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**Memorandum**

**Office of** ................................................................................................

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

**Subject** HREC-SUT Submission form for Clinical Trial / Experimental Research/ Biomedical Research

…………………………………………………………………………………………………………….

**To** Chair of Human Research Ethics Committee, Suranaree University of Technology

I, ............................................, of (Office/Faculty of Affiliation) ............................................. would like to submit a research proposal, entitled (............................................................) for approval of ethics in human research. I have submitted the following documents online via HREC-SUT’s Online Submission system (<https://ec.sut.ac.th>) for your considerations (Please select relevant items).

HREC-SUT’s Submission Form with version number and date specified (Please note that the information in the submission form should be consistent with that in the research proposal.)

Research proposal with version number and date specified.

Information Sheet for research subjects with version number and date specified.

Informed Consent Form for research subjects with version number and date specified.

Research tools with versions number and date specified (e.g., case record forms, investigator’s brochure, advertisement posters, etc.)

Copy of approved form for thesis / independent study (in case of graduate students).

Request permission for use of biological specimens from a hospital director, *if applicable*

Signed permission to use leftover specimens from Principal Investigator and Subjects’ Information Sheets from previous protocol, *if applicable*

Letter of permission request to use the data from the hospital director or from a person who has authority to grant permission for data use, *if applicable*

Signed permission from Principal Investigator to use data from previously approved research, *if applicable*

Signed permission to use biospecimens deposited in a biobank, *if applicable*

Certificate for Ethics in Human Research

Principal Investigator’s and Thesis Advisor’s Curriculum Vitae in English with signed and date

Conflict of Interest Form

Submission fee receipt

Thank you for your kind consideration.

|  |  |
| --- | --- |
| Signature……………………………….…………… | Signature …………………….………….… |
| (……………………………….…………) | (……………………………….……………) |
| Project Advisor (In case principal investigator is a student/resident)/Co-Investigator  Date............................................................... | Principal investigator  Date............................................................... |
| Signature……………………………….…………… | Signature …………………….………….… |
| (……………………………….…………) | (……………………………….……………) |
| Head of department  Date............................................................... | Head of research  Date............................................................... |
| Signature………………………………….……….......... | |
| (……………………………….…………………….) | |
| Dean of faculty | |

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**HREC-SUT’s Submission Form for   
Clinical Trial / Experimental Research / Biomedical Research/Health science**

**Please complete all the items as listed in the form. If any item is not applicable to the submitted project, write ‘not applicable’. Do not leave any item blank.**

**Please provide information regarding the following items.   
Mark X in the checkbox 🞎 that is applicable to the submitted project.**

|  |
| --- |
| **Part 1: General Information and Research Methodology** |

* 1. **Research Title in English**

……………………………………………………………………………………………………………

* 1. **Principal Investigator and affiliation in both Thai (if applicable) and English with mobile phone number and email address**

……………………………………………………………………………………………………………

* 1. **Co- investigator(s) and affiliation(s) in Thai and English**

(N.B: Please make sure that both the principal investigator and all co-investigators have been trained in the relevant Ethics in Human Research course (ICH-GCP), and a copy of a certificate of each investigator has been uploaded in the user profile of the online submission system [<https://ec.sut.ac.th>].)

……………………………………………………………………………………………………………

* 1. **Executive summary (Please specify the target disease or health problem, target population, knowledge gap, or rationale of the study, no more than 1 page in length)**

………………………………………………………………………………………………………..

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?

* 1. **Research Objective (s)** **(Please clearly state the objective (s) and ensure consistency with that in the research proposal.)**

………………………………………………………………………………………………………

* 1. **Benefits of this research project once the study is completed.**

……………………………………………………………………………………………………………

* 1. **Study design**

Randomized Controlled Trial

Please explain the method of randomization / subject allocation ……………

Please explain the method of allocation concealment.…………………………

Quasi-Experimental Study

Cohort Study

Case-Control Study

Cross-Sectional Study

Descriptive Study

Diagnostic Study

Other (Please specify ............................................)

