Institutional Review Board Naresuan University	Research Ethical Application (Non-Intervention 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----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

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

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

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

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----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

***If the study involves multiple phases, separate the details for each phase in Section C – Section I. (Example)**

1. Research Design	Choose an item.		
2. Number of Study sites	Choose an item.		
Study site	Click or tap here to enter text.		
3. Research Population			
Population (Please specify)	Click or tap here to enter text.		
Total Population	Click or tap here to enter text.		
Indicate how you calculate the research population			
Click or tap here to enter text.			
4. Participant Group			
Number of Participant Group	Choose an item.	Group	
• Group 1	Choose an item.	Total Click or tap here to enter text.	people
Age Range	Choose an item.	Ability to speak, listen, read, and write	Choose an item.
• Group 2	Choose an item.	Total Click or tap here to enter text.	people
Age Range	Choose an item.	Ability to speak, listen, read, and write	Choose an item.
Sample size determination	Choose an item.		
Selection procedures and random sampling or distribution techniques	Choose an item.		
Click or tap here to enter text.			
Details of the sample calculation	Choose an item.		

Click or tap here to enter text.

----------Section D - Recruitment and Informed Consent Process----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

1. Does the research study involve direct contact with the participants? Choose an item.	
2. Details for Participant Group 1	
2.1 Initial Contact with Potential Participants	Choose an item.
• Channel of Contacting Potential Participants	Channel 1 Choose an item. Channel 2 Choose an item. Channel 3 Choose an item.
• Location for Contacting Potential Participants	Location 1 Choose an item. Location 2 Choose an item.
*Please specify the channel used and provide details when contacting potential participants via online channels Click or tap here to enter text.	
• Person(s) responsible for contacting potential participants	Choose an item.
2.2 Process of Informed Consent	Choose an item.
• Consent Process	Choose an item.
*If the investigators choose a consent process that is not written consent, please state the reasons.	Click or tap here to enter text.
• Person(s) who need to request consent	Choose an item.

• Person(s) responsible for providing research information to participants	Choose an item.
• Person(s) responsible for obtaining consent from participants	Choose an item.
- Does the investigator or team have a power relationship with the participants? For example, teacher-student, doctor-patient, etc.	Choose an item. If yes, please provide additional details on the process that will ensure the consent process for participants is free from any coercion, intimidation, or undue influence, both directly and indirectly. Click or tap here to enter text.
• Location of Consent Request	Choose an item.
2.3 Compensation for participants' travel expenses and time loss.	Choose an item.
• Indicate the compensation (Baht)	Number of times: Click or tap here to enter text. times Amount per time: Click or tap here to enter text. Baht Total amount: Click or tap here to enter text. Baht
• Souvenir (Specify the type of souvenir or any other items to be given to participants)	Click or tap here to enter text.
3. Details for Participant Group 2 (If there is only one participant group, remove item 3)	
3.1 Initial Contact with Potential Participants	Choose an item.

• Channel of Contacting Potential Participants	Channel 1 Choose an item. Channel 2 Choose an item. Channel 3 Choose an item.
• Location for Contacting Potential Participants	Location 1 Choose an item. Location 2 Choose an item.
*Please specify the channel used and provide details when contacting potential participants via online channels Click or tap here to enter text.	
• Person(s) responsible for contacting potential participants	Choose an item.
3.2 Process of Informed Consent	Choose an item.
• Consent Process	Choose an item.
*If the investigators choose a consent process that is not written consent, please state the reasons.	Click or tap here to enter text.
• Person(s) who need to request consent	Choose an item.
• Person(s) responsible for providing research information to participants	Choose an item.
• Person(s) responsible for obtaining consent from participants	Choose an item.
- Does the investigator or team have a power relationship with the participants? For	Choose an item. If yes, please provide additional details on the process that will ensure the consent process for participants is free

example, teacher-student, doctor-patient, etc. • Location of Consent Request	from any coercion, intimidation, or undue influence, both directly and indirectly. Click or tap here to enter text. Choose an item.
3.3 Compensation for participants' travel expenses and time loss.	Choose an item.
• Indicate the compensation (Baht)	Number of times: Click or tap here to enter text. times Amount per time: Click or tap here to enter text. Baht Total amount: Click or tap here to enter text. Baht
• Souvenir (Specify the type of souvenir or any other items to be given to participants)	Click or tap here to enter text.

