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**SUTEC’s submission Form for Ethics in Human Research for**

**Clinical trials/Experimental Studies**

The applicant must submit details on related topics (respond to every item, if an item is not applicable to the submitted project, write ‘not applicable’. Do not leave any item blank).

1. **Research title**:

2. **Principal investigator and affiliation**:

 **Phone number**

 **E-mail**:

3. **Co- investigator(s) and affiliation(s)**:

 **Phone number**

 **E-mail**:

4. **Significance of problems to be studied (executive summary)**

5. **Objectives (Write clearly)**

6. **Concrete benefits of the project once completed**:

7. **Types of studies and research design**:

□ a. Treatment study (Specify).............................

□ b. Diagnostic study (Specify).............................

□ c. Epidemiological study (Specify).............................

□ d. Descriptive study (Specify).............................

□ e. Others (Specify).............................

8. **Background of study in humans**

a. Brief research background with references

b. Dose this study has been conducted in humans before?

c. If this study has been conducted in humans, explain why it needs to be replicated?

d. If this study has not been conducted in humans, has it been fully studied in animals?

9. **Population and research subjects**

a. Number of research subjects

b. How is the number calculated (show statistical formula and calculation method)?

c. Inclusion criteria

d. Exclusion criteria

e. Withdrawal of participant criteria means indications that point to dangers that will happen to the volunteers if the research protocol continues.

f. Termination of study criteria e.g. numerous cases of adverse side effects, or after a period of research study it is found that the study cannot proof the expected efficacy. If this is not appicable, please state “none”.

g. Are healthy subjects included in the study?

h. Are the following vulnerable subjects (those who cannot make critical decisions) included in the study?

 No

 Yes, they are

* Infants, children
* Pregnant women
* Elderly
* Patients with chronic diseases
* People who cannot give consent by themselves
* People with disability
* Prisoners, alien laborers, in some cases people who are socially disadvantaged, students, and minorities
* Others (Specify)..............................................

**If there are vulnerable subjects, please state reasons why this group of subjects must be included in the study. Please also suggest how you plan to protect these vulnerable subjects.**

i**.** Method(s) used in getting access to the target population and persuading them to join the project (e.g. advertisement, ads in printed media, radio commercials, or asking for co-operations from the doctor who treats the patients)

j. If there is a monetary or non-monetary reward, please give details and value of the reward.

k. If the study is a randomized controlled trial (RCT), please give details on how the subjects are divided into groups.

10. **Possible effects on the research participants and their compensations**

a. Explain if there is any physical, mental, social, and economic risk.

b. How has the researcher planned to prevent complications and take care of the participants in case of a complication?

c. Who will pay for medical care in case of a complication?

d. How has the researcher arranged for insurance for damage/injury?

11. **Treatment method or practice used in the study**

a. Explain how the method used in the study is similar to or different from the routine practice.

b. What are the alternative diagnoses or treatments?

c. If a placebo is used in the control group, state reasons why this must be used. Give an evaluation of possible risks and benefits.

12. **Does this study involve the test of herbal medicine and natural products?**

 No. Go to item 14

 Yes. Specify if the herbal medicine or drug formulation used has one of the following characteristics.

* A study of medicine in the traditional Thai drug formulation or traditional Thai medicine textbooks that is in accordance with the indication and use of traditional Thai or alternative medicine
* A study of medicine in the traditional Thai drug formulation or traditional Thai medicine textbooks that is in accordance with the indication and use of conventional or alternative medicine
* A study of herbal medicine the use of which is indicated in non-existing conventional medicine, but (the use) can be cited according to the principles of traditional Thai or alternative medicine
* Use of foods or food supplements for health benefits
* A clinical trial study that uses medicine prepared from natural substances in a modern process (pure or semi-pure extracts, and new derivatives)

13. **The researcher is to provide the following documents. Make a check mark (√) in the box in front of the documents provided.**

 If the drug/food/food supplement has been approved by the Food and Drug Administration, attach Package Insert/leaflet.

 Document showing indications of use that is in accordance with alternative medicine: targeted disease, dosage, length of time, etc. (Give references of books, traditional Thai drug formulation, or traditional Thai medicine textbooks)

 Information on safety in humans, or in laboratory animals if the herbal medicine has not been tested in humans.

 Method of herbal drug preparation – is the natural product used the original ancient medicine or is it a coarse extract? Show the preparation procedure.

 Scientific reports that support the action of drug under study: study in animals, observations in humans

 If this is a study of food or food supplement, provide proofs whether it is generally consumed, a local food, or food that is registered as food for humans.

14. **Does this study involve the test of conventional medicine?**

 No. Go to item 15.

