**AF 03-07**

**แบบเสนอโครงการวิจัยเพื่อการพิจารณาจริยธรรมการวิจัยในมนุษย์ (ฉบับภาษาอังกฤษ)**

**(Research Protocol for Ethical Review)**

**REC Research Protocol Submission Form**

 **Silpakorn University**

**Instructions** Please complete **all items** in this form and fill in the information in accordance to your research proposal. Please do not delete any item, if any item does not apply to your research, indicate as “not applicable.”

1. Protocol title ……………………………………………………………………………………………………………………………..

2. Principal investigator name ………………………………………………………………………………….……………………

 Status **🌕** Faculty member of ……………………………………………..……………………………………………..

**🌕** Other staff, specify position and organization…………………………………………………...

**🌕** Student of …………………………………………………………………………………………………………...

Level **🌕**Bachelor program **🌕**Master program **🌕**Doctoral program

 Work address ……………………………………………………………………………………………………………………………

 Contact address ………………………………………………………………………………………………………….……………

 Telephone number (conveniently accessible) ………………………………………………………………………

 E-mail address: ………………………………………………………………………………………………………………………..…

3. Co-investigator name/ Advisor

(List all co-investigators: name, status, work address, contact address, telephone number, and e-mail address. If this is a thesis, list all advisor and co-advisor information).

 3.1 Co-investigator name/ Advisor ………………………………………………………………………………….……….

 Status **🌕** Faculty member of ……………………………………………..…………………………………...……

 **🌕** Other staff, specify position and organization…………………………………………..……

 **🌕** Student of ……………………………………………………………………………………………………..

Level **🌕**Bachelor program **🌕**Master program **🌕**Doctoral program

 Work address………………………………………………………………………………………………………………………

 Contact address …………………………………………………………………………………………………….…………

 Telephone number (conveniently accessible) ………………………………………………………………..

 E-mail address: …………………………………………………………………………………………………………..………

 3.2 Co-investigator name / Advisor …………………………………………………………………………….…………….

 Status **🌕** Faculty member of ……………………………………………..……………………………………..…

 **🌕** Other staff, specify position and organization………………………….……………………

 **🌕** Student of ……………………………………………………………………………………………..………..

Level **🌕**Bachelor program **🌕**Master program **🌕**Doctoral program

 Work address ……………………………………………………………………………………………………………………

 Contact address ………………………………………………………………………………………………………….…..

 Telephone number (conveniently accessible) ……………………………………………………………….

E-mail address: …………………… ………………………………………………………………………………………….…

4. Source of funding

 **🌕** Self-funding

 **🌕** Applying for funding, please specify ……………………………………………………………………..….

**🌕** Funding agency ......………………………

**🌕** Funding status……………………….………

 **🌕** **\*** Receive funding

**🌕** Inside Silpakorn University, please specify funding agency ......…………………

 **🌕** Outside Silpakorn University, please specify funding agency ......……………..

**🌕** Budget amount (Baht) ………………………………………………………………………………...

 **\* Please provide grant approval document when available.**

**\*\*\*All items below should be consistent with the submitted research protocol.\*\*\***

5. Background and significance of the research

6. Research objectives

7. Research methodology

7.1 Type of research

 ❏ Biomedical Research

❏ Clinical Research

 ❏ Social Behavioral Research

 ❏ Epidemiological Research

 ❏ Other Research Category, please specify……………………………………………….

 7.2 Research design

 ❏ Descriptive study

 ❏ Quasi – Experimental study

 ❏ Experimental study

 ❏ Qualitative study

 ❏ Action research/ Participatory action research

 ❏ Pilot study

 ❏ Other, please specify………………………………………………

 7.3 Research population

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

7.4 Vulnerable subjects

 ❏ Vulnerable subjects

❏ children ❏ mental disability

 ❏ chronic illness ❏ others, please specified…………..…………………………

 ❏ Non-vulnerable subjects

 ❏ Healthy volunteers

7.5 Eligibility criteria and subject allocation

 7.5.1. Inclusion criteria …………………………………………………………………………..……….…….

 7.5.2. Exclusion criteria ……………………………………………….........…………….…………………….

 7.5.3. Termination criteria ……………………………………………………….……………..…………….

 7.5.4. Subject allocation …………………………………………………………………………….………….

7.6 Sample size:

7.6.1 Sample size calculation: provide source of reference and calculation

 formula (if used) …………………………………………………………………..........………………

7.6.2 Estimated number of sample size ……………………………….....………………………..

7.7 In case of subject withdrawal, describe procedures:

 7.7.1 Subject management ………………………………………………………………………….………

 7.7.2 Data management ………………………………………………………………………...…….………

7.7.3 Subject replacement ……………………………………………………………………….…….……

8. Research setting (sites or locations the research will be conducted)

 **🌕** Single center, please specify ……………………………………………………………………………………

**🌕** Multicenter

**🌕** Only in Thailand (specify the number and name of the study sites)

🌕 List of site within Silpakorn University, please specify……………………………………………………………………………………………………………...………

