

Institutional Review Board Naresuan University

Research Ethical
Application
(Non-Intervention Study)

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

-----Section A -

Investigators----

Back to Section A Section B Section C Section D Section E Section F Section G Section H 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.

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3. Number of Research	Choose an	peop	If applicable, please	
Assistants	item.	le	specify names and	
			roles/responsibilities.	
Name - Surname 1. Click or tap her			re to enter text. Roles /	
	Responsibilities Click or tap here to enter text.			
Human Research Ethic	Click or tap here to enter text.			
Training				
Section B - Scientific				

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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.

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

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

			on i. (<u>Laampie)</u>		
1. Research D	esign	Choose an i	Choose an item.		
2. Number of Study sites		Choose an item.			
Study site		Click or tap	here to enter text.		
3. Research P	opulation				
Population	Click or tap	here to enter	text.		
(Please					
specify)					
Total	Click or tap	here to enter	text.		
Population					
Indicate how y	ou calculate	the research	population		
Click or tap he		xt.			
4. Participant	Group				
Number of Pa	rticipant	Choose an	Group		
Group		item.			
• Group 1	Choose an i	tem.	Total Click or tap here to	people	
			enter text.		
Age Choose an i		tem.	Ability to speak, listen,	Choose	
Range			read, and write	an item.	
• Group 2	Choose an i	tem.	Total Click or tap here to	people	
_			enter text.	01	
Age	Choose an i	tem.	Ability to speak, listen,	Choose	
Range			read, and write	an item.	
Sample size		Choose an item.			
determination					
Selection procedures and		Choose an item.			
random sampling or					
distribution techniques					
Click or tap here to enter tex			tom		
Details of the sample		Choose an i	leiii.		
calculation					
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-Section D - Recruitment and Informed **Consent Process----**

Back to Section A Section B Section C Section D Section E Section F Section B Section B Section B Section K 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	Choose an item.			
Participants				
 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.			
• •	used and provide details when contacting annels Click or tap here to enter text.			
 Person(s) responsible for contacting potential 	Choose an item.			
participants				
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. • Person(s) who need to	Click or tap here to enter text.			
request consent	Choose an item.			

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 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.	

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IF 01/6.0 NU-IRB# Channel of Contacting Channel 1 Choose an item. **Potential Participants** Channel 2 Choose an item. Channel 3 Choose an item. Location 1 Choose an item. Location for Contacting Potential Participants 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 Choose an item. contacting potential participants 3.2 Process of Informed Choose an item. Consent Choose an item. Consent Process *If the investigators choose a Click or tap here to enter text. consent process that is not written consent, please state the reasons. Person(s) who need to Choose an item. 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 Does the investigator or Choose an item. If yes, please provide additional details team have a power on the process that will ensure the relationship with the consent process for participants is free participants? For

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NU-IRB#example, teacher-student, doctor-patient, etc.	IF 01/6.0 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.
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 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.

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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 channot participate in the study due to incre compared to the general population or	ased risks or potential harm
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 Sec	tion F Section G Section H Section I Section J Section K Section Etion M
Screening Procedure of research partic	cipants
1. Click or tap here to enter text.	
2. Click or tap here to enter text.	
*Note: Consent must be obtained from the screening process, as screening is procedure.	
S	ection G - Participant
Withdrawal	
Back to Section A Section B Section C Section D Section E Sec	tion F Section G Section H Section I Section J Section K Section Etion M
1. Withdrawal Criteria	
Withdrawal criteria specify the condition	ns under which a participant must be
removed from a research study. These	·
participant safety and typically include:	
The occurrence of serious advers	
 Development of conditions that corrisk 	ould put the participant at increased
 Significant protocol deviations that 	t may compromise participant safety

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 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-----

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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