The investigator will provide comprehensive and sufficient information about the research study, allowing participants to consider and decide to participate willingly, without using any coercion, intimidation, or inducement. The investigator will allow participants sufficient time to understand the research study information before deciding to join. Participation or non-participation in the research study will not affect Choose an item. of the participant.

----------Section E - Selection Criteria----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

1. Inclusion Criteria

Refers to the standards that define the qualifications of potential participants who are eligible to enter the study, ensuring selection without bias or coercion.

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

2. Exclusion Criteria

Refers to the standards that define characteristics of individuals who should not participate in the study due to increased risks or potential harm compared to the general population or other participants.

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

----------Section F - Screening Procedure----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

Screening Procedure of research participants

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

***Note:** Consent must be obtained from potential participants before starting the screening process, as screening is considered part of the research procedure.

----------Section G - Participant Withdrawal----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

1. Withdrawal Criteria

Withdrawal criteria specify the conditions under which a participant must be removed from a research study. These criteria are established to protect participant safety and typically include:

- The occurrence of serious adverse events related to the research
- Development of conditions that could put the participant at increased risk
- Significant protocol deviations that may compromise participant safety

- At the investigator's discretion if they determine continued participation poses an unacceptable risk

At the participant's request to withdraw from the study

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

2. The process after withdrawal of participants from the research (If no action is taken, specify 'No action taken')

Click or tap here to enter text.

3. How will the data from withdrawn participants be handled? Will their data be excluded from analysis or analyzed together with the complete research dataset?

Click or tap here to enter text.

----------Section H - Study Termination----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

Termination Criteria

Refer to predetermined conditions that specify when a research study must be terminated if participants experience danger or serious harm as a result of their participation.

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

***Note: Serious Adverse Event (SAE)** is an adverse event that results in one of the following events;

- Death
- Life-threatening
- In-patient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- A congenital anomaly/birth defect occurred

----------Section I - Data Collection and Analysis----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

1. Steps/Procedure for Data Collection/Handling with Participants (Please write details for each appointment separately)	
Click or tap here to enter text.	
2. Data collection tools	Choose an item.
1. Choose an item. Detail 2. Choose an item. Detail	
3. Research tools and Validity/reliability	Choose an item.
The qualification of experts	1. Click or tap here to enter text. 2. Click or tap here to enter text. 3. Click or tap here to enter text.
Number of experts	Choose an item.
Method for testing tool's quality	Click or tap here to enter text.
Details of the Method for testing the tool's quality	Click or tap here to enter text.
Acceptance Criteria for Tools (IOC with references)	Click or tap here to enter text.
4. Tool Testing	Choose an item.
4.1 Research Population	
Population (Please specify)	Click or tap here to enter text.
Total Population	Click or tap here to enter text.
• Indicate how you calculate the research population	
Click or tap here to enter text.	
• Group 2	Choose an item. Total Click or tap here to enter text. People

Age Range	Choose an item.
Ability to speak, listen, read, and write	Choose an item.
Sample size determination	Choose an item.
Selection procedures and random sampling or distribution techniques	Choose an item.
Click or tap here to enter text.	
Details of the sample calculation	Choose an item.
Click or tap here to enter text.	
4.2 Initial Contact with Potential Participants	Choose an item.
• Channel of Contacting Potential Participants	Channel 1 Choose an item. Channel 2 Choose an item. Channel 3 Choose an item.
• Location for Contacting Potential Participants	Location 1 Choose an item. Location 2 Choose an item.
*Please specify the channel used and provide details when contacting potential participants via online channels Click or tap here to enter text.	
• Person(s) responsible for contacting potential participants	Choose an item.
4.3 Process of Informed Consent	Choose an item.
• Consent Process	Choose an item.
*If the investigators choose a consent process that is not written consent, please state the reasons.	Click or tap here to enter text.

• Person(s) who need to request consent	Choose an item.
• Person(s) responsible for providing research information to participants	Choose an item.
• Person(s) responsible for obtaining consent from participants	Choose an item.
- Does the investigator or team have a power relationship with the participants? For example, teacher-student, doctor-patient, etc.	Choose an item. If yes, please provide additional details on the process that will ensure the consent process for participants is free from any coercion, intimidation, or undue influence, both directly and indirectly. Click or tap here to enter text.
• Location of Consent Request	Choose an item.
4.4 Compensation for participants' travel expenses and time loss.	Choose an item.
• Indicate the compensation (Baht)	Number of times: Click or tap here to enter text. times Amount per time: Click or tap here to enter text. Baht Total amount: Click or tap here to enter text. Baht
• Souvenir (Specify the type of souvenir or any other items to be given to participants)	Click or tap here to enter text.
4.5 Inclusion Criteria	

Refers to the standards that define the qualifications of potential participants who are eligible to enter the study, ensuring selection without bias or coercion.

