Institutional Review Board Naresuan University	Research Ethical Application (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 Section N Section O

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 Section N Section O

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 on humans before? Choose an item.

If conducted on humans before, please provide a summary of the study results. Click or tap here to enter text.

If conducted on humans before, why must the study be repeated? Click or tap here to enter text.

If not conducted on humans, has the experimental study been performed on laboratory animals before? Choose an item.

If experiments have been conducted on laboratory animals or in vitro, please provide details regarding efficacy and safety. 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 Section N Section O

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

1. Type of study	Choose an item.
Study Design	Choose an item.
2. Number of Study sites	Choose an item.
Study site	Click or tap here to enter text.
3. Has this research study been registered for a clinical trial?	Choose an item.
If registered, please provide the Clinical Trial registration number or specify the registration status.	Click or tap here to enter text.

4. Research Population

Population (Please specify)	Click or tap here to enter text.
Total Population	Click or tap here to enter text.
Blinding Process	Choose an item.

If applicable, please specify details of the blinding process. Click or tap here to enter text.

5. Subject Group

Number of Subject Group	Choose an item.	Group	
• Group 1	Choose an item.	Total Click or tap here to enter text.	subject

Age Range	Choose an item.		
Type of Subject Group	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.	subject
Age Range	Choose an item.		
Type of Subject Group	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 Section N Section O

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	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 for Participant Selection	Choose an item.
• Channel of Contacting Participants	Channel 1 Choose an item. Channel 2 Choose an item. Channel 3 Choose an item.
• Location for Contacting Participants	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 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	Click or tap here to enter text.

written consent, please state the reasons. • 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.
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.

During participation in the research study, if new information is discovered that may affect the safety of the participant, the investigator will promptly inform the participant. This allows the participant to decide whether to continue participating in the research study or to withdraw from the study.

*If the study consists of multiple phases, please separate the details in Section D - Recruitment and Informed Consent Process for each phase of the study.

----------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 Section N Section O

*If the study consists of multiple phases, please separate the details in Sections D to J for each phase of the study.

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 Section N Section O

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 Section N Section O

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 Section N Section O

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 - Investigational Product/Device/Program----------

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 Section N Section O

1. Trial Group Choose an item.

Click or tap here to enter text.

2. Control group/Comparison group	Choose an item.
Click or tap here to enter text.	
3. Other applicable details (Choose to fill either choice number 3.1, 3.2, 3.3, 3.4, or 3.5. and remove any not applicable)	

3.1 **Modern/Herbal medicine** Choose an item.

3.1.1 Investigational Product Choose an item.

(If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item.
Generic Name	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Manufacturing facility/Organization	Click or tap here to enter text.
GMP certification of Manufacturing sites for Pharmaceutical Production	Choose an item.
Person(s) responsible for preparing the investigational drug	Click or tap here to enter text.
Indication	Click or tap here to enter text. Has this indication been approved by the Food and Drug Administration? Choose an item. If certified, indicate the institution that has approved the indications Choose an item.
Dosage Strength	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.
Dose rationale	Click or tap here to enter text.
Efficacy information	Click or tap here to enter text.
Adverse Reaction	Click or tap here to enter text.
Precaution	Click or tap here to enter text.

Person(s) responsible for managing investigational product	Click or tap here to enter text.
Product storage	Click or tap here to enter text.
Registration	Choose an item. Registration number..... (if any)
Production Procedure (if applicable)	Click or tap here to enter text.

If the product has not been released in the market, specify the details regarding its components, quantities, and/or the functions of its components.

Click or tap here to enter text.

Current medical practices related to the treatment of the specific disease or symptoms indicate the use of this investigational product.

Click or tap here to enter text.

Image of the label for an investigational product already released to market.	Choose an item.

(Insert image) If not applicable, please remove this row.

Image of the label for an investigational product not yet released to market	Choose an item.

(Insert image) If not applicable, please remove this row.

Should the participant take this investigational product back home for personal use?	Choose an item.

