identifiable form (or “**Personal Data**”). “Personal Data” means data about you / your child / your ward, which makes you / your child / your ward identifiable from (i) such data, and/or from (ii) other information which we have or likely have access to. This includes medical conditions, medications, investigations and treatment history.  Information and Personal Data collected for this study will be kept confidential and stored for a minimum of 10 years in a secure environment within NTU (or state where it will be stored) with restricted access given only to the Principal Investigator, study team members and School Administrators. Your records, to the extent of the applicable laws and regulations, will not be made publicly available, in accordance with NTU Personal Data Protection Statement.  However, the Sponsoring company *(Name of company, if relevant)*, government ministries or regulatory agencies *(HSA, FDA, etc. if relevant)*, NTU Institutional Review Board will be granted direct access to your Personal Data (or medical records) to check study procedures and data, without making any of your information public. Your Personal Data may be shared with government bodies when acquisitioned by law or when ordered to do so by a court or legislations.  By signing the Informed Consent Form attached, you (or your legally acceptable representative, if relevant) are authorizing (i) collection, access to, use and storage of your Personal Data, and (ii) disclosure to, and use and storage by, authorised service providers and relevant third parties, whether located in Singapore or overseas, for the purposes of this study or future research studies, *and (insert other purposes for which Institution or Company may wish to collect, use and disclose the data, e.g., other similar research studies conducted by the Institution or Company).*  Data collected are the property of NTU *(or list other Institution or Company)*. In the event of any publication regarding this study, only aggregated research data without identifiable personal details will be used, and your identity will remain confidential.  *(If Investigators intend to* ***transfer*** *human tissues or blood or biological materials and/or health information / data out of Singapore, please include either of the below statements where relevant):*  Any heath information / data / human tissues / blood / biological materials and/or information containing your Personal Data that is collected for the purposes described in this Participant Information Sheet and Consent Form will be stored in Singapore. Only anonymised *(or de-identified)* human tissues / blood / biological materials and/or data will be transferred out of Singapore to *(Insert Name of overseas collaborator/company)*.  **OR**  Your human tissues / blood / human biological materials and/or health information / data containing your Personal Data will be transferred out of Singapore to *(Insert Name of overseas collaborator/company)* in an <identifiable form / anonymised form> for the purposes described in this Participant Information Sheet and Consent Form. *(Name of institution receiving the human tissues / blood / human biological materials and/or data)* will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act (PDPA) while your Personal Data to be transferred remains in its possession or under its control.  *(Compulsory section: If Investigators intend to use participant’s health information / data / human tissues / blood / human biological materials* ***only*** *for the purposes of the* ***current research****, please add the following.)*  Any <*individually-identifiable / anonymized*> <*data / human tissues / blood / human biological materials*> obtained during the course of this study will be stored and used **only** for the purposes of this study for a period not exceeding *(Insert intended duration of storage)*, and human tissue / blood / human biological materials will be destroyed and discarded after completion of the study.  Your *Personal Data* will **not** be used for future research, unless otherwise consented by you in the accompanying Consent Form.  *(If Investigators intend to use participants’ health information / data or keep the leftover human tissues / blood / human biological materials for* ***future research*** *in any way beyond the completion of the study, then the following information must be disclosed here.)*   1. *Specific purpose for which the health information / data / human tissues / blood / human biological materials will be used, if this information is available; but if not available, the purpose may be stated as for general research;* 2. *Period of storage including whether the health information / data / human tissues / blood / human biological materials will be stored in an individually-identifiable form;* 3. *Provisions to ensure privacy and confidentiality; including whether the health information / data / human tissues / blood / biological materials will be used in an individually-identifiable form;* 4. *Whether the health information / data / human tissues / blood / human biological materials will be transferred outside of Singapore (regardless of whether it is individually-identifiable or anonymised); and* 5. *Whether the human tissues / blood / human biological materials may / will be used for future restricted human biomedical research involving human-animal combinations.*   *(If investigators intend to use participants’ Personal Data / anonymized data for* ***future research****, then explicit consent from the participant should be obtained in the Consent Form. )*  Your <*health information / personal data / human tissues / blood / human biological materials*> collected in this study will be used in an individually-identifiable form for future research **only** if **explicit consent** has been provided by you in the accompanying Consent Form and approval has been obtained from the Institutional Review Board or local ethics committee. | | **14. Whom To Contact if You Have Questions?** | | If you have any questions, complaints or feedback about this research study and in case of any injuries during the course of the study, you may contact the Principal Investigator, *(Insert Name and contact details here.)*  The study has been reviewed by the Ethics Committee – Economics for ethics approval. If you want an independent opinion to discuss problems and questions (complaints / feedback), obtain information and offer inputs on your rights as a research participant, please contact:  **Economics Ethics Committee c/o Head of Economics Programme**  Nanyang Technological University  48 Nanyang Avenue  Singapore 639818  Email: [H-Economics@ntu.edu.sg](mailto:H-Economics@ntu.edu.sg) | |