* 1. Treatment method or practice used in the study.
     1. Explain the standard treatment for the target disease being studied ……………….…………………………
     2. Explain how the method used in the study is different from that in 1.8.1 …………………………………
     3. Specify the clinical practice guideline that will be used (if applicable) ..............................................
     4. Specify alternative method(s) for diagnosis or treatment of the target disease……………………………
  2. **Is a placebo used with the control group?**

|  |  |
| --- | --- |
|  | No. There is no control group in this study |
|  | No. No placebo used with the control group, and they are treated according to the standard practice |
|  | Yes. Placebo used with the control group. Please specify that the use of placebo does not violate the principles of ethics in human research in the Declaration of Helsinki since it is applicable to the following case: |
|  | No proven intervention exists for the target disease being investigated.  There is proven intervention for the target disease being investigated, but for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention. Please elaborate……………………................................................. |
| If placebo is used, explain the manufacturing or preparation of the placebo, and specify the manufacturer………………….………………….……………….……………….……… | |

* 1. **Does this study involve the test of herbal medicine or natural products?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes. |
|  | Please select only one of the following characteristics of the herbal medicine or natural products.  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 (purified or semi-purified extracts, and new derivatives) |
|  | **The following document (s) are submitted**:  The package insert/leaflet if the drug/food/food supplement has been approved by the Food and Drug Administration, please attach.  Document showing indications of use that is in accordance with alternative medicine: target disease, dosage, duration of treatment, 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  Proof whether it is generally consumed, a local food, or food that is registered as food for humans. if this is a study of food or food supplement, provide |

* 1. **Does this study involve the test of conventional drugs?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes. Please provide the following details:  Name of the drug(s): ………………………………………………  Route of administration, dosage, and frequency ………………………………  The drug is approved by the Food and Drug Administration (FDA), Ministry of Public Health for the treatment of..............  (Please attach the package insert.)  The drug has not been approved by FDA, but it has been studied in humans.  (Please attach the investigator’s brochure with an issue number and date.)  The drug has not been approved by FDA nor has it been studied in humans but is has been studied in animals.  (Please attach the research report or other related references.) |

* 1. **Does this study involve testing the efficacy or safety of a medical device?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes. Please fill out the medical device form AF/01-10/04.0 and attach it with this submission. |

* 1. **Does this study involve diagnostic tests, interventions, or procedures?**

|  |  |
| --- | --- |
|  | No |
|  | Yes. Please specify:  Computed tomography (CT), or other examinations with high levels of radiation.  External-beam radiation (Please specify: ……………………………………………….)  Anesthetics (Please specify: …………………………………………………………)  Tracheal intubation, nasogastric intubation, catheterization (Please specify: ……….)  Operation (Please specify ……………………………………………………………)  Other (Please specify: ……………………………………………………………….) |

* 1. **Are biospecimen collected from the subjects?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes. Please specify:  blood  urine  stool  tissue  other (Please specify: ……………………)  Please specify the method and frequency of the specimen collection……………………… |
| If the specimens are collected, will the specimens be kept after the study has been completed? | |
|  | No. |
|  | Yes. Please specify:  Storage place: ...........................  Duration of storage: ............  Name of the person in charge of the specimen: ..................  Contact number of person in charge: ............... |

**1.15 Research Procedure**

......................................................................................................................................................

**1.16 Data collection process**

......................................................................................................................................................

**17. Outcome measurement / Data Analysis**

……………………………………………………………....................................................

|  |
| --- |
| **Part 2: Population and Subjects** |

* 1. **Number of Subjects** **(Sample size)**

Number of subject groups: .......................................................

Number of subjects in each group: ...................................

...............................................................................................................................................................

* 1. **Sampling size determination (Please specify the method of sample size calculation. Provide the sample size formula with reference, if applicable):**

..............................................................................................................................................................

* 1. **Inclusion criteria:**

..............................................................................................................................................................

* 1. **Exclusion criteria:**

..............................................................................................................................................................