Note: Prepare the label with the following details: investigational drug code, participant code, indications, instructions for use, special precautions (if any), manufacturing date (DD/MM/YYYY), expiry date (DD/MM/YYYY), and the statement "For research purposes only"; then attach a photo of the drug label.

(Insert image) If not applicable, please remove this row.

Does this investigational product need to be divided or repackaged?	Choose an item.

Click or tap here to enter text. (Provide additional details, such as the containers for packaging, quantities, person(s) responsible for packaging, and the location for the packaging process.)
Other Information Click or tap here to enter text.

***Note**:

1. In addition, investigators are encouraged to provide any relevant additional information beyond the specified requirements
2. Investigators must maintain records of investigational drug receipt and dispensing, including at least the details shown in the attached example.

3.1.2 Placebo or drug used in the control group Choose an item. If there is no control group, remove the table below.

(If any part is not applicable, indicate it as not applicable)

Generic Name	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Manufacturing facility/Organization	Click or tap here to enter text.
GMP certification of Manufacturing sites for Production	Choose an item.
Person(s) responsible for preparing placebo or drugs used in the control group.	Click or tap here to enter text.
Indication	Click or tap here to enter text. Has this indication been approved by the Food and Drug Administration? Choose an item. If certified, indicate the institution that has approved the indications Choose an item.
Dosage Strength	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.
Dose rationale	Click or tap here to enter text.

Efficacy information	Click or tap here to enter text.
Adverse Reaction	Click or tap here to enter text.
Precaution	Click or tap here to enter text.
Person(s) responsible for managing the placebo or products used in the control group	Click or tap here to enter text.
Product storage	Click or tap here to enter text.
Registration	Choose an item. Registration number..... (if any)
Production Procedure (if applicable)	Click or tap here to enter text.

If the product has not been released in the market, specify the details regarding its components, quantities, and/or the functions of its components.

Click or tap here to enter text.

Current medical practices related to the treatment of the specific disease or symptoms indicate the use of this investigational product.

Click or tap here to enter text.

Image of the label for an investigational product already released to market.	Choose an item.

(Insert image) If not applicable, please remove this row.

Image of the label for an investigational product not yet released to market	Choose an item.

(Insert image) If not applicable, please remove this row.

Should the participant take this investigational product back home for personal use?	Choose an item.

Note: Prepare the label with the following details: investigational drug code, participant code, indications, instructions for use, special precautions (if any), manufacturing date (DD/MM/YYYY), expiry date (DD/MM/YYYY), and

the statement "For research purposes only"; then attach a photo of the drug label.

(Insert image) If not applicable, please remove this row.

Does this investigational product need to be divided or repackaged?	Choose an item.

Click or tap here to enter text. (Provide additional details, such as the containers for packaging, quantities, person(s) responsible for packaging, and the location for the packaging process.)

Other Information Click or tap here to enter text.

***Note**:

1. In addition, investigators are encouraged to provide any relevant additional information beyond the specified requirements
2. Investigators must maintain records of investigational drug receipt and dispensing, including at least the details shown in the attached example.

3.2 **Herb/Supplement/Cosmetic/Food** Choose an item.

3.2.1 Investigator product Choose an item.

(If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item.
Generic Name	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Indication	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.

Formula/Recipe (Components, Quantities, and/or Functions of Substances) for each formulation (Specify for each formulation) for both the control and placebo products.

Click or tap here to enter text.

Dose rationale	Click or tap here to enter text.
Product Efficacy information	Click or tap here to enter text.
Adverse Reaction	Click or tap here to enter text.
Precaution	Click or tap here to enter text.
Product storage	Click or tap here to enter text.

Registration	Choose an item. Registration number..... (if any)
Manufacturing facility/Organization	Click or tap here to enter text.
GMP certification of Manufacturing sites	Choose an item.
Quality Assurance	Click or tap here to enter text. (In case the manufacturing facility has not yet been GMP certified.)
Production Procedure (if applicable)	Click or tap here to enter text.
Person(s) responsible for preparing the investigational product.	Click or tap here to enter text.
Person(s) responsible for managing the investigational product.	Click or tap here to enter text.
Image of the label for an investigational product already released on the market.	Choose an item.
(Insert image) If not applicable, please remove this row.	
Image of the label for an investigational product not yet released to market	Choose an item.
(Insert image) If not applicable, please remove this row.	
Should the participant take this product back home for personal use?	Choose an item.

