**Memorandum**

**Affiliation**................................................................... **Tel.**.......................................

**No.** …….....…....……/......................  **Date**.................................................

**Re:** Application for ethical review

**To:** Chairman of the PSU Human Research Ethics Committee, Prince of Songkla University

 Name.............................................Affiliation.............................would like to submit my research project, titled (in Thai and English).........................…….….…..........................................

for the ethical review. I have enclosed the following pertinent documents:

1. Proof of PRPM database registration (if applicable) Set

2. Application fee submission form (AO-027) and proof of payment Set

3. Application for ethical review (AP-002) Sets

4. Completed research project (AP-023 or AP-024) Sets

5. Statement of purpose to research participants (AP-017 OR AP-018) Sets

6. Informed Consent form (AP-019 OR AP-020) Sets

7. Consent form for participants ages 7-13 (AP-021 OR AP-022) Sets

8. Waiver of Consent (AP-006) Sets

9. Bio of principal investigator and co-investigator(s) (in Thai or English) Sets

along with proof of ethical review training certificate (with date and signature)

10. Research tools such as interview questions, data collection forms, Sets survey/questionnaire, biophysiological measures

11. Investigator’s brochure or other relevant materials related Sets

to herbal medicines (if applicable)

12. Research/experiment manual (if applicable) Sets

13. Legal documents (if applicable) such as insurance paperwork, Sets

Material Transfer Agreement draft Clinical Trial Agreement draft

and Data Sharing Agreement

14. Miscellaneous (if applicable) such as brochure/poster, volunteer ID card Sets

15. Memorandum Sets

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| --- | --- |
| Signature………………………………….…………. | Signature ………………………………….…………. |
|  (……..…………………….………………) |  (……………………..…….………………) |
|  Faculty Advisor (PSU student-led project) |  Principal Investigator |
|  **The above project has been approved by its original affiliation****and allow to site visit in case of necessary** |
|  Signature ………………………………….………….…………… |
|  (…………………….……………………..…………….) |
|  Position .................................................................. Chief of original affiliation |

**Application for the Human Research Ethics Review**

**Health Science Study**

Please provide sufficient and concise details. Do not skip any question, write “N/A” if irrelevant.

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| 1. **Research Title** (in Thai and English)
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| 1. **Principal Investigator,** affiliation (Thai and English). Include telephone number, e-mail address, and a list of responsibilities.
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| 1. **Co-Investigator,** affiliation (Thai and English). Include telephone number, e-mail address, and a list of responsibilities.
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|  |
| 1. **Research Summary** (No longer than 4 pages on A4 paper, use time new roman font size 12, single-space, no need to include any references.
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|  |
| 1. **Type of Study and Research Methodology** (mark ⌧ where applicable, please provide additional description)
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| □ Experimental/Quasi-experimental study, specify:.................................................................................................................□ Descriptive study, specify:…………………………..…………………………..………………….………………………………□ Survey study, specify: …….………………………………………………………………………………………………………………□ Others, specify:………………………………………………………………………………………………………… |
| 1. **Is this project a multi-center study or a set of projects?** (mark ⌧ where applicable)
 |
| □ No □ Yes If yes, identify the centers and provide a list of principal investigators from each of the centers. (Note: Material transfer agreement must be presented should any biological sample be processed or stored at other centers. Data sharing agreement must be filled out by the Principal Investigator if data from multiple centers is to be combined. The agreement must indicate names of both the owner of data and central data custodians.)  |
| **7. Does this research receive consultation from any research methodologist or biostatistician?** |
| 1. Research methodologist □ None □ consulted with Name…………………………..…….. Signature…………………….……
2. Biostatistician □ None □ Consulted with Name…………………………..…….. Signature…………………….……
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| **8. Research Procedure** (Mark ⌧ where applicable) |
| * 1. **Inserting tools or substances into the body**

□ None□ Yes, specify ..................................................................................... (such as catheter, feeding tube/testing substance, also specify parts of the body, duration, and frequency)* 1. **Inspection/Operation: Does this research procedure involve non-invasive procedure?**

