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| **Human Subjects Research – Expedited Review Form**  **Guidelines for completing this research protocol:**   * *Please type the information in English. Handwritten forms or forms written in Vietnamese will not be accepted.* ***Submit completed applications via email to:*** [***research@vinuni.edu.vn***](mailto:research@vinuni.edu.vn) * *Instructions on the review process and guidance to submitting applications, can be found on the VPRO website. You may also contact the VPRO by email at* [*research@vinuni.edu.vn*](mailto:research@vinuni.edu.vn) * *This form had the following sections. Not all are required. Please note the sections that might apply for your research and complete those sections.*  |  |  | | --- | --- | | **Section** | **Required for** | | Part 1: Determination of Human subject research | All studies | | Part 2: Eligibility for Expedited/Short Review | All studies | | Part 3: Project Information | All studies | | Part 4: Research Team | All studies | | PART 5: Conflicts of Interest | All studies | | Part 6: Research Summary | All studies | | Part 7: Primary Data Collection Details | Studies involving prospective data collection | | *PART 8: Secondary Data Analysis Details* | Studies involving use of secondary (previously collected) data | | PART 9: CONFIDENTIALITY AND PRIVACY | All studies | | PART 10: Risks and Benefits to participants | All studies | | PART 11: Consent Process | All studies | | Part 12: Investigator Assurances | All studies | | Checklist of documentation |  | |
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|  | **PART I: Human subject research** |  |  | | |  | |
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| Does your research involve: | | | | | *If you answered "Yes", please mark "X" in the corresponding box.*  *If you answered “No” to both the questions, then your project is not considered human subjects research, and you do not need to submit an application to the ERC.* | | |
| A. Obtaining information or biospecimens from living individuals, through intervention or interaction with individuals, and using, studying, or analyzing the information or biospecimens | | | |  |
| B. Obtaining, using, studying, analysing or generating identifiable information or identifiable biospecimens. | | | |  |
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|  | **Part 2: Eligibility for Expedited/Short Review** |  |  |  |  |
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| *Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories may be eligible for expedited review by the IRB. Select all of the following that apply to your proposed study.* | | | | | |
| 1. Study involves no more than minimal risk of physical, reputational, financial or social harm for participants (any more than they would experience in normal, everyday life). | | | | |  |
| 1. Use of data from voice, video, digital, or image recordings | | | | |  |
| 1. Observation only, with no intervention or manipulation | | | | |  |
| 1. Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) | | | | |  |
| 1. Research employs survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies | | | | |  |
| 1. Taste tests, moderate exercise, diet control and manipulation, sleep tests and others | | | | |  |
| 1. Games, experiments, behaviour manipulation exercises | | | | |  |
| 1. Study with a **drug or a medical device that have already been approved by the MOH**, and is being used in accordance with its approved labelling. | | | | |  |
| 1. Study involving educational practices and standardized tests | | | | |  |
| 1. Involves collecting **biomedical samples using non-invasive measures**, such as hair or nail clippings, external secretions such as urine, sweat, saliva, skin samples collected via a swab, sputum, and other materials that result from other medical procedures (not related to the study). | | | | |  |
| 1. Involves collecting **biomedical data by non-invasive measures** using approved medical devices, physical sensors, MRI, Ultrasound, EEG, ECG, diagnostic infrared imaging, body measurement, etc. | | | | |  |
| 1. Study involves use of previously collected **(Secondary Data)** either (1) without identifiers or (2) available in the public domain | | | | |  |
| 1. Study involves **non-public secondary data with identifiers** | | | | |  |
| 1. **Continuing review of a previously approved study** that was approved via expedited review and does not involve any new procedures that could alter the risk/benefit profile of the study. | | | | |  |
| 1. My research involves procedures other than those listed here. | | | | |  |

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| *If your research involves procedures other than those listed above, it does not qualify for expedited review, and you must submit an application for Full Committee Review by the Vinmec ERC.*  **Note:** the criteria for expedited review of studies is derived from the [US Federal Regulations on Protection of Human Subjects in Research 45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) |

