Research Proposal Involving Human Subjects for Researcher

Instructions ***(Please delete this part on your submitted copy.)***

To comply with research ethics in human subjects, please use this form as guidelines on preparation for a research proposal involving human subjects
by adjusting texts to be consistent with your proposal.

1. ***Bold front:*** *It is necessary information to be written in the proposal.*

2. ***Normal front:*** *It is information relevant to your research proposal. If any items don't apply to it, indicate them as "not applicable"*

3. ***Italic front:*** *It is suggested information for completing the proposal, which you shall delete it on your submitted copy*

1. Title of Proposal *(Indicate the title in Thai and English.)*

(Thai).....
.....

(English).....
.....

2. Name and address of principal investigator *(Indicate name, position, workplace, qualifications, telephone number, fax number and email address of principal investigator, and attach curriculum vitae of principal investigator as well as co-investigators)*

Principal investigator: **(Thai)**

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(English)

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School/College: **(Thai)**

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(English)

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Qualification:

.....
.....

Tel: ..... **E-mail:**

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3. Funding source:

(Specify the source and amount of fund. If you're applying for funding support, indicate as "waiting for approval of funding". If you use your own funding, indicate as "personal fund")

4. Background and significance of the research

(Describe magnitude and priority of the problems leading to the Research Proposal. Explain general information, situations or circumstances related to the research with reliable references and figures in order that the proposal will easily be considered.

5. Research objective(s)

(Describe an objective of the research clearly in order that the committee who considers the proposal can get what the research question is and how it will be answered. If there are several objectives, indicate the primary one and the secondary ones.

6. Research methodology

6.1 Subjects/ samples of the research

(Describe the subjects involved in your study and their residence)

6.1.1 Inclusion criteria

(Describe qualifications of the subjects or samples in consistent with the research design.)

6.1.2 Exclusion criteria

(Describe reasons why the samples are excluded from inclusion criteria as written in 6.1.1. For example, the participants have complications, discomfort to provide the information during the study, and unwillingness to participate in the study.)

6.1.3 Sample size determination

(Specify the number of samples used in the study together with its calculation. Investigators can use data about incidence, prevalence or between-group differences (insert reference number) from previous studies to determine an appropriate sample size, or they can consult with statisticians to adjust sample size in advance. In case of qualitative research, Investigators should estimate the proper number of the samples.)

6.2 Research setting

(Specify all research sites such as government agencies or provinces)

6.3 Intervention

6.3.1 Research design *(Specify the research design such as experimental research, quasi-experimental research, descriptive research, survey research, psychological research, etc.)*

6.3.2 Study procedures *(Describe steps clearly)*

-Drug trails *(Identify chemical name, trade name, category, dose, frequency, registration in Thailand and foreign country (Specify the country), clinical trial with case record form)*

- Questionnaires *(Describe the details about questionnaires such as the points of the question, the number of the questions, and how to answer the questions etc. Describe how to inspect the quality of research instruments such as validity and reliability. Please cite if a questionnaire of other researcher is used. Also, the investigator should indicate frequency and duration of the query.*

- Data from medical records, biopsy or samples left from testing

(Specify how to collect and record the data, how to use other equipment if any, how to get permission from the hospital, and how to access the information with attached case record form)

- Diagnosis and testing *(Describe whether some testing samples must be taken out of the bodies of the participants. If any, specify the amount, frequency, tools, steps and chemical used for the test.)*

6.4 Duration of the research

(identify the date of the research starting from.....until..... and the period of experiment or data collection from the first participant to the last one such as 6 months. This will start after the approval by Ethics Committee in Human Research, Walailak University.

7. Ethical Consideration

7.1 Reasons and necessity to conduct this research in human subjects *(Describe reasons why the research must be done with these people. Explain needs of studying in human subjects and being unable to conduct other research designs such as computer simulation models or animal testing.)*

7.2 Potential benefits to subjects from taking part in the research

(Describe the benefits for the participants and others after the study ends.)

If the participants don't gain direct benefits, it should be noted that 'this research is not directly beneficial to the participants'

7.3 Potential risks to subjects

7.3.1 Potential Risks and unexpected side effects

(Describe details of possible risks or discomforts during the study and data collection. The participants should be informed despite mild cases such as bruising and infection from blood drawing, or even spending a small amount of time answering questionnaires. The participants might have discomforts from interviews such as being disturbed, worried, sad, ashamed, or reluctant by the questions.)

7.3.2. Preventive and alleviation measures in case of any possible risks

(Describe prevention and alleviation available in the study. For example, the investigator will be careful and polite to the participants and will instantly stop when participants feel uncomfortable. The participants will be interviewed in private areas etc.

7.3.3 Side effects and prevention in case of medical or vaccine experiments

(Specify possible drug allergy or side effects which could cause danger, disability or death, together with their prevention.)

7.3.4 Compensation for negative effects of research participation

Describe the compensation or assistance In case of unexpected side effects in the wake of the research. For instance, the participants shall receive medical treatments of acceptable standard. The investigator will be in charge of medical expenses: …… (Specify the name of responsible investigator and his/her institute)

7.3.5 Responsible investigator of compensation for treatments in case of complications or unexpected side effects

(Specify the name of investigator and his/her institute, who will be in charge of compensation for treatment.)

7.3.6 Name of hands-on person or principal investigator and his/her contact number in case of problems related to the study

(Specify name and contact number of a hands-on person whom the participants can get in touch with round the clock.)

7.4 Evidences or information (references) concerning safety for subjects

7.5 Withdrawal criteria

(Specify criteria of withdrawal from the research. For example, after the collection of data, there is a chance to cause danger to the participants, a condition that the

research cannot be continued as planned, or a situation that the funding is canceled.)

7.6 method of inviting the participants for the research

(Describe methods of approaching the participants such as invitation via personal contact, announcement, advertisement on newspapers or website etc.)

7.7 Confidential process of data collection which information cannot be accessible by uninvolving people

(Describe how personal information is secured and how relevant information
is protected from illegal searching or self-identification. Ensure that the investigator must get permission before sharing pictures or names of the participants)

7.8 participant information sheet (if any)

(Indicate the number of attached document)

7.9 Informed consent form (if any)

(Indicate the number of attached document)

8. Names, qualifications and addresses of co-investigators (if any)

8.1 Name:
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Qualification:

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Address:

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Tel:

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E-mail address:

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8.2 Name:

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Address:

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Address:

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Tel:

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E-mail address:
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9. As principal investigator, I certify that I will strictly adhere to the information provided in the research proposal. In case of any revision, I will instantly notify Ethics Committee in Human Research for approval.

Signater: .....(Principal Investigator)
(.....)