Online Survey Consent Template

<**Project Title**>   
You are invited to participate in a research study on <in layman’s terms, clearly state what the study is about>. This study is conducted by <include name, title, and School of PI> from Nanyang Technological University.

This study will take approximately <total anticipated time required for participants to complete the survey> of your time. You will be asked to complete an online survey about <include a description of the types of questions participants will be asked>. <Insert the number of participants, if needed, add explanation or description of the group> will be recruited for this research.

Your participation in this study is completely voluntary, and you have the right to withdraw from the study at any time without any penalty. You may skip any questions you do not wish to answer. If you do not wish to complete this survey, just close your browser.

Your participation in this research will be kept confidential, and data will be averaged and reported in aggregate. Your responses will be anonymous and IP addresses will not be collected to guarantee complete anonymity. Possible outlets of dissemination may be <include how results may be disseminated>. Although your participation in this research may not benefit you personally, it will help us understand <describe the possible benefits to society which may reasonably be expected or how the study may contribute to generalizable knowledge>. <You will be compensated $xxx for the time and effort taken to participate in the study. It will be paid through (provide information on how subject will receive the reimbursement) or There will be no compensation provided.>

<Include a statement regarding any reasonably foreseeable risks or discomforts to participants from completing the survey **OR** If there are no known risks, include a statement something like: There are no risks to individuals participating in this survey beyond those that exist in daily life.>

If you have questions about this project, you may contact <PI’s name and contact information (both phone number and email address)>.

This project has been reviewed and approved by NTU-Institutional Review Board. Questions concerning your rights as a participant in this research may be directed to the NTU-IRB at [IRB@ntu.edu.sg](mailto:IRB@ntu.edu.sg) or call 6592 2495.

Please print a copy of this consent form for your records, if you so desire.

|  |  |
| --- | --- |
| I have read and understood the above consent form. I certify that I am 21 years old or older and, by clicking the next button to enter the survey, I indicate my willingness to voluntarily take part in the study. | (route to survey page) |
| I do not wish to participate in this study. | (route to Home page) |

**PARENTAL CONSENT FORM**

This research is carried out for the degree in Economics at NTU Singapore

**Investigator name:**

**Telephone:**

**Email:**

1. **Purpose of the study:** [Describe the purpose of the study]

2. **Procedures to be followed:** [Describe what steps you will take and what is expected of the participant]

3. **Confidentiality:** All data collected will remain confidential and will be used for research purposes only.

4. **Duration:**

5. **Potential risks:** There is no foreseeable risk to you.

6. **Potential benefits.** There are no direct benefits to you. [But explain the significance of this study]

7. **Participation is voluntary.** Your participation is voluntary, and you may choose to withdraw from the

study at any time. You may also wish to skip any questions in the questionnaire if you do not wish to

answer them. You will be given a copy of this consent form later.

8. **Questions?** If you have any questions or concerns about this research study, please feel free to contact

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. If you have questions regarding your rights as a research participant, please

contact the Economics Ethics Committee at (Email: H-Economics@ntu.edu.sg).

9. **Consent:** I,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, give consent for myself and my child to

participate in this study. I have been informed of the purpose and contents of this research project.

Parent’s Name & Signature: ……………………………………………………

Date : ……………………………………………………