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NU-IRB#		IF 01/6.0 ection I - Data Collection and			
Analysis					
Back to Section A Section		ection E Section F Section G Section H Section I Section J Section K Section			
1. Steps/Proce	L Section M 1. Steps/Procedure for Data Collection/Handling with Participants (Please				
write details fo	r each appointme	ent separately)			
Click or tap h	nere to enter text				
2. Data collecti	ion tools	Choose an item.			
1. Choose a	n item.	al Revis			
Detail		all licely.			
2. Choose a	n item.				
Detail					
3. Research to		Choose an item.			
Validity/reliabili					
The qualifica	ition 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 e	•	Choose an item.			
Method for testing tool's		Click or tap here to enter text.			
quality					
Details of the		Click or tap here to enter text.			
testing the tool	•				
Acceptance		Click or tap here to enter text.			
Tools (IOC with	n references)				
4. Tool Testing		Choose an item.			
4.1 Researc	· ·				
Population	Click or tap her	re to enter text.			
(Please					
specify)					
	Total Click or tap here to enter text.				
Population	Population				
Indicate h	ow you calculate	e the research population			
Click or ta	ap here to enter t	ext.			
• Group 2	Choose an item.	. Total Click or tap here to People enter text.			

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Age Choose an item.		tem.	Ability to speak, listen,	Choose an	
Range			read, and write	item.	
Sample size Ch		Choose	an item.		
determination	n				
Selection pr	ocedures	Choose	an item.		
and random	sampling				
or distribution	n				
techniques					
Click or tap	here to enter	text.			
Details of the calculation	e sample	Choose	an item.		
Click or tap	here to enter	text.			
4.2 Initial Co	ontact with		Choose an item.	97 //	
Potential Parti	cipants				
Channel	of Contacting		Channel 1 Choose an ite	∍m.	
Potential	Participants				
			Channel 2 Choose an ite	em .	
			Channel 3 Choose an ite		
 Location for Contacting Potential Participants 			ocation 1 Choose an ite		
		9			
1 oternar	1 artioipanto				
		L	ocation 2 Choose an ite	em.	
*Please s	specify the ch	nannel us	ed and provide details	when contacting	
	•		nnels Click or tap here t	•	
Person(s) responsible	for C	Choose an item.		
contactin	g potential				
participar	• .				
4 2 Droces	of Informed		Phonon on item		
4.3 Process Consent	of Informed		Choose an item.		
	Droops		Choose an item.		
Consent	Piocess		onouse an item.		
*If the investigators choose a			Click or tap here to ente	r text.	
consent proce					
written consen	it, please stat	te the			
reasons.					
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 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.

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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--

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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 <u>directly benefit</u> 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.

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5. Specify how the investigator will impleme participant safety.	ent measures to ensure
Click or tap here to enter text.	
6. Describe how the investigator will implem	nent 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.

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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 J Section K Section M Section M Section M Section D Section M Section

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

Activities						Mo	ontl	า				
		2	3	4	5	6	7	8	9	1 0	1 1	1 2
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-----

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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.

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-----Section M - Signature and

Agreement-----

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

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).

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• 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			Da	Click or tap to enter
Investigator			te	the date
	(
)		
Co-Investigator			Da	Click or tap to enter
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Co-Investigator			te	the date
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Co-Investigator			Da	Click or tap to enter
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Co-Investigator			te	the date
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For Undergraduated and Graduated Students
As the faculty advisor, I confirm that I have reviewed and approved this research protocol.

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Advisor	Da Click or tap to enter te the date					
()						
Note: Investigators are required to complete all sections of the form						
Address: Naresuan University						
Pan Health Sciences	4 th Floor Mahathammaracha					
el 1	Building, Division of Research and					

Addre	Address: Naresuan University Institutional Review Board							
Pan	Health Science	ces		4 th Floor Mahathammaracha				
el 1				Building, Division of Research and				
Tel.	055-96875	E-m	nu-irb-board1@nu.ac.	Innovation, Naresuan University,				
	2	ail	th	Phitsanulok, 65000 Thailand				
Pan	Technology a	nd Sc	ocial Sciences and	. CV				
el 2	Humanities							
Tel.	055-96864	E-m	nu-irb-board2@nu.ac.					
	2	ail	th					
Pan	Medical Scien	nces		3 rd Floor Sirindhorn Building,				
el 3				Naresuan University Hospital,				
Tel.	055-96529	E-m	nu-irb-board3@nu.ac.	Phitsanulok, 65000 Thailand				
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