Note: Prepare the label with the following details: investigational drug code, participant code, indications, instructions for use, special precautions (if any), manufacturing date (DD/MM/YYYY), expiry date (DD/MM/YYYY), and the statement "For research purposes only"; then attach a photo of the drug label.

(Insert image) If not applicable, please remove this row.	
Does this product need to be divided or repackaged?	Choose an item.
Click or tap here to enter text. (Specify additional details such as packaging containers, quantities, person(s) responsible for packaging, and the location used for packaging.) If not applicable, remove this row.	
Other Information If not applicable, remove this row.	Click or tap here to enter text.

***Note**:

1. In addition, investigators are encouraged to provide any relevant additional information beyond the specified requirements
2. Investigators must maintain records of investigational drug receipt and dispensing, including at least the details shown in the attached example.
3. Please provide additional details and submit documents, such as notification documents, GMP certification for the manufacturing facility, QA processes for quality control of all types of product components, and MSDS for all product components.

3.2.2 Placebo or the product used in the control group Choose an item. If no control group, please remove the table below

(If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item.
Generic Name	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Indication	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.
Formula/Recipe (Components, Quantities, and/or Functions of Substances) for each formulation (Specify for each formulation) for both	Click or tap here to enter text.

the control and placebo products.	
Dose rationale	Click or tap here to enter text.
Product Efficacy information	Click or tap here to enter text.
Adverse Reaction	Click or tap here to enter text.
Precaution	Click or tap here to enter text.
Product storage	Click or tap here to enter text.
Registration	Choose an item. Registration number..... (if any)
Manufacturing facility/Organization	Click or tap here to enter text.
GMP certification of Manufacturing sites	Choose an item.
Quality Assurance	Click or tap here to enter text. (In case the manufacturing facility has not yet been GMP certified.)
Production Procedure (if applicable)	Click or tap here to enter text.
Person(s) responsible for preparing the investigational product.	Click or tap here to enter text.
Person(s) responsible for managing the investigational product.	Click or tap here to enter text.
Image of the label for an investigational product already released on the market.	Choose an item.
(Insert image) If not applicable, please remove this row.	
Image of the label for an investigational product not yet released to market	Choose an item.
(Insert image) If not applicable, please remove this row.	

Should the participant take this product back home for personal use?	Choose an item.

Note: Prepare the label with the following details: investigational drug code, participant code, indications, instructions for use, special precautions (if any), manufacturing date (DD/MM/YYYY), expiry date (DD/MM/YYYY), and the statement "For research purposes only"; then attach a photo of the drug label.

(Insert image) If not applicable, please remove this row.

Does this product need to be divided or repackaged?	Choose an item.

Click or tap here to enter text. (Specify additional details such as packaging containers, quantities, person(s) responsible for packaging, and the location used for packaging.) If not applicable, remove this row.

Other Information If not applicable, remove this row.	Click or tap here to enter text.

***Note**:

1. In addition, investigators are encouraged to provide any relevant additional information beyond the specified requirements
2. Investigators must maintain records of investigational drug receipt and dispensing, including at least the details shown in the attached example.
3. Please provide additional details and submit documents, such as notification documents, GMP certification for the manufacturing facility, QA processes for quality control of all types of product components, and MSDS for all product components.

3.3 **Medical procedures/Treatment procedures (excluding investigational products)** Choose an item.

3.3.1 Trial Group Choose an item.

(If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item.
Details of the medical procedure/treatment procedure	
Click or tap here to enter text.	

Person(s) responsible for providing the intervention	Click or tap here to enter text.
Indications or objectives for providing the intervention	Click or tap here to enter text.
Efficacy information for this intervention	Click or tap here to enter text.
Adverse reactions to this intervention	Click or tap here to enter text.
Precautions/Practices	Click or tap here to enter text.
Other Information	Click or tap here to enter text.