 🌕 List of site outside Silpakorn University, please specify……………………………

 **🌕** Collaboration with overseas (specify the country, number and name of the study sites) ……………………………………………………………………………………………

 🌕List of site within Silpakorn University, please specify……………………..………

 🌕List of site outside Silpakorn University, please specify……………..….…….….

 🌕List of site outside Thailand, please specify………………………………….……

9. Duration of the research ……………………………………………………………………………………………….…………..

10. Research procedures

10.1 Recruitment Process

 - Indicate site/location where potentials subjects will be identified and recruited.

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

 - Describe the recruitment process *(who will provide study information, how potential subjects will be identified and recruited in details)*

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

 - Are there advertisements/materials that will be used to invited subjects? If any,

 indicate and provide these documents for a review. In case subjects are students or employees under influence of the investigator, advertisements should be used to ensure their voluntary participation.

10.2 Informed consent process Describe how the process will be structured and indicate the documents used.

 10.2.1 Recruitment process

 Describe Screening Process

 ……………………………………………………………….…

 ……………………………………………………………….….

 Describe Enrollment Process

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

 …………………………………………………………………..

 10.2.2 Person(s) who will conduct informed consents (please check)

**🌕** principal investigator

**🌕** co-investigator

**🌕** research assistant, please specify…………………………………………………

**🌕** others, please specify……………………………………………………………………

 10.2.3 Participant information sheet and informed consent form are written

 separately

 **🌕** Adult subject (age >18 years old) who can make his/her own decision

 🌕 Participant information sheet

 🌕 Informed consent form

 **🌕** Child subject between 13-17 years old

🌕 Participant information sheet for a child and parent/guardian

🌕 Informed consent form for a child and parent/guardian

 *Note: Child and parent/guardian sign together in the same document.*

**🌕** Child subject between 7-12 years old

🌕 Participant information sheet for parent/guardian

🌕 Informed consent form for parent/guardian

🌕 Assent form for a child

 **🌕** Child subject less than 7 years old (parent/guardian read and sign on

 behalf of the child).

🌕 Participant information sheet for parent/guardian

🌕 Informed consent form for parent/guardian

**🌕** Subject unable to consent (e.g. mental illness, mentally ill

 cognitively impaired)

🌕 Participant information sheet for parent/ guardian/ legally

 authorized representation

🌕 Informed consent form for parent/ guardian/ legally authorized representation

 10.2.4 Waiver of informed consent

 **🌕** Waive informed consent process:

 Specify the reason…………………………………………………………………..

 **🌕** Waive written consent. (Provide both participant information sheet and informed consent form, but a signature is not required).

 Specify the reason…………………………………………………………………..

10.3 Research procedures *Provide a detailed description of all research procedures, including what an individual subject will do or what will be performed, number of times, and the duration of an individual subject’s participation in the study .*………………………………………………

 10.4 Experimental process (if any) …………………………………………………………………………………

-describe intervention program/ efficacy and safety assessment

-describe experimental group procedure

-describe control /comparison group procedure

10.5 Data collection process …………………………………………………………………………………………

*-describe all data collection tools (case record form, questionnaires, interview questions, telephone script, etc.) and their psychometric properties.*

 *(Submit all data collection forms for review)*

11. Outcomes measurement (if any) …………………………………………………………………………………………

*Describe outcomes of the study in accordance with objectives of research study and sample size calculation.*

12. Data analysis

*Statistics or methods used for data analysis ………………………………………………………*

*………………………………………………………………………………………………………………………………….*

13. If there is specimen collection, specimen sent outside Silpakorn University

**🌕** No

**🌕** Yes

**🌕** Not applicable

14. Ethical Consideration

*Describe how participants are treated according to principles of human research ethics. For example, completely voluntary consent, no coercion or undue influence, speaking in a respectful manner, measures used to protect subject’s right, methods to prevent adverse effects.*

