

 **Memorandum**

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

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

**Subject:** Human Research Ethics Proposal Form for Expedited/ Full Board Review

**To:** Chairperson of KMUTT-IRB Committee via IRB Subcommittee at the Faculty/Office/Institution .................................................................

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:

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **List of Documents**  | **Yes** | **No**(please indicate) |
|  | IRB Checklist |  |  |
|  | Memorandum and IRB Form-02  |  |  |
|  | Research Proposal/Concept Proposal |  |  |
|  | Principal Investigator’s Curriculum Vitae |  |  |
|  | Certificate of Attendance in IRB training of all investigators and the advisor |  |  |
|  | Details of research instruments/ equipment (questionnaire, interview questions and other research instruments) |  |  |
|  | (7.1) Participant Information Sheet(7.2) Informed Consent Form  |  |  |
|  | Evaluation of the Project/Thesis Proposal Examination |  |  |
|  | Others such as Permission Request Letter for Data Collection/ A Form of Waiver of Consent |  |  |
|  | All documents file (**Attachment**: MS Word attached files, except 5. IRB Training Certificate and 8. 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** |
| Full Project Duration ..................(months, years)From: Month…………. Year………… To: Month…………. Year……………  |
| **Duration of Data Collection Process** |
| Full Data Collection Process Duration ..................(months, years)From: Month…………. Year………… To: Month…………. Year…………… **(You can start collecting data after the project has been approved by the KMUTT-IRB)** |
| **3** | **Significance of the Project**   |
|  |  |
| **4** | **Objectives of the Project**   |
|  |  |
| **5** | **Benefits of the Project**   |
|  |  |
| **6** | **Research Methodology (you can 🗹 more than one)** (please see in the proposal/in the complete report on page no. …….) |
|  | 🞎 6.1 Qualitative research🞎 6.2 Quantitative research🞎 6.3 Medicine testing or medical supplies (please specify the type and usage).................................🞎 6.4 Research from existing data 6.4.1 Please specify type of data ……………. 6.4.2 Consent from data owner 🞎 Yes (please attach informed consent document) 🞎 No (please attach Draft for permission to collect data)🞎 6.5 Research from existing specimens of other research (tissues or biopsy)🞎 6.6 Others, please specify …………………………………………………………………………………. |
| **7**  | **Data Collection** |
|  | - Please specify data collection process from participants and type of research tools - If conducting a research project in Phase......, please specify data collection process and type of research tools each phase- Please attach Research Tools e.g., record of data collection process and/or questionnaire and/or interview questions, etc.- Please specify the equipment testing or application from the participant (If any)- Duration of collecting data from Participants e.g., how many days, how many times, how many hours, how many minutes, etc. |
| **8** | **Research site** |
|  | 🞎 Only in Thailand, please specify (number of sites, site name) ………………………………………🞎 Multinational project with other countries, please specify (which country, how many sites in Thailand, site names) ………………………………………………………………………………………….…………… |
| **9** |  **Explain the experiment procedure and give reasons why it is considered as minimal risk.** |
|  |  |
| **10** | **Background and human subject research**  |
|  |  |
| **11** | **Participants** |
|  | 11.1 Number of participants and please justify the appropriateness of sample size **(clarify in detail and if there are more than 1 group of participants, please specify the number of participants in each group completely.)**   |
| 11.2 Please specify characteristics and participant selection process. **(clarify in detail and if there are more than 1 group of participants, please specify the characteristics of participants in each group completely.)**   |
| 11.3 Please specify subject allocation process for experiment and control group. (if any) |
| 11.4 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)** |
| 11.5 Participant recruitment process (e.g. advertisement) |
| 11.6 Participant compensation (please specify in detail) |
| **12.** | **Informed Consent Process** |
|  | 🞎 With signature (Please attach Information Sheet and Informed Consent Form)🞎 Waiver of Consent* see in the IRB DOC-06: To do a Waiver of Consent
* Please attach A Form of Waiver of Consent, IRB Form-07
* You can start collecting data after the project has been approved by the KMUTT-IRB
 |
| **13** | **Benefits for the participants and community as well as strengthening of the community** |
|  |  |
| **14**  | **Effects that may be on the participants or the community** (e.g. Dangerous/harmful to body, emotion, society, economy, and investigators. Preparation of protection measure or solutions by Principal Investigator) |
|  |  |
| **15** | **Privacy Confidentiality protection of Participants’ information/community in the project** |
|  | 🞎 coded🞎 recorded by 🞎photograph 🞎 VDO 🞎 sound recorder 🞎 Others, please specify |
| **Specify who has access to the information (Please specify for consideration according to the confidentiality guidelines according to the Personal Data Protection Act B.E. 2562 (2019))** |
| Please specify………………………………………......................................................................................................……… …………………………………………………………………………………………………………………..................................…………......... |
| **Data Retention Period (After Data Collection)** |
| Please specify………………………………………......................................................................................................……… …………………………………………………………………………………………………………………..................................…………......... |
| **Data Destruction (Please specify for consideration according to the confidentiality guidelines according to the Personal Data Protection Act B.E. 2562 (2019))** |
| How the information will be disposed of after the storage period.Please specify………………………………………......................................................................................................……… …………………………………………………………………………………………………………………..................................…………......... When the information will be disposed of after the storage period.Please specify………………………………………......................................................................................................……… …………………………………………………………………………………………………………………..................................…………......... |
| **16** | **Sending specimen outside the university** |
|  | 🞎 No 🞎 Yes * Must attach Material Transfer Agreement, MTA
* Forms Download; https://ethics.kmutt.ac.th/download/
 |
| **17** | **Outcome Measurement/Data Analysis.** **PI must specify the outcome of the project that will be used to calculate sample size, assessment of efficacy, assessment of safety statistics, statistical analysis or data analysis.** |
|  |  |
| **18** | **Institution Research Protocol Considerations** |
|  | 🞎 Thesis/Project Proposal Committee Approved by the faculty of ………………......................................  on: Date …….. Month…………. Year………….🞎 The advisor approved on: Date ……..Month………….Year…………….🞎 Others …………………………………………………………………………… |
| **19** | **IRB training. Please attach each investigator’s certificate. (Certificate of training is valid for 2 years)** |
|  | 1. Researcher …………………….….………….…….................................................……. DD/MM/YY………………………….2. Researcher ………………………..…………..................................................…………. DD/MM/YY…………………………. |
| **20** | **Principal Investigator Commitment** |
|  | 20.1 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.20.2 I acknowledge that the proposal must be approved from IRB Committee before starting the project.20.3 I acknowledge that my project’s co-investigators must obtain IRB Committee’s approval from his/her institution to collect data.20.4 I acknowledge that I must explain, point out to the participants or the authorized representative as follows: 20.4.1 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. 20.4.2 Information about dangers, side effects and complications that may occur during and after the project. 20.4.3 Participants have the right to withdraw from the project at any time without any effect on the project or causing any damaging consequences.20.5 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.20.6 I have an informed consent form signed by the participant or authorized person to participate in the project. Signature ……………………………….(……………………………………….........................….IN PRINT)Date: …………………………………. |
| **For IRB Subcommittee of Faculty/Office/Institution 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: ………......…….. |