* 1. **Withdrawal of participant criteria**

(This refers to the indications for withdrawal of the intervention from an individual subject for the sake of the subject’s safety, e.g., severe side effects from the investigational drug or intervention)

|  |  |
| --- | --- |
|  | **No**. There are no withdrawal of participant criteria. |
|  | **Yes**. There are withdrawal of participant criteria as follows: |
|  | 1)……  2)…. |

* 1. **Early termination of study criteria**

(This refers to scenarios that will result in termination of the entire study prior to complete subject recruitment; i.e., the level of risks is higher than expected or the effectiveness of the drug investigated has been proved in an interim analysis.)

|  |  |
| --- | --- |
|  | **No**. There are no early termination of study criteria. |
|  | **Yes.** There are early termination of study criteria as follows: |
|  | 1)……  2)…. |

* 1. **Are healthy subjects included in the study?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes. |

* 1. **Are vulnerable subjects, which refer to those who cannot make critical decisions, included in the study? Please specify the measures for additional protection these vulnerable subjects.**

|  |  |  |
| --- | --- | --- |
|  | No. |  |
|  | Yes. Please specify | **Preventive measures** |
|  | subjects who cannot give consent by themselves:  infants and children  patients with intellectual disabilities  dementia patients | • Parents, guardians, or legally authorized representative give consent for the subjects (Please specify: ……………….)  • Other (Please specify: ........................) |
|  | subjects who cannot make critical decisions:  patients in critical condition  patients in a state of unconsciousness | • Parents, guardians, or legally authorized representative give consent for the subjects (Please specify: …………………….)  • Wait until the subjects recover from the critical condition and give consent by themselves......................  • Doctors or specialists, who are not the investigators, evaluate that patients are illegible to participating in the study………………………………………….  • Other (Please specify: ........................) |
|  | subjects cannot make decision by themselves:  psychiatric patients  patients with communication disabilities (e.g., the deft and illiterate patients)  dementia patients | • Parents, guardians, or legal representatives give consent for the subjects (Please specify: ………….….)  • Specialists, who are not the investigators, evaluate that decision making ability of the subjects prior to informed consent (Please specify: ……….)  • Interpreters or sign language interpreters help communicate with subjects (Please specify: ………………)  • Give subjects more time to read and understand the information sheet before deciding (Pease specify: ………………………….) |
|  | patients whose voluntariness may be diminished:  patients with chronic diseases  prisoners  alien laborers  subordinates  the socially disadvantaged.  pregnant women  people who cannot reveal their identities (e.g., illegals, or persons who do not wish to disclose their sexual orientation / gender identity)  school/university students in case that the investigators are teachers or lecturers of the students) | • The person who asks for consent is not the treating physician or one who has an influence over or ability to coerce the subjects |
|  | Other (Please specify: ...............................................................................) | |

If venerable subjects are included, please provide the following details to justify their involvement (If not, skip this item and proceed to item 2.9):

* + 1. Please explain how this research is responsive to the health needs or priorities of this group. ………………………………………………………………………………………………
    2. Please explain why this research cannot be carried out in a non-vulnerable group. ………………………………………………………………………………………………
    3. Please explain how this group stands to benefit from the knowledge, practices, or interventions that result from this research. …………………………………….…………………………………………………………
  1. **Risks (Please specify the risks and the preventive measures in minimizing the risks.)**

|  |  |  |
| --- | --- | --- |
|  | **RISK** | **Measures to minimize risk** |
|  | Physical risks. Please specify: …………………… |  |
|  | Psychological risks.Please specify: …………………… |  |
|  | Social risks. Please specify: …………………… |  |
|  | Economic risks. Please specify: …………………… |  |

* 1. **Who will pay for medical care in case of complications?**

|  |  |
| --- | --- |
|  | Subjects receive the treatment based on their medical care rights. (This is not applicable for healthy subjects.) |
|  | A research sponsor or the investigator is responsible for the medical expenses. |
|  | A health insurance policy is provided for the subjects.  (Please attach the insurance policy.) |
|  | Not applicable (There is no physical risk in this study.) |