 Yes. Give name of the medicine with the following details separately according to types of medicine

1. .................................................. (Indicate usage, amount, and frequency.)
* The medicine is approved by the Food and Drug Administration (FDA), Ministry of Public Health for the treatment of........................................................(The Package Insert is attached.)
* The medicine has not been approved by FDA, but it has been studied in humans and Investigator’s Brochure Issue no………. dated………. Is attached)
* The medicine has not been approved by FDA nor has it been studied in humans, but is has been studied in animals and the research report or related references are attached.
* Others. Specify..............................................................

15. **Does this study involve a test of medical device**?

* No.
* Yes. Give name of the medical device ....................................... with the following details:

a. Details of FDA approval

* + The device is approved by FDA for the treatment of ......................................... The device specifications and operation manual are attached.
	+ The device has not been approved by FDA, but it is an adaptation or improvement of a device that is FDA approved. The specifications and operation manual of the new and original device are attached together with information on the technical comparison of the new device with the original one.
	+ The device has not been approved by FDA, and it is a newly invented device and has been studied in humans. Related research reports as well as device specifications and operation manual are attached.
	+ The device has not been approved by FDA, and it is a new invention that has been studied in animals but not in humans. Related research reports as well as device specifications and operation manual are attached.
	+ **Others. Specify.** ................................................................................................................................

 b. Methods of using the medical device

* External use. Specify. .................................................................................................
* Internal use. Specify. .................................................................................................

16. **Details of examinations involved in the study** (Specify examined areas, length of time, and frequency)

a. Specify the examinations with invasive procedure. ........................... (For example, local or general radiation, general anesthetics, tube or camera insertion)

b. Specify the examinations with non-invasive procedure ........................ (For example x-ray, ECG, EEG, taking blood pressure)

17. **What are the specimens that will be taken out of the subjects’ body? What is the amount of the specimen, and how often will be the specimen taken?**

18. **Subjects’ Written or Verbal Informed Consent.** Make a check mark (√) in the box.

* + a. Written consent (Attach the informed consent form and the information sheet.)
	+ b. Verbal consent
	+ c. Initial verbal consent followed by written consent. (State additional reasons for the issues below and how the written consent will be later secured. Also attach the information sheet for the subjects or representatives.)
1. Does this study involve subjects under critical conditions? Why are these subjects recruited into the study while there are standard treatment procedures?
2. Reason for not being able to secure written consent
3. Does recruiting subjects under critical conditions into the study have a direct benefit for the subjects?
4. Reasons for not being able to conduct this study if permission for a verbal consent is refused.

19. **Explain the process of obtaining subject’s consent** :

 19.1) Who is the person who asks for consent? (Consider that the subjects give their consent without undue influence /coercion). .........................................................................................

 19.2) When are the subjects asked for consent? (Consider that the subjects have an opportunity to ask questions about research and adequate time before making decision) ..............................................................................................................................................................................

 19.3) Where does the process of consent take place? (Consider that the place provides privacy and keep the confidentiality of the subjects as well as convenience for the subjects asking questions about becoming a research subject). Please give details. ..............................................................................................................................................................................

20. **Does the research protocol make use of a standard handbook or guidance?**

 [ ] No [ ] Yes, please identify

 [ ] The handbook or guidance has been approved by a professional association or Royal college

 Please identify ……………………………………………... (please attach proof)

 [ ] The handbook or guidance has received permission to be used by the department/office where it is going to be used. Please identify ………………………………………………

 Name of the person in charge of the department/office

 ………………………………………………………………

 Signature …………………………………………………….

 [ ] The handbook or guidance has been approved by an expert or experts

 Name of expert …………………………….............................

 Signature........................................................

 Name of expert ……………………………........................

 Signature........................................................

 Name of expert ……………………………........................

 Signature........................................................

21. **Is this a multicenter study?** If so, please give name(s) of the researchers and participating organization/institution (in Thailand) ………………………………………………………………

Please give name(s) of sponsors such as pharmaceutical/chemical companies, *if applicable.*

22. **Details of the entire budget for the research project**

23. Affiliations of researchers with the companies supporting the research projects such as

* Shareholder of the supporting company. State number of shares held.
* Owner of medicine or medical device patent, or
* Receiving a consultant salary of ………………….baht per month
* Invited to be lecturer from the company, or supported for attending conferences abroad in the past year. Give details.........................................................................................................
* Others. Specify. .........................................................................................................................................
* No affiliation

24. **Do you have experience in ethics in conducting research studies?**

* The researcher and research team have attended the following training courses for ethics in research studies. Give individual details and proved proofs of attendance.