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

4.6 Exclusion Criteria

Refers to the standards that define characteristics of individuals who should not participate in the study due to increased risks or potential harm compared to the general population or other participants.

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

4.7 Steps/Procedure for Data Collection and Participant Interaction with the Try-Out Group

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

***Note:** Consent must be obtained from potential participants before starting the screening process, as screening is considered part of the research procedure.

4.8 Withdrawal Criteria

Withdrawal criteria specify the conditions under which a participant must be removed from a research study. These criteria are established to protect participant safety and typically include:

- The occurrence of serious adverse events related to the research
- Development of conditions that could put the participant at increased risk
- Significant protocol deviations that may compromise participant safety
- At the investigator's discretion if they determine continued participation poses an unacceptable risk

At the participant's request to withdraw from the study

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

4.8.1 The process after withdrawal of participants from the research (If no action is taken, specify 'No action taken')
Click or tap here to enter text.
4.8.2 How will the data from withdrawn participants be handled? Will their data be excluded from analysis or analyzed together with the complete research dataset?
Click or tap here to enter text.
5. Scientific Instruments Choose an item.
Click or tap here to enter text.
Click or tap here to enter text.
6. Outcomes
Click or tap here to enter text.
7. Data Analysis and Statistics
Click or tap here to enter text.

----------Section J - Ethical Consideration----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

1. Specify the process of providing information and obtaining consent, demonstrating independence in the decision to participate in the research study. Also, explain the investigator's principles for selecting methods to record consent for research participation.
Click or tap here to enter text.
2. Specify the reasons for choosing the research approach with vulnerable groups (such as those under 20 years old, the elderly, pregnant women, prisoners, patients, those under legal guardianship, etc.) or specific populations (if applicable).
Click or tap here to enter text.
3. Specify whether participation in the research study will directly benefit the participants and whether there are anticipated indirect benefits for the community or the public.
Click or tap here to enter text.
4. Specify any potential risks or concerns that participants may face by participating in this research study.

Click or tap here to enter text.

5. Specify how the investigator will implement measures to ensure participant safety.

Click or tap here to enter text.

6. Describe how the investigator will implement measures to ensure participant well-being if any unexpected incidents occur.

Click or tap here to enter text.

7. Specify how the investigator/sponsor will take responsibility for unexpected incidents or harm to participants.

Click or tap here to enter text.

8. Explain the principles for determining the "Inclusion Criteria" (characteristics of research participants) to ensure equal opportunities for research participation.

Click or tap here to enter text.

9. Explain the principles for determining the "Exclusion Criteria", considering safety and the prevention of potential harm to participants.

Click or tap here to enter text.

10. Explain whether the allocation to each group is equal and how it is conducted (in cases where the research study involves dividing participants into control and trial groups) (if applicable).

Click or tap here to enter text.

11. Explain how participant privacy will be maintained during the consent process and research data collection.

Click or tap here to enter text.

12. 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.

13. 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.

14. 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.

15. Explain the reporting, presentation, and dissemination of research results, including whether identification details that could reveal participant 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 K - Research Activities and Timeline----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

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 L - References----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

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 M - Signature and Agreement----------

Back to Section A Section B Section C Section D Section E Section F Section G Section H Section I Section J Section K Section L Section M

Investigator's Responsibility

- The investigator will not conduct any research activities involving participants before receiving protocol approval from NU-IRB.
- The investigator will not conduct any research activities with participants before obtaining consent from the volunteers (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

(……)

For Undergraduated and Graduated Students

As the faculty advisor, I confirm that I have reviewed and approved this research protocol.

Advisor (……)	Date Click or tap to enter the date

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

Address: Naresuan University Institutional Review Board				
Panel 1	Health Sciences			4th Floor Mahathammaracha Building, Division of Research and Innovation, Naresuan University, Phitsanulok, 65000 Thailand
Tel.	055-968752	E-mail	nu-irb-board1@nu.ac.th	
Panel 2	Technology and Social Sciences and Humanities			
Tel.	055-968642	E-mail	nu-irb-board2@nu.ac.th	
Panel 3	Medical Sciences			3rd Floor Sirindhorn Building, Naresuan University Hospital, Phitsanulok, 65000 Thailand
Tel.	055-965296	E-mail	nu-irb-board3@nu.ac.th	