**Memorandum**

**Office**: …………………………..…………..… **Tel:**...............................................

**Ref:** ………………/…………………………..  **Date:** ………….…….............…………

**Subject:** Human Research Ethics Proposal Form for Exemption Review

**To:** Chairperson of KMUTT-IRB Committee via Faculty/Institution’s IRB SubCommittee

My name is ……………………………………………………………... I am (Position) ………………………………………………..at [Dept. / Affiliation] ……………………………………………………………... I would like to submit the research proposal entitled “……………………………………………………………………………………………….” for the human research ethics approval and I have attached one (1) copy of each document as follows:

|  |  |  |
| --- | --- | --- |
| **List of Documents** | **Yes** | **No**  **(please indicate)** |
| 1. IRB Checklist |  |  |
| 1. Memorandum and IRB Form-01 |  |  |
| 1. Research Proposal/Concept Proposal |  |  |
| 1. Certificate of Attendance in IRB training of all investigators and/or the advisor |  |  |
| 1. Details of research instruments/ equipment (questionnaire, interview questions and other research instruments) |  |  |
| 1. Evaluation of the Project/Thesis Proposal Examination |  |  |
| 1. All documents file (**Attachment**: MS Word attached files, except 4. IRB Training Certificate and 6.Thesis/Project Proposal Examination attached as PDF) |  |  |

Signature ……………………………….

(……………………….............................………………….)

Principal Investigator/Student

Signature ……………………………….

(……………………….............................………………….)