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|  | **PART 3: Project Information** | |  |  | |  | |  | |
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|  | 1. **Project title** |  | | | | |  | |
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|  | 1. **Principal Investigator(s)** | **Full Name** | | | | |  | |
|  | **College/Department** | | |  | |  | |
|  |  | **Tel** | | |  | |  | |
|  |  | **Email** | | |  | |  | |
|  |  | **Address** | | |  | |  | |
|  |  |  | | |  | |  | |
|  |  | **MARK ONE:**  Faculty  Academic Professional/Staff  Student | | | | |  | |
|  |  | If the PI is a student, a VinUni faculty or staff member must serve as Advisor. Please provide that information below. | | | | |  | |
|  | 1. **Supervisor**   (If any) | Full name | | | | |  | |
|  | **Title** | | |  | |  | |
|  | **College/**  **Department** | | |  | |  | |
|  | **Tel** | | |  | |  | |
|  |  | **Email** | | | | |  | |
|  | | | | | | | | |
| 1. **FUNDING INFORMATION: Please indicate if any of the following are true.** | | | | | | | | |
| Is your research funded? | | | | | | | | |
| A. YES | |  | | | | | | |
| B. NO | |  | | | | | | |
|  | | | | | | | | |
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| *If you answered "Yes", please mark "X" in the corresponding box and indicate the funding agency* | | | | | | | | |
| 1. **STUDY DURATION** | | | | | | | | |
| **Approximately when will the study start and end (including data collection, analysis and reporting)**  \_\_\_ months from \_\_/\_\_/\_\_\_\_\_ to \_\_/\_\_/\_\_\_\_\_  **Approximately when will the data be collected (for primary data only)**  \_\_\_ months from \_\_/\_\_/\_\_\_\_\_ to \_\_/\_\_/\_\_\_\_\_ | | | | | | | | |
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|  | **PART 4: Research Team** |  |  |  |  |
|  |  |  |  |  |
| *List all other investigators on this project.*   |  |  |  |  | | --- | --- | --- | --- | | **Name** | **VinUni affiliation**  ***(if no VinUni affiliation, write the name of the external organization)*** | **Email** | **Role on this project *(conducting, research procedures, analysis only, etc.)*** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | |
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|  | **PART 5: Conflicts of Interest** | |  |  |  | | |
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| **Please indicate if you or any other member of the research team have any of the following financial interests.** | | | | | | | |
| **A. Financial connections with the external research sponsor (e.g., investigator is a consultant for the research sponsor).** | | | | | | |  |
| A. YES | |  | | | | |
| B. NO | |  | | | | |
| **B. Financial interest in the outcomes of the research (e.g., research outcomes, or intellectual property developed in this protocol may be personally useful to the researcher).** | | | | | | |
| A. YES | |  | | | | |
| B. NO | |  | | | | |
|  | | *If you answered Yes to any of the statements, the ERC may ask you for more information and may require some additional protections.* | | | | |  |
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|  | **PART 6: Research Summary** |  |  |  |  |
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| RESEARCH SUMMARY | | | | | |
| **5A. In a language easily understood by an educated person who is not an expert in this field of study, briefly summarize *(no more than 200 words)* the purpose of this research. Specify the research question, the hypothesis (if any), objectives and unique contribution of this study.** | | | | | |
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|  | **PART 7: Primary data collection details** |  |  | | |  |  |
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| ***For Research Involving Primary Data Collection Only (skip if you are ONLY using secondary data)*** | | | | | | | |
| RESEARCH PROCEDURES | | | | | | | |
| 1. Briefly describe the research procedures in sequential order. | | | | | | | |
| **B. List the locations where will the research activities take place (e.g., VinUni campus, dorm rooms, homes, offices, cafes, other public places etc.)** | | | | | | | |
| C. What is the duration of participants’ involvement each time and how many times will participants engage in research activities? | | | | | | | |
| **D. Describe the type of data that will be collected from the participants** *(***e.g.,** *if survey, then describe the information asked for in the survey; if biospecimens, then type, amount and the method of collection; if imaging, then type of equipment, type of data, etc)* | | | | | | | |
| PARTICIPANTS AND RECRUITMENT | | | | | | | |
| A. What is the estimated total number of participants? | | | | | | | |
| **B. Select all participant populations that will be recruited/invited for the study.** | | | | | | | |
| **AGE** | | | | | | | |
| Adults (18+ years old) | | | | | | |  |
| Minors (≤17 years old) | | | | | | |  |
| Specific age range, *please specify:* | | | | | | |  |
| **GENDER** | | | | | | | |
| No targeted gender (both men and women will be recruited/included) | | | | | | |  |
| Targeted gender | | | | | | |  |
| Men/boys | | | |  | Women/girls | |  |
| Other, *please specify*: | | | | | | |  |
| **RACE/ETHNICITY** | | | | | | | |
| No targeted race or ethnicity (all races and ethnicities will be recruited/included) | | | | | | |  |
| Targeted race or ethnicity, *please specify*: | | | | | | |  |
| **COLLEGE STUDENTS** | | | | | | | |
| No targeted college population | | | | | | |  |
| VinUni general student body | | | | | | |  |
| Targeted VinUni student population, *provide the instructor or course information, or other specific characteristics*: | | | | | | |  |
| **OTHER TARGETED POPULATIONS** | | | | | | | |
| People who are illiterate or educational disadvantaged | | | | | | |  |
| People who are low-income or economically disadvantaged | | | | | | |  |
| People with particular disease or health conditions | | | | | | |  |
| Other, *please specify*: | | | | | | |  |
| **D. Select all recruitment procedures that will be used.** | | | | | | | |
| Student subject pool, *please specify*: | | | |  | Email | |  |
| Website ad, Facebook or other social media site, or other online recruitment | | | |  | Flyers or paper mail | |  |
| Other, *please specify*: | | | |  | Verbal announcement | |  |
| 1. **Briefly describe the reason for selecting the participants and the steps of approaching and selecting each type of participant for the study)** | | | | | | |  |
| **Please attach drafts or final copies of all recruitment materials with your application.** | | | | | | |  |
| **F. Will subjects receive compensation or rewards before, during, or after participation?** | | | | | | | |
| YES. *If yes, please provide the amount of compensation* | | | | | | |  |
| NO | | | | | | |  |