25. This research project expects

 a. to start collecting data in (month) ……., (year) ……, and finish in (month) …… (year) ……

 b. to spend a total of …………year(s) ……month(s)

I hereby certify that the above information is truthful, and the person filling in the information clearly understand every piece of the information given.

|  |  |
| --- | --- |
| Signature………………………………….………….…………… |  Signature ……………………….………….…………… |
| (……………………………….…………) |  (……………………………….……………) |
| Project AdvisorIn case the principal investigator is a student/ /resident |  Principal investigator |

 Signature ……………………….………….……………

 (……………………………….……………)

 Co-investigator

 Signature ……………………….………….……………

 (……………………………….……………)

 Co-investigator

 Signature ……………………….………….……………

 (……………………………….……………)

 Co-investigator

**This protocol has been approved by the affiliated organization.**

Signature ………………………………….………….……………

 (……………………………….……………)

 Chair, School of …………………………

Signature ………………………………….………….……………

 (……………………………….……………)

 Head, research department

Signature ………………………………….………….……………

 (……………………………….……………)

 Dean, Institute of……………………………………….

**AF/16-08/02.0**

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| **Human Research Ethics Committee**โลโก้มทสขาวดำ **Suranaree University of Technology** | **แบบขอรับการยกเว้นการขอความยินยอมจากอาสาสมัคร (Waiver of Informed Consent)** |
| 1 | ชื่อโครงการวิจัย |
| 2 | ชื่อหัวหน้าโครงการวิจัย |
| 3 | ชนิดของการยกเว้นการขอความยินยอมจากอาสาสมัคร โปรดเลือกตอบเฉพาะ 3.1 หรือ 3.2 ข้อใดข้อหนึ่งเท่านั้น |
| 3.1 | **ยกเว้นการลงนามเป็นลายลักษณ์อักษร** ในแบบยินยอมของอาสาสมัครบางคนหรือทั้งหมด (Waiver of documentation of consent) และโปรดแสดงเหตุผลในการขอยกเว้น |
| 1) การวิจัยมีความเสี่ยงต่ออาสาสมัครไม่มากเกินกว่าความเสี่ยงที่อาสาสมัครจะได้รับในการดำเนินกิจวัตร ประจำวัน เพราะ.....................................................................................................................และไม่เกี่ยวข้องการกระทำต่ออาสาสมัครที่จำเป็นต้องขอความยินยอมเป็นลายลักษณ์อักษร (เช่นหัตถการที่เกี่ยวข้องกับการตรวจวินิจฉัยและการรักษาเป็นต้น)(21 CFR 56.109(c); 45 CFR 46.117(c) (2)).  |
| 2) การลงนามเป็นลายลักษณ์อักษรในแบบยินยอมของอาสาสมัครเป็นข้อมูลเดียวที่เชื่อมโยงระหว่างตัวตน ของอาสาสมัครกับการวิจัย และความเสี่ยงหลักของการวิจัยทำให้อาสาสมัครตกอยู่ในภาวะอันตราย หากมีการเปิดเผยความลับของอาสาสมัคร เพราะ...............................................................(45 CFR 46.117(c)(1)).  |
| 3.2 | **ขอยกเว้นการขอความยินยอมจากอาสาสมัคร** (Waiver of Informed Consent) (45 CFR 46.116(d)). |
| 1) การวิจัยมีความเสี่ยงต่ออาสาสมัครไม่มากเกินกว่าความเสี่ยงที่อาสาสมัครจะได้รับในการดำเนินกิจวัตร ประจำวัน เพราะ..........................................................................................................................................  |
| 2) การยกเว้นการขอความยินยอมจากอาสาสมัครจะไม่ส่งผลกระทบต่อสิทธิและความเป็นอยู่ที่ดีของอาสาสมัคร เพราะ........................................................................................................................................ |
| 3) ผู้วิจัยไม่สามารถทำวิจัยได้หากไม่ยกเว้นการขอความยินยอมจากอาสาสมัคร เพราะ................................................................................................................................................... |
| 4) อาสาสมัครจะได้รับแจ้งเพิ่มเติมเกี่ยวกับการวิจัยหรือไม่ และได้รับข้อมูลอย่างไร............................................................................................................................................................. |

 หมายเหตุ : การขอยกเว้นการขอความยินยอมจากอาสาสมัครไม่สามารถกระทำได้หากเป็นโครงการวิจัย ที่เกี่ยวข้องยาหรือเครื่องมือแพทย์ที่อยู่ในระหว่างการวิจัยเพื่อขอขึ้นทะเบียนยาขององค์กรอาหารและยาของประเทศสหรัฐอเมริกา

ลงชื่อ.........................................

 (........................................)

 หัวหน้าโครงการวิจัย

วันที่...........................................

\*\*กรอกข้อมูลข้อ 3.1 เท่านั้น