* 1. **Benefits** (Please specify only the possible benefits that are not beyond the expectation.)

|  |  |
| --- | --- |
|  | Prospect of **DIRECT benefits** from participating in the study. Please specify:……………………  (N.B: Examples of direct benefits include recovery / alleviation from the disease) |
|  | Prospect of **INDIRECT benefits** from participating in the study. Please specify: ……………………  (N.B: Examples of Indirect benefits include comprehensive testing or close follow-up which may lead to a better treatment outcome.) |
|  | No prospect of benefits, but the findings from the study may provide a better understanding about the disease or can lead to a better treatment in the future. |

* 1. **How are subjects recruited?**

|  |  |
| --- | --- |
|  | Asking for cooperation from attending physicians to help identify potential subjects (Please specify: …………………………………….) |
|  | Recruitment poster (Please specify the location where the poster will be placed: …………………)  (N.B: Please attach the recruitment poster.) |
|  | Broadcasting via media, e.g., printed media or radio commercial (Please specify: ……………….…)  (N.B.: Please attach the script.) |
|  | Posting on social media or chat applications (Please specify: ………….…………………)  (N.B: This method is not recommended since posts on social media can be shared by other people who might revise the information of the original post which has been approved by the ethics committee. If the investigator selects this method, please explain how to prevent this problem) |
|  | Other (Please specify: ………………………………………………………………) |

* 1. **Are there any monetary payments / compensation / non-monetary reward / travel expenses for the subjects?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes.  monetary payment (Please specify the number of payments: ………… and the amount of each payment: ……………………. Baht.  non-monetary reward or a gift (Please specify the type of reward/gift and its monetary value……………………………) |

|  |
| --- |
| **Part 3: Informed Consent Process and Confidentiality** |

* 1. **Informed Consent Process**

|  |  |
| --- | --- |
|  | **written consent** (Please attach the information sheet and informed consent form.) |
|  | **Implied consent by action** (i.e., completing a self-response questionnaire and returning the questionnaire to the investigator anonymously) |
|  | **verbal consent** due to **both** of the following conditions being met (Please attach the information sheet.)   1. The study contains risk no greater than those encountered in daily life and does not involve treatments or procedures for which written consent from the subject is otherwise required (e.g., diagnostic examination and medical treatment  (Please explain the reasons: ………………………………………………………… 2. Signing the informed consent form is the only information that can link the identity of the subjects with the study, and the principal risk is harm resulting from a breach of confidentiality.  (Please explain the reasons: …………………………………………………………… |
|  | **Initial verbal consent followed by written consent** due all the following 4 conditions being met: (Please 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. Research in emergency patients or patients in critical condition. Please indicate why it is necessary to perform the research in these patients, especially when there is standard treatment……………………………………………………………………………… 2. Not being able to secure written consent immediately due to……………………… 3. Recruiting the subjects under critical conditions into the study can bring a direct benefit to the subjects. Please explain the reasons: …………………… 4. This study cannot be carried out without permission for a verbal consent due to ………………………………………………………………………………………… |
|  | **Waiver of informed consent** due to **all** of the following 4 conditions being met:   1. The study contains risks no greater than those the research subjects receive in their daily life (Please specify: .........................................................................) 2. Waiving the informed consent does not affect the subjects’ rights and well-being (Please specify: ........................................................................................) 3. The research study cannot be carried out if the informed consent is not waived.   (Please explain the reasons: ……………………………….......................)   1. The research subjects will be notified further about the study after they finish participating in the study.   (Please specify: .....................................................................................................) |

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

* + 1. Who is the person who asks for consent?..................................................................

(N.B: The person who asks for consent should not have an influence on the subject’s decision to participate, e.g., a treating physician should not be the person who asks for consent from his/her patients and a teacher/lecturer should not be the person who asks for consent from his/her students.)

* + 1. When are the subjects asked for consent?...............................................................................