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|  | **PART 8: Secondary Data Analysis Details** |  |  |  |
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| *For Research Involving the use of Secondary Data or previously collected biomaterials (skip if you are not using secondary data)* | | | | |
| **A. Describe the secondary dataset or biomaterials, as well as the source *(the type of information in the dataset, who the data is from or about, how it was collected, and how is it available to the research team, etc.)*** | | | | |
| **B. Does the secondary data/samples contain identifiable information about living individuals? If yes, list the identifiers included in the data set. Briefly describe how the data will be used to protect the confidentiality and privacy of these individuals.** | | | | |
| **C. If using biomaterials, describe how and where the materials will be stored, handled, transported and disposed of.** | | | | |

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|  | **PART 9: Confidentiality and Privacy** |  |  |  |  |
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| **A. How are participant data, records, or specimens identified when received or collected by researchers? Identifiers include, but are not limited to, name, date of birth, email address, street address, phone number, audio or video recordings, ID (license, ID, passport, etc.)** | | | | | |
| No identifiers are collected or received | | | | |  |
| Direct identifiers (name, DOB, national ID, photo or video, phone number, etc.) | | | | |  |
| Indirect identifiers (e.g. a code or pseudonym used to track participants) | | | | |  |
| If collecting indirect identifiers, does the research team have access to the identity key? | | | | | |
| YES | | | | |  |
| NO | | | | |  |
| **B. Select all methods used to safeguard research records during storage** | | | | |  |
| Written consent, assent, or parental permission forms are stored separately from the data | | | | |  |
| Data is collected or given to research team without identifiers | | | | |  |
| Data is recorded by research team without identifiers | | | | |  |
| Direct identifiers are deleted and no identity key exists as soon as possible | | | | |  |
| Participant codes or pseudonyms are used on all data and the existing identity key is stored separately from the data | | | | |  |
| Electronic data is stored in a secure, location, *please specify* | | | | |  |
| Hard-copy data is stored in a secure location on VinUni campus, *please specify* | | | | |  |
| Other, *please specify*: | | | | |  |
| **C. How long will identifiable data be kept?** | | | | | |
| 1. **If data will be de-identified, describe how it will be de-identified.** | | | | | |

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|  | **PART 10: Risks and Benefits to participants** |  |  |  |
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| **A. Describe any risks that participants may face as a result of participating in this study. These could be physical (injury, discomfort, or illness), mental (stress, distress, emotional reaction), reputational or social (loss of privacy or confidentiality), economic (financial harm, additional cost), etc.** | | | | |
| **B. Is there any direct benefit to the participants from taking part in this study? (financial incentive for taking part in the study is not a benefit)** | | | | |
| **C. Describe how your study mitigates the risk to participants. If there are no risks, you can write N/A.** | | | | |

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|  | **PART 11: Consent Process** |  |  |  |  |
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| 1. **Describe the informed consent process for primary data collection as well as for the use of secondary data with identifiers. How will you ensure that participation is voluntary, with no possibility of coercion, and that the participants are well informed of the risks and benefits of the study.**   *Note: If the study involves minors/individuals with limited autonomy, or cognitive abilities, include the consenting process for the individual’s guardian.* | | | | |  |
| **B. Copies of the consent form(s) are attached.** | | | | | |
| YES | | | | |  |
| NOT APPLICABLE | | | | |  |

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|  | **PART 12: Investigator Assurances** |  |  |  |  |
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| I certify that the information provided in this document is complete and accurate to the best of my knowledge. | | | | |  |
| I agree to inform the VinUni VPO and the Vinmec's ERC immediately of any adverse effects arising from this study (e.g., unexpected adverse effect to the participants, or community, complaints, etc.) | | | | |  |
| I agree that I will seek permission from the Vinmec's ERC before making any changes to this research. I understand that making any changes without the permission of the ERC is an act of non-compliance with the ERC policies and may jeopardize the entire project. | | | | |  |
| **Signature of the PI**    Principal Investigator Date  If the PI is a student, the supervisor or faculty advisor must certify below.  I certify that I have reviewed the application and approve of the work that is proposed. I also confirm that I will be supervising the PI and the research team for this study.    Signature of the Faculty Advisor (if the PI is a student)    Faculty/Staff Advisor Date | | | | | |

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| **CHECKLIST: documents to include in your application** |
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1. Completed application form with the appropriate signatures

2. Consent documents

3. Recruitment or invitation documents’

4. Approval from another ERC if applicable

5. Approval/permission from Vinmec company or another collaborating organization, if applicable

6. Approval from VinUni competent authority

6. Any other documents that will aid in the review of this application

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| --- | --- |
|  | ..., day ... month ... year 20...  **VinUniversity Representative**  (Signature and Seal) |