14.1 Describe reasons and necessity to conduct this research in human

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

14.2 Describe potential benefits to subjects from taking part in the research, benefits to society or others and/or benefits to subjects after the study ends (if any)

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

 14.3 Potential risks to subjects

14.3.1 Are there other research studies similar to this study? Any adverse event(s) found in previous research studies? Describe details, probability, and magnitude of adverse effects. ………………………………………………………………………………………….…………………………

14.3.2 Describe measures to prevent and minimize adverse effects.

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

14.3.3 Indicate name of persons responsible for cost of care incurred in case of adverse events related to the study.

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

14.3.4 Indicate name of contact persons or physician and 24 hour-telephone number in case of adverse events related to the study.

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

14.3.5 For a clinical research, describe how the investigator informs physician or physician in charge of care regarding patient’s participation in the study. ……………………………………………………………………………………………………..............…..

14.3.6 Compensation for adverse effects from research participation

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

 14.4 Payment and reimbursement

**🌕** Payment for participation

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

**🌕** Reimbursement for participation (e.g. laboratory test, transportation)

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

 14.5 Evidences or information (references) concerning safety and/or benefits for

 subjects (provide a list of all references in proper format). ……………………………….

14.6 Measures to protect confidentiality and safeguard subject’s personal data

 **🌕** Use of code instead of name/ individual identifiers in data record forms

 **🌕** Data will be recorded as 🌕 photograph 🌕 video 🌕 audio

**🌕** None of data will be recorded as the above medias/forms

If the above methods of data record will be used, indicate individual who will have access to the data, how long the data will be stored and how to destroy.

15. Expected Number of Publications and Tentative Titles

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

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

16. Documents submitted with the research submission form include:

 **🌕** Research submission form: 1 original copy, 3 photocopies, and an electronic file

 **🌕** Research protocol/proposal: 4 copies and an electronic file

 **🌕** Participant information sheet: 13 copies and an electronic file

 **🌕** Informed consent form: 13 copies and an electronic file

 **🌕** Principal investigator’s curriculum vitae: 4 copies

**🌕** Letter of commitment for research conduct after REC approval: 1 original copy and 3 photocopies

**🌕** Data collection tools such as questionnaire, interview questions/guide, observation forms /guide, etc.: 4 copies and an electronic file

**🌕** Case report form or case record form: 4 copies

**🌕** Letter of request for permission for data collection from an authorized person at the research site: 4 copies

**🌕**Letter of request for permission to use patient’s medical record (if any research data will be collected from medical records): 4 copies

**🌕** Proof of REC submission fee or proof of fee waiver: 1 original copy

**🌕** Advertisements/ materials for research study: 4 copies

**🌕** Materials given to subjects (e.g. brochure, booklet, CD, pictures), specify: 4 copies

**🌕** In case of submission the research protocol for approval from the REC of research setting, a certificate of approval, participant information sheet, and consent form from such REC are required.

**🌕** If principle investigator is a student, please submit the following:

- Document stated the result of thesis proposal defense from Faculty of Graduate

 Studies (GR. 33): 4 copies

- Curriculum vitae of thesis major advisor: 4 copies

 - Certificate of human subject protection training of the principle investigator: 4 copies

 - Letter of request for permission for data collection from an authorized person at the research site (GR.28): 4 copies

17. Contract

 1. As the principle investigator and co-investigators of this research, I and research team members, whose names and signatures appear on this document, will conduct the research according to the research protocol approved by the REC-SU. I and research team members will comply with principles of human research ethics in obtaining consent with respect to the right and welfare of subjects as priority.

2. If research protocol amendment is needed, I will inform REC-SU and acquire approval prior to continuation. If changes made to the study affect research subjects, I will inform about the changes and re-consent the subjects.

3. I will report all adverse events/unexpected events that occur during the study period to comply with REC regulations and time frame for notification. I will provide assistance to the best of my ability.

4. I and research team members have knowledge and understanding in every step of the proposed protocol and have ability in resolving or handling adverse events that may occur during the study period

 Signature .............................. Principal Investigator Signature….…......................... Co-investigator name/ Advisor (all members)

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

 Date……/……………/....…........ Date….../…………..…/…….........

18. Acknowledged by

**🌕** Head of Department Signature...........................................

**🌕** Direct superior authorized personnel (................................................)

**🌕** Thesis major advisor Date……/……………/....…...........