***Note**: Investigators can provide additional relevant information beyond the specified requirements.

3.3.2 Control group Choose an item. If no control group, please remove the table below.

(If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item.
Details of the medical procedure/treatment procedure for control group	
Click or tap here to enter text.	
Person(s) responsible for providing the intervention	Click or tap here to enter text.
Indications or objectives for providing the intervention	Click or tap here to enter text.
Efficacy information for this intervention	Click or tap here to enter text.
Adverse reactions to this intervention	Click or tap here to enter text.

Precautions/Practices	Click or tap here to enter text.
Other Information	Click or tap here to enter text.

*** Note**: Investigators can provide additional relevant information beyond the specified requirements.

3.4 **Device** Choose an item. If not applicable, please remove the information under this section

Definition of the medical device according to the Medical Device Act (Version 2) **B.E.** 2562.

"Medical Device" means
(1) an instrument, tool, mechanical device, object used for bodily insertion, fluid for laboratory examination, product, software, or any other object specifically intended by the manufacturer or product owner for one or more of the following uses with a human or animal body, either solely or as a constituent or accessory of any other object:

- diagnosis, prevention, monitoring, treatment, relief, or cure of disease;
- diagnosis, monitoring, treatment, relief, or cure of injury;
- inspection, replacement, remedy, alteration, support, sustainment, or aid pertaining to the anatomy or body process;
- life support or aid;
- contraception or promotion of fertility;
- assistance or compensation for a disability or handicap;
- generation of data from the examination of specimens extracted for medical or diagnostic purposes;
- disinfection or sterilization of medical devices.

(2) an accessory to be used together with the medical device under (1); or
(3) other instruments, tools, mechanical device products, or objects as prescribed by Notification of the Minister as medical devices.

The accomplishment of purposes of the articles stated in (1) which occurs within a human or animal body must not be the result of a pharmacological, immunological or metabolic process."

Reference: Medical Device Act (Version 2) B.E. 2562, Royal Thai Government Gazette, Volume 136, Section 56 A, Page 186.

3.4.1 Trial Group Choose an item.

Detail (If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item. If it is a medical device (Specify the type) Choose an item.
Classification of Risk for Medical Devices	Choose an item.
Device Name	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Registration	Choose an item. Registration number..... (if any)
Manufacturing facility/Organization	Click or tap here to enter text.
Functioning principles	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.
Precautions	Click or tap here to enter text.
Effectiveness/User Experience	Click or tap here to enter text.
Information in Humans	
Safety Information	Click or tap here to enter text.
Device Images	
Specification of Device	Click or tap here to enter text.
Sensitivity of Device	Click or tap here to enter text.
Safety-related Testing, such as Electrical Testing, Weight Endurance Testing, etc.	
Click or tap here to enter text.	
For other Information, please remove this row if not applicable	Click or tap here to enter text.

***Note**:

1. In addition, investigators can provide any additional information beyond the specified requirements.
2. If it is an imported medical device, please provide the following details: 2.1. Certificate from Thai FDA and 2.2 Certificate of Free Sale
3. 'Significant risk medical device' refers to equipment with a high level of risk, meaning devices that pose a significant risk of death or permanent disability when used, may require surgery or the use of certain medications to prevent death, and/or disability resulting from the use of such devices (Ethical Guidelines for Human Research in Thailand, B.E.2550 (2007), page 42).

3.4.2 Control Group Choose an item. If there is no control group, please remove the table below.

Detail (If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item. If it is a medical device (Specify the type) Choose an item.
Classification of Risk for Medical Devices	Choose an item.
Device Name	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Registration	Choose an item. Registration number..... (if any)
Manufacturing facility/Organization	Click or tap here to enter text.
Functioning principles	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.
Precautions	Click or tap here to enter text.
Effectiveness/User Experience	Click or tap here to enter text.
Information in Humans	
Safety Information	Click or tap here to enter text.
Device Images	

Specification of Device	Click or tap here to enter text.
Sensitivity of Device	Click or tap here to enter text.
Safety-related Testing, such as Electrical Testing, Weight Endurance Testing, etc.	
Click or tap here to enter text.	
For other Information, please remove this row if not applicable	Click or tap here to enter text.

