Application Form for Expedited Review of Research Involving Human

Faculty of Associated Medical Sciences, Chiang Mai University

**Part 1. General Information**

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| --- | --- | --- | --- |
| 1. Protocol Title | | | |
| 2. Name of Principal investigator | Academic Title | | Workplace Tel.    E-mail address |
| Dept, Faculty | |
| 3. Advisor # | Dept, Faculty | | Workplace Tel.  E-mail address |
| 4. Is this a post – graduate research study?  Yes  No | | If yes, is this a thesis/research for  Bachelor’s  Master’s  Ph.D. (Date proposal approved      ) | |
| Has the thesis been formally approved by the advisory committee? | | Approved  Pending Review / Under Consideration | |
| 5. Program/Research proposal falls under the Faculty of Associated Medical Sciences Notice on Expedited ResearchSection….      (Please describe in short how the Program/Research proposal fits that criteria) | | | |
| 6. Study Summary (Objectives, design, methodology, data analysis) | | | |
| 7. Program/Research Proposal Period      Year(s)       Month(s) | | | |
| 8. Funding source and budget approval | | | |
| 9. Do all co-investigators have signed the protocol?  All (please attach document)  Some  In case, not all co-investigator have signed the protocol, please give the reason .. | | | |

**Part 2. Ethical Issues**

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| 10. Study subjects will be:  Healthy (Number=    )  Patient (Number=    )  Other.. | Age range[[1]](#footnote-1)δ | |
| Specify disease: | |
| 11. Does study include blood draws?  Yes  No | If yes, specify time of draw, volume of blood to be collected, total number of draws and the reasons blood draw will be necessary .. | |
| 12. Is there an informed consent process in this study?  Yes    Request waiver/alteration of informed consent) | If requesting an exemption, specify why … | |
| 13. Will written informed consent forms be signed by subjects?  Yes    Request waiver/alteration of informed consent) | If requesting an exemption, specify why… | |
| 14. Please specify the potential risks and discomforts that subjects might incur as a direct result of participation in this study | | |
| 15. Please specify the procedures that will be implemented to limit or safeguard against the above-mentioned risks | | |
| 16. How would you keep participants’ information?  Hard copy  Keep files in computer  Other …  16 a. What is your system to keep the participants’ information safely from accessing by others?  16 b. How long will you keep the participants’ information?      After that how would you destroy it? | | |
| 17. Will you publish the photograph of participants in publication?  Yes  No  17 a. If Yes: Would you cover the part of the body that can lead to participant’s identity?  Yes  No: Please provide reasons …  17 b. Will you ask for informed consent if you need to publish the photographs of participants?  Yes (please provide evidence or document)  No : Please provide reasons… | | |
| 18. Do you have a conflict of interest with the sponsor of this study?  Yes  No  **If yes, please specify:**  I am the owner of the product used in this study  I hold shares in or receive benefits from the company manufacturing the substance used in the research  I serve as a consultant for the company manufacturing the substance used in this study  I receive financial compensation for conducting research from the company manufacturing the substance used  Other (please specify): .... | | |
| 19. Do all study staff acknowledge and agree to conduct themselves according to the regulations governing human subjects research protection, such as Medical Council (no.5) 2001 sub-section 6 for human subject protection and patient rights, the declaration of Helsinki (revised 2008), and Faculty of Associated Medical Sciences regulations and guidelines for researchers  All acknowledge and agree  Some acknowledge and agree  Not sure | | |
| 20. Do the principle investigator(s) have any formal human subjects protection training?  GCP (Good Clinical Practice)  Ethical issues in human subjects protection  (Please attach a certificate of training along with this form) | | Certificate of training (please attach)  Date issued .....  Date expired … |
| 21. We confirm that all information provided in this document is true and correct to the best of our knowledge. All investigators clearly understand all information relevant to this proposal and the full research protocol, and have attached the full research proposal/protocol and other relevant documents as noted above. We (I and the research team) will conduct this study in strict accordance to all ethical guidelines and regulations governing human subjects research  (Sign)  (     )  Principal investigator  Date…  (Sign) All Co-investigator[[2]](#footnote-2)∅    (     ) (     )    (     ) (     )    (     ) (     )    (     ) (     ) | | |
| 22 .The investigators would like to receive the committee certificate in  Thai  English  Certificate is not needed but approval form is attached herewith for endorsement | | |

1. # In case the study is for student’s degree/training)

   δ Please specify age range, e.g., 3 months to 2 years, or 20 years and above, etc. [↑](#footnote-ref-1)
2. ∅ Signature not necessary if they appear in the research proposal or if the study is multi-centered [↑](#footnote-ref-2)