□ None□ Yes, specify ........................................................................................................................ (such as ECG EEG, blood pressure, parts of the body, duration, and frequency) |
| **9. Will there be any specimens collected from the participants? (such as blood, urine, tumor)** (Mark ⌧ where applicable) |
| □None □ Yes, specify types of specimens, amount, frequency of collection, the lab where the samples are tested, storage or destruction management of the samples. |
| **10. Does the research procedure involve interviews/tests/evaluations?**  |
| □None □ Yes, specify accuracy of each tool, copyright, Thai translation (must be done by an accredited entity), user’s qualifications, duration, frequency, etc.  |
| 1. **Research methods/tests/procedures and alternatives for the participants**
 |
| * 1. How is the research method similar or different from regular routine?
	2. What are the options in the event of any participants opting out of the study?
	3. If using placebo (drugs, substance, or procedure), explain the reasons along with risk/benefit assessment presented to the participants.
 |
| **12. Potential risks and discomfort**  |
| * 1. Indicate any physical, mental, societal, or economical risks and discomfort that may occur to the participants.
	2. Share any plans to mitigate or prevent any of above risks and to treat any complications.
	3. Provide measures to protect and preserve confidentiality of the participants.
 |
| **13. Provide concrete benefits of the research project.** |
|  |
| 1. **Research participants**
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| * 1. Number of participants (for multi-center project, provide the number per each center)
	2. Detail statistical calculation or other methods from which the number above is derived (Include the formula and references)
	3. Detail the inclusion criteria
	4. Detail the exclusion criteria
	5. Detail the subject withdrawal criteria such as in case of the participants facing adverse events or have extreme resistance
	6. Detail the termination of study criteria such as the percentage by which the complication rate may not exceed or when an interim analysis proves the research to be ineffective
 |
| 1. **Vulnerable participants** (individuals who are unable to make decisions independently) (Mark ⌧ where applicable)
 |
| □ None □ Yes, there are vulnerable participants (Mark Ä on all that applies)* Infants, children (<18 years old)
* Elderly (> 60 years old)
* Pregnant women
* Patients with chronic or terminal illness
* Individuals with intellectual disabilities or neuropsychiatric diseases
* Prisoners, migrant/foreign workers, socially disadvantaged individuals such as the poor, the minorities, the illiterates
* Students, subordinates, employees
* Individuals who are unable to provide consent on their own such as patients in critical conditions.
* Others, specify ............................................................................................................................

**Explain the necessity to include vulnerable participants** ........................................................................................................................................ |
| 1. **Recruit participants** Describe recruiting strategies such as ads in media, print, radio,orthroughinternal connections (Must enclose relevant materials)
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| 1. **Incentives** If applicable, provide numbers or other details
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| 1. **Compensation**
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| * 1. If participants are compensated for time and travel, provide details
	2. Individuals responsible for compensation should any complications occur
	3. Any insurance procured against potential damages/injuries? If yes, specify
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| 1. **Consent** (Mark ⌧ only one of below)
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| □ Written consent (enclose a copy of informed consent)□ Verbal consent□ Verbal and written consent (enclose a copy of informed consent)□ Consent by action□ Waiver of consent(Note: If written consent is not obtained, provide rationale and enclose waivers)1.)Does the study involve participants/subjects under crisis condition? Why the study needs to involve these participants/subjects while there are standard treatment procedures?    2.) Reasons for not being to get written consent from participants/subjects   3.) Whether the study involve these participants/subjects under crisis condition for their any utilities directly?   4.)Reasons for not being to conduct the study if permission in getting verbal consent has not been approved.    5.) Reasons for waiver of consenting process    |
| 1. **Consenting process**

Detail the process of inviting the participants and acquiring consent (such as how the information is presented, the persons responsible for providing information and collecting consents, what is the location, how long is the duration, are there any legal representatives participating, what are the tactics used to minimize the sense of obligation among the participants)  |
|  |
| **21. Does the project involve testing “modern medicine”?** (Mark ⌧ where applicable)  |
| □ None□ Yes (Provide following details for each of drug)**1) Name of drug......................................................................................** (Specify name, use, dosage, frequency, duration)**Safety measures** (Mark Ä where applicable)* Approved by FDA Thailand ...................................................................................

(Enclose package insert) (Will the study follow the instruction as indicated on the label? □ Yes □ No) * Approved by FDA of (name country)..................................indicate.......................................................

(Enclose package insert) (Not yet approved by any FDA but it is a human study (Enclose Investigator’s Brochure Issue No........................ Dated.................................................................................)* No human study, but animal testing (Enclosed materials include ....................................................................................................................................................... )
 |
| 1. **Will the project test any “medical equipment” ?** (Mark ⌧ where applicable)
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| □ None □ Yes, specify type of equipment and any relevant details **1)Name of equipment.................................................................................................****Details of approval from the Food and Drug Administration (FDA)** * Approved by FDA, see enclosed supporting documentation ............................................ (Enclose device specification and operating manual)
* Not yet approved by the FDA, but is a modification of equipment that has been approved by the FDA (Enclose device specification and operating manual)
* Not yet approved by the FDA, but is a newly invented device that has been used in human research (Enclose device specification and operating manual)
* Not yet approved by the FDA, but is a newly invented device that has never been used in human research (Enclose device specification and operating manual)
* Others, specify.....................................................................................................................
 |
| 1. **Does the project involve testing “herbal medicine and natural products”?**

