NU-NRE

Naresuan University Network Research Ethics

Research Ethical Application (Human Material Study)

Protocol title (TH)	Click or tap here to enter text.
Protocol title (ENG)	Click or tap here to enter text.
Sponsor	Click or tap here to enter text.
Has this research been reviewed and approved by any other institution's research ethics committee?	Choose an item.
- If you have been considered by other institutions' research ethics committees, please specify.	Click or tap here to enter text.

----------Section A - Investigators----------

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1. Principal Investigator	
Name - Surname	Click or tap here to enter text.
Department	Click or tap here to enter text.
Faculty	Choose an item.
Expertise	Click or tap here to enter text.
Research Responsibility	Click or tap here to enter text.
2. Co-Investigator (if applicable)	
Name - Surname	Click or tap here to enter text.
Department	Click or tap here to enter text.
Faculty	Choose an item.
Expertise	Click or tap here to enter text.
Research Responsibility	Click or tap here to enter text.

3. Number of Research Assistants	Choose an item.	people	If applicable, please specify names and roles/responsibilities.

Name - Surname	1. Click or tap here to enter text. Roles / Responsibilities Click or tap here to enter text.
Human Research Ethic Training	Click or tap here to enter text.

----------Section B - Scientific Merit----------

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1. Rationale and Background (please specify references)

Click or tap here to enter text.

2. Literature Review

Click or tap here to enter text.

3. Has this research been conducted before? Choose an item.

If this research has been conducted before, why must the study be repeated? Click or tap here to enter text.

4. Research Questions/Objectives/Hypothesis/Delimitation

- Research Questions (If yes, please specify)

Click or tap here to enter text.

- Objectives

Click or tap here to enter text.

- Hypothesis (If yes, please specify)

Click or tap here to enter text.

- Delimitation

Click or tap here to enter text.

5. Keywords (specify 3 – 5 words)

Thai	Click or tap here to enter text.
English	Click or tap here to enter text.

----------Section C - Research Design, Population and Sample----------

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1. Type/Name of Human Material	Click or tap here to enter text.
Source of Human Material	Choose an item. Owner of the Material is Click or tap here to enter text.
2. Requesting Permission from the Owner of Human Material	Choose an item.
Process of Requesting Permission	Click or tap here to enter text.
3. Number of Samples	Choose an item. Specify the number if applicable Click or tap here to enter text.
4. Quantity/Volume of Samples	Choose an item. Specify the quantity/volume if applicable Click or tap here to enter text.
5. Number of Study Sites	Choose an item.
Study Sites	Click or tap here to enter text.

----------Section D - Selection Criteria----------

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1. Inclusion Criteria

Refers to the criteria that define the characteristics of research samples to be included in the study.

1. Click or tap here to enter text.
2. Click or tap here to enter text.

2. Exclusion Criteria

Refers to criteria that define the characteristics of the sample, where inclusion in the study may pose potential risks.

1. Click or tap here to enter text.
2. Click or tap here to enter text.

----------Section E - Data Collection and Analysis----------

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1. Steps/Method for Experimentation and Data Collection

Click or tap here to enter text.

2. Data collection tools Choose an item.

1. Choose an item.
   Detail Click or tap here to enter text.
2. Choose an item.
   Detail Click or tap here to enter text.

3. Scientific Instruments Choose an item.

Click or tap here to enter text.
Click or tap here to enter text.

4. Outcomes

Click or tap here to enter text.

5. Data Analysis and Statistics

Click or tap here to enter text.

----------Section F - Storage and Future Use of Unused Samples----------

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Storage of Biological Samples for Future Research Choose an item.

- Details of the biological samples collected for future research Click or tap here to enter text.
- Storage location: Click or tap here to enter text. Duration of preservation: Click or tap here to enter text. years
- Scope of future research using these biological samples: Click or tap here to enter text.
- Sample Collection Process: Click or tap here to enter text.
- Sample Destruction Process: Click or tap here to enter text.

----------Section G - Ethical Consideration----------

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1. Specify how the results of this research study will be beneficial.

Click or tap here to enter text.