Head of Department/Program Director/Advisor

**Instructions**: Please complete the form carefully and sign before submission.

|  |  |  |
| --- | --- | --- |
| **1** | **Details of Principal Investigator/Advisor** | |
|  | Name-Surname (Thai and English) | |
| Department/Major/Centre | Faculty/Office/Institution |
| Tel: | Email: |
| **Details of Student /** **Coordinator** | |
| Name-Surname (Thai and English) | |
| 🞎 Undergraduate Program 🞎 Master Program 🞎 Doctoral Program | |
| Department/Major/Centre | Faculty/Office/Institution |
| Tel: | Email: |
| **2** | **Project’s Title** | |
|  | (in Thai) | |
|  | (in English) | |
|  | **Funding Status**  🞎 No funding  🞎 Funded  🞎 University funding Specify source of funding ……………………………………..  🞎 External funding Specify source of funding ……………………………………..  🞎 Currently applying for funding  🞎 University funding Specify source of funding ……………………………………..  🞎 External funding Specify source of funding ……………………………………..  **Duration of Project**  From: Month…………. Year………… To: Month…………. Year…………… | |
| **3** | **Participants of the Project** | |
|  | Participants are vulnerable subjects 🞎 No 🞎 Yes, please specify  🞎 fetus/embryo  🞎 children (under 13 years old)  🞎 pregnant women  🞎 students/subordinates  🞎 patients with serious illness or chronic illness  🞎 disadvantaged group, e.g. beggar, disability, prostitutes, etc.  🞎 prisoners, alien workers  🞎 others, please specify………………………………………….  **(If any type of these vulnerable subjects is the participant of your research, you must request an Expedited/Full Board Review by completing IRB Form-02)** | |
| **4.** | **Research Category (Please select an item from 4.1-4.6 that is true to your project.)** | |
| 4.1 | Educational Research 🞎 Yes 🞎 No **(Go to item 4.2)** | |
|  | 4.1.1 Research is conducted in schools or education institution  🞎 Yes 🞎 No **(Request an Expedited/Full Board Review)** | |
|  | 4.1.2 Research involving teaching and learning in accordance with an educational standard.  🞎 Yes 🞎 No **(Request an Expedited/Full Board Review)** | |
|  | 4.1.3 Research on the effectiveness of instructional techniques, classroom management methods, curriculum evaluation, and quality assurance.  🞎 Yes 🞎 No **(Request an Expedited/Full Board Review)** | |
|  | 4.1.4 Research involving the use of educational tests such as cognitive, diagnostic, or attitude achievement.  🞎 Yes 🞎 No **(Request an Expedited/Full Board Review)** | |
| 4.2 | Research involves the use of survey procedures, interview procedures, or observation of public behavior.  🞎 Yes 🞎 No **(Go to item 4.3)** | |
|  | 4.2.1 Participants are vulnerable subjects 🞎 Yes 🞎 No Please specify  🞎 fetus/embryo  🞎 children (under 13 years old)  🞎 pregnant women  🞎 students/subordinates  🞎 patients with serious illness or chronic illness  🞎 disadvantaged group, e.g. beggar, disability, prostitutes, etc.  🞎 prisoners, alien workers  🞎 others, please specify………………………………………….  **(If any type of these vulnerable subjects is the participant of your research, you must request an Expedited/Full Board Review by completing IRB Form-02)** | |
|  | 4.2.2 If research using test results/record of an organization, you must receive consent from authorized personnel.  🞎 Informed consent  🞎 No consent **(Request an Expedited/Full Board Review)**  🞎 No information | |
|  | 4.2.3 Using information recorded by the principal Investigator in a manner that subjects can be identified directly (ID, Government Official ID, medical records) or indirectly (through coded system which can link to that people).  🞎 Yes **(Request for Expedited/Full Board Review)**  🞎 No | |
|  | 4.2.4 Research data involves sensitive issues 🞎 No 🞎 Yes , please specify  🞎 Behavior or sexual attitudes  🞎 Alcohol consumption or drug intake  🞎 Immoral or illegal acts  🞎 Psychological illness or contagious diseases that are not acceptable by society e.g. HIV/AIDS, TB, etc.  🞎 Others, please specify: ………………………………………………………………  **(If your answer is ‘Yes’ in any item, you must request an Expedited/Full Board Review)** | |
|  | 4.2.5 Any disclosure of research responses may psychologically affect the participants or could be damaging to the subject’s financial status, employability, education or any future promotions.  🞎 Yes **(Request an Expedited/Full Board Review)** 🞎 No | |
| 4.3 | Public Service Project 🞎 Yes 🞎No **(Go to item 4.4)** | |
|  | 4.3.1 Demonstration Project/Survey Project/or Evaluative project has been approved by the head or authorized personnel.  🞎 Yes 🞎 No **(Request an Expedited/Full Board Review)** | |
|  | 4.3.2 Research aims to assess the effectiveness/alternative education/work development or policy.  🞎 Yes 🞎 No **(Request an Expedited/Full Board Review)** | |
|  | 4.3.3 The information of participants is disclosed.  🞎 Yes **(Request an Expedited/Full Board Review)** 🞎 No | |
| 4.4 | Survey research for food, products, or service satisfactory. 🞎 Yes 🞎No **(Continue to item 4.5)** | |
|  | 4.4.1 Food product or service has ingredients that are not approved by the Food and Drug Administration or addictive substances or harmful substances.  🞎 Yes **(Request an Expedited/Full Board Review)** 🞎 No | |
|  | 4.4.2 The participants have been informed about any possible side effects from the ingredients/process of food, products or services.  🞎 Yes **(Request an Expedited/Full Board Review)** 🞎 No | |
| 4.5 | Research in scientific laboratory. 🞎 Yes 🞎No **(Go to item 4.6)** | |
|  | 4.5.1 Research uses isolated micro-organisms and culture in the laboratory for specimen in a manner that subjects can be identified.  🞎 Yes **(Request an Expedited/Full Board Review)**  🞎 No  🞎 Do not use isolated micro-organisms | |
|  | 4.5.2 Research uses cultured cell from genetically modified human tissue for Cell line in a manner that subjects cannot be identified.  🞎 Yes  🞎 No **(Request an Expedited/Full Board Review)**  🞎 Do not use | |
|  | 4.5.3 Research uses specimen from blood, bones, tissues, secretion or other human biological specimen in a manner that subjects can be identified.  🞎 Yes **(Request an Expedited/Full Board Review)**  🞎 No  🞎 Do not use | |
|  | 4.5.4 Research involves looking for contaminants, chemicals, diseases or bio-materials that directly affect the participants.  🞎 Yes **(Request for Expedited/Full Board Review)**  🞎 No  🞎 Do not involve | |
| 4.6 | Other research categories (in case that your answer in 4.1-4.5 is ‘🗹 No’ in all items)  ---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------- | |
| **5** | **Principal Investigator Commitment** | |
|  | 5.1 I, as the principal investigator, and my co-investigators, as listed and signed in this document, will conduct this study according to the protocol approved by KMUTT--IRB. I acknowledge that I will follow the regulations for conducting human subjects research.  5.2 I acknowledge that the proposal must be approved from IRB Committee before starting the project.  5.3. I acknowledge that my project’s co-investigators must obtain IRB Committee’s approval from his/her institution to collect data.  5.4 I acknowledge that I must explain, point out to the participants or the authorized representative as follows:  5.4.1 Information of the projects e.g. objectives, procedures especially the role of the participants or authorized representatives, is provided to the participant or authorized representative correctly and completely. Also, adequate time must be given before the participants or authorized representative makes decision to participate in the project by signing the informed consent form.  5.4.2 Information about dangers, side effects and complications that may occur during and after the project.  5.4.3 Participants have the right to withdraw from the project at any time without any effect on the project or causing any damaging consequences.  5.5 I will keep participants’ private information private and confidential by not disclosing any information of the participant to others. The information will be kept in a secure location. Only authorized personnel have access and at the end of the study, the information will be destroyed. In case of serious adverse events and unanticipated events, there will be privacy and confidentiality protection to prevent any damaging consequence to the participants.  Signature ……………………………….  (……………………………………….........................….IN PRINT)  Date: …………………………………. | |
| **For IRB SubCommittee of Faculty/Office Only** | | |
| **🞎 Eligible for Exemption Review**  Other comments: …………….…………………………………………………………………………………………………………………………..…..  **🞎 Eligible for Expedited Review**  Other comments: …………….…………………………………………………………………………………………………………………………..…..  **🞎 Eligible for Full-Board Review**  Other comments: …………….…………………………………………………………………………………………………………………………..…..  Resolution of the meeting………………./………………… Date: …………………………..  Signature ……………………………….  (……………………………………….........................….IN PRINT)  Date: …………………………………. | | |
| **For IRB Committee** | | |
| **🞎 Eligible for Exemption Review**  🞎 : Issue COE and report to the next IRB Committee Meeting  🞎 : Inform the Principal Investigator to further explain/amend………………………………  **🞎 Eligible for Expedited Review**  🞎 : Inform the Principal Investigator to prepare all required documents for reviewing again.  🞎 : Submit to the ....................... committee members for review consideration, namely …………………….................................................................................................................................................................……..    **🞎 Eligible for Full-Board Review**  🞎 : Inform the Principal Investigator to prepare all required documents for reviewing again.  🞎 : Submit to the ....................... committee members for review consideration, namely …………………….................................................................................................................................................................……..  🞎 Submit to the IRB Committee for review  🞎 Other …………………….……………………………………………………………  Signature ……………………………………………. (IRB Secretary) Date: ……….....……….. | | |
| **For IRB Chairperson**  🞎 Agree and please proceed accordingly  🞎 Disagree (reasons): ………………………………………………………………...  🞎 Other comments: …………………………………………………………………..  Signature ……………….……….………………. (IRB Chairperson) Date: ………......…….. | | |