(N.B.: Please specify the period of time or situation that informed consent will take place. Make sure that the subjects have ample opportunity to ask questions about participation and adequate time before deciding.)

* + 1. Where are the subjects asked for consent?.......................................................................

(N.B.**:** Please clearly state the place where informed consent takes place. It should be private without risk of confidentiality breach and convenient for the subjects to ask questions about participation.)

* 1. **How are privacy and confidentiality of the subjects protected during conducting the study and when presenting the findings?**Please specify: ………………………………………………………………………………………

|  |
| --- |
| **Part 4: Other Related Information** |

**4.1 Is this a multicenter study?**

|  |  |
| --- | --- |
|  | No. |
|  | Yes. Please specify:  Name of the main organization/institution in charge: ………………………………………  Name of the principal investigator of the main organization/institution in charge: ……………………  Name of all participating organizations/institutions   1. …………….. 2. …………….. 3. …………….. |

**4.2 Sponsors** (Please select the source of funding / grant.)

|  |  |
| --- | --- |
|  | Personal funding of the investigator |
|  | Suranaree University of Technology research grant (Please specify: ……….……………………..…………………………….) |
|  | Researchers grant from government sectors (Please specify: ……………………………………………….…) |
|  | Researchers grant from non-profit organizations (Please specify: …………………………………………….) |
|  | Researchers grant from private corporations / companies (Please specify: ……………………………) |

4**.3** **Research responsibilities of the principal investigator**

* + 1. The number of the on-going research projects the PI is in charge of …… projects.
    2. The number of the subjects under the PI’s care ………. cases
    3. How do you plan to manage these projects without causing risks to the subjects or your other obligations?
  1. **Conflict of interest**

|  |  |
| --- | --- |
|  | The principal investigator AND co-investigators do not have a conflict of interest in this study. |
|  | The principal investigator OR co-investigator(s) do have a conflict of interest in this study. Please give details.   1. Name of investigator who has the conflict of interest…………………………………………………… 2. Characteristics of conflicts of interest   Holding shares of the sponsoring company, please give the number of shares held.  Holding copyright or patent of the drug or medical device used in the study.  Receiving a monthly salary of ..................................baht for consultancy from the sponsoring company  Being invited to be a lecturer at the company or receiving support to attend a conference abroad in the past year, please give details. .............................................  Others, please give details………………………………………………………………………………….  How will the researcher handle the conflict of interest so that the well-being of subjects and accuracy of research data are not affected? Please specify ………………………………………………………………………… |

* 1. **This project  
     will proceed only after approval from the ethics committee,**it is expected to span a total period of……….year(s) ……….month(s)

**4.6 Contract**

1. The research team and I are named and have signed this document. The research will be conducted as specified in the research program approved by the Human Research Ethics Committee of Suranaree University of Technology. Informed consent was obtained from the research participants in accordance with the ethical guidelines for human research, as specified in the research project proposal form. The dignity, rights, and welfare of the research participants will be respected.

2. If it is necessary to modify the research project, I will notify the Ethics Committee and seek approval before implementing any changes. I will inform the participants of any modifications that may affect them and obtain their informed consent.

3. I will promptly report any adverse or unforeseen events that occur during the research, in accordance with the regulations of the Ethics Committee. I will make every effort to address and correct any adverse events that arise during the research.

4. The research team and I possess knowledge and understanding of the proposed research process at every stage. We can resolve problems or adverse events that may occur during the study, ensuring the safety and welfare of the research participants.

5. Upon completion of the research, I will provide a summary of the operations and notify the closure of the research project. If the research duration exceeds 1 year, I will report the project's progress and apply for a renewal of accreditation before the expiration of the current accreditation.

I hereby certify that the above statements are true, and I clearly understand their meaning in all respects. Furthermore, we have not contacted or collected data from any volunteers who are not part of this research project.

|  |  |
| --- | --- |
| Signature………………………………….……… | Signature ………………….…………… |
| (……………………………….…………) | (……………………………….……………) |
| Project Advisor  In 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……………………………………….