2. Describe whether the data collection process involves gathering private information and, if so, explain the investigator's procedures for ensuring participant anonymity.

Click or tap here to enter text.

3. Describe where the research data will be stored, how it will be stored, who will have access, how long it will be retained, and the method of data destruction (Confidentiality).

Click or tap here to enter text.

4. Explain how the research results will impact the community. Additionally, describe any preventive measures the investigator has to manage potential impacts (if applicable).

Click or tap here to enter text.

5. Explain the reporting, presentation, and dissemination of research results, including whether identification details that could reveal identity will be included, and if so, describe the process for confirming consent for identity disclosure before publication.

Click or tap here to enter text.

----------Section H - Research Activities and Timeline----------

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Duration of Study Period is from the date of …. month … year… until the date of …. month … year ….

Activities	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
1. Click or tap here to enter text.												
2. Click or tap here to enter text.												
3. Click or tap here to enter text.												
4. Click or tap here to enter text.												
5. Click or tap here to enter text.												

----------Section I - References----------

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1. Click or tap here to enter text.
2. Click or tap here to enter text.
3. Click or tap here to enter text.
4. Click or tap here to enter text.
5. Click or tap here to enter text.

----------Section J - Signature and Agreement----------

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Investigator's Responsibility

- The investigator will not conduct any research activities involving participants before receiving protocol approval from NU-IRB.
- The investigator will not engage in any research activities with participants before obtaining an NU-IRB approval letter and consent from the participants (if applicable).
- The investigator will provide appropriate training for all team members to adhere to Good Clinical Practice (GCP) or fundamental principles of human subject protection in research (HSP).
- In case of any changes to the research study, the investigator must submit an amendment report for review and approval.
- If a serious adverse event (SAE) occurs, the investigator will immediately report it to NU-IRB.
- If privacy breaches or confidentiality disclosures are identified, the investigator must promptly report them to NU-IRB.

- In the event of non-compliance or deviations from the research study protocol, the investigator must submit a Non-compliance/Deviation Report to NU-IRB immediately.
- The investigator is required to submit progress reports and request certification renewal within 30 days before the expiration date (only for expedited and full board-reviewed research studies).
- Upon completion of the research study, the investigator must submit a Final Report (applies to exemption review cases specified in the approval letter, and all expedited and full board-reviewed research studies).
- If the research study is terminated before the scheduled completion, the investigator must submit a Termination Report.

"I will follow the FERCIT (Forum of Ethic Review Committee in Thailand) ethical guidelines for research on human subjects in Thailand B.E. 2550, Declaration of Helsinki, Belmont Report, The National and International Ethical Guidelines for Biomedical Research Involving Human Subjects of CIOMS (The Council for International Organizations of Medical Sciences), the WHO (World Health Organization) Guidelines for Good Clinical Practice; WHO-GCP, ICH (The International Conference on Harmonization) Guidelines for Good Clinical Practice; ICH-GCP, and NU-IRB (Naresuan University Institutional Review Board) Guidelines"

Principal Investigator

(……)

Date Click or tap to enter the date

Co-Investigator

(……)

Date Click or tap to enter the date

Co-Investigator

(……)

Date Click or tap to enter the date

Co-Investigator Date Click or tap to enter the date

(.....)

Co-Investigator Date Click or tap to enter the date

(.....)

Note: Investigators are required to complete all sections of the form

ที่อยู่ สำนักงานคณะกรรมการจริยธรรมการวิจัยในมนุษย์เครือข่ายมหาวิทยาลัยนเรศวร	
กลุ่ม 4	กองการวิจัยและนวัตกรรม งานจัดการมาตรฐานและเครือข่าย คณะกรรมการจริยธรรมการวิจัยในมนุษย์ ชั้น 4 อาคารมหาธรรมราชา มหาวิทยาลัยนเรศวร เลขที่ 99 หมู่ 9 ตำบลท่าโพธิ์ อำเภอเมืองพิษณุโลก จังหวัดพิษณุโลก 65000
โทร. 055-968 640 อีเมล nu-nrec@nu.ac.th	

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