(Mark ⌧ where applicable) |
| □ None□ Yes**Type of products** (Mark Ä only on one option)* Medicine that is listed in the Thai Traditional Medicine Formulary or Thai Traditional Medicine Textbook, used as instructed by Thai Traditional and Alternative Medicine
* Medicine that is listed in the Thai Traditional Medicine Formulary or Thai Traditional Medicine Textbook, used as instructed by modern medicine that follows the principle of Thai Traditional and Alternative Medicine
* Herbal medicine, used as instructed by modern medicine that does not follow the principle of Thai Traditional and Alternative Medicine
* Food or dietary supplements consumed for health benefits
* Medicine derived from natural substance through modern processing (pure or semi-pure extracts and new derivatives)

**Supporting documents** (Mark Ä where applicable)* Package Insert, if approved by the FDA
* Document showing instructions guided by alternative medicine: Prospective disease, instructions, dosage, duration, etc. (provide references to the Thai Traditional Medicine Formulary or Thai Traditional Medicine Textbook)
* Safety information about lab animals, if the herbal medicine has never been tested on human
* Preparation methods of the herbal/natural products (provide documents with detailed instructions)
* Scientific report that supports use of the medicinal/herbal properties in the study
* In case of testing food or dietary supplements, provide evidence to show they are commonly consumed, local food, or certified human food
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| 1. **Total budget** (Show details in table format)
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|  |
| 1. **Source of funds/sponsors** (Provide a list of source from which each fund is received or approved)
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| 1. **Duration**
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| Data is expected to be collected from Month……….………………….Year (B.E.)……..……. until Month…………………….Year (B.E.)……………Planned complete project duration ………………….…year(s)…………….……..month(s) |
| **27. Does the principal investigator have any stake in the research project?** (Please answer truthfully) |
| □ None □ Yes □ The research project is not funded by any entity in private sector□ The researcher does not have any relations whatsoever with private sponsors (beyond receiving funding for the project)□ The researcher has received an invitation to be a guest lecturer from private entities (provide details) ……………………………………………………………………………□ The researchers are sponsored by private entities to attend an academic conference or training within Thailand (provide details) ..........................................................................................................................................................□ The researchers are sponsored by private entities to attend an academic conference or training abroad (provide details) ..........................................................................................................................................................□ Holds stock of the private sponsor’s company (provide quantity and value of shares) □ Owns copyright of drugs or medical equipment □ Serves as a consultant to the private sponsor’s company, receives salary or consulting fee................... THB/month □ Other (such as professor-student, supervisor-supervisee etc., specify............................................................................................................................................. |
| 1. **Principal Investigator’s Responsibilities**
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| 1. Number of projects the principal investigator currently oversees (not including this project) ………projects including

1) Project titled …………………………………………………...……… number of volunteers under supervision ……2) Project titled ……………………………………………..…….……… number of volunteers under supervision ……3) Project titled …………………………………………………………… number of volunteers under supervision ……Total number of volunteers under supervision ……1. How does the researcher plan on manage the above projects without imposing risks or issues to the volunteers or the regular job?

……………………………………………………………………………………………………………………………………………………… |
| 1. **Ethical experience of the principal investigator and co-investigator** (Must be trained every 2 years) \*\*

(ICH-GCP, Human Subject Protection Course, CITI (PSU), NIH, NIDA)  |
| Principal Investigator and Co-investigator have received the following ethical trainings (specify details per individual and enclosed valid proofs)1. Name............................................................. Training course.............................. Date ...................................
2. Name............................................................. Training course.............................. Date ...................................
3. Name............................................................. Training course.............................. Date ...................................
 |
| 1. **Where has ethical review application been submitted for this research project?**
 |

* the PSU Human Research Ethics Committee, Prince of Songkla University
* Other HREC (Specify)........................................................................................................................................................

I certify that

 □ all above information is true and accurate

 □ I have read and understood all of the above questions and contents

 □ adhere to the human research ethical guidelines

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| --- | --- |
|  Signature……………………………….…………… |  Signature ………………….………………..…………… |
|  (……………………………..…………….) |  (…………………………………………..………) |
|  Advisor  (If the Principal Investigator is a student) |  Principal Investigator Signature ....................................................... (..........................................................) Co-Investigator Signature ....................................................... (..........................................................) Co-Investigator Signature ....................................................... (..........................................................) Co-Investigator  |
|  **The above project has been approved by its original affiliation****and allow to site visit in case of necessary** |
|  Signature ………………………………….………….…………… |
|  (…………………….……………………..…………….) |
|  Position .................................................................. Chief of original affiliation |