*** Note**:

1. In addition, investigators can provide any additional information beyond the specified requirements.
2. If it is an imported medical device, please provide the following details: 2.1. Certificate from Thai FDA and 2.2 Certificate of Free Sale
3. 'Significant risk medical device' refers to equipment with a high level of risk, meaning devices that pose a significant risk of death or permanent disability when used, may require surgery or the use of certain medications to prevent death, and/or disability resulting from the use of such devices (Ethical Guidelines for Human Research in Thailand, B.E.2550 (2007), page 42).

3.5 Programs/Applications/Devices Related to Clinical Patient Assessment

Choose an item.

Definition of the medical device according to the Medical Device Act (Version 2) B.E. 2562.

“Medical Device” means (1) an instrument, tool, mechanical device, object used for bodily insertion, fluid for laboratory examination, product, software, or any other object specifically intended by the manufacturer or product owner for one or more of the following uses with a human or animal body, either solely or as a constituent or accessory of any other object:

- diagnosis, prevention, monitoring, treatment, relief, or cure of disease;
- diagnosis, monitoring, treatment, relief, or cure of injury;
- inspection, replacement, remedy, alteration, support, sustainment, or aid pertaining to the anatomy or body process;
- life support or aid;
- contraception or promotion of fertility;
- assistance or compensation for a disability or handicap;
- generation of data from the examination of specimens extracted for medical or diagnostic purposes;
- disinfection or sterilization of medical devices.

(2) an accessory to be used together with the medical device under (1); or (3) other instruments, tools, mechanical device products, or objects as prescribed by Notification of the Minister as medical devices.

The accomplishment of purposes of the articles stated in (1) which occurs within a human or animal body must not be the result of a pharmacological, immunological or metabolic process."

Reference: Medical Device Act (Version 2) B.E. 2562, Royal Thai Government Gazette, Volume 136, Section 56 A, Page 186.

3.5.1 Trial Group Choose an item.

Detail (If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item. If it is a medical device (Specify the type) Choose an item.
Classification of Risk for Medical Devices	Choose an item.
Name of the program/application/device related to clinical patient assessment	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Company/Organization/Copyright Owner	Click or tap here to enter text.
Functioning principles	Click or tap here to enter text.

Instructions for Use	Click or tap here to enter text.
Precautions	Click or tap here to enter text.
Effectiveness/User Experience	Click or tap here to enter text.
Information in Humans	
Safety Information/Precautions	Click or tap here to enter text.
Participant's Practice	Click or tap here to enter text.
Operating System, Login/Logout Procedures, Installation/Uninstallation of the Application	
Click or tap here to enter text.	
Structure of the Program/Application	
Click or tap here to enter text.	
(Draft) Content of the Program/Application/Device Related to Clinical Patient Assessment	
Click or tap here to enter text.	
Images, Videos, Audio Clips, or Other Devices	Choose an item.
Assessment Validity of Content	Click or tap here to enter text.
Assessment of the Validity of the Program/Application/Device Related to Clinical Patient Assessment	
Click or tap here to enter text.	
Data Security of the Program/Application	Click or tap here to enter text.
Other information	Click or tap here to enter text.

***Note**:

1. In addition, investigators can provide any additional information beyond the specified requirements.
2. 'Significant risk medical device' refers to equipment with a high level of risk, meaning devices that pose a significant risk of death or permanent disability when used, may require surgery or the use of certain medications to prevent death, and/or disability resulting from the use of

such devices (Ethical Guidelines for Human Research in Thailand, B.E.2550 (2007), page 42).

3.5.2 Control Group Choose an item. If there is no control group, please remove the table below.

Detail (If any part is not applicable, indicate it as not applicable)

Type of Intervention	Choose an item. If it is a medical device (Specify the type) Choose an item.
Classification of Risk for Medical Devices	Choose an item.
Name of the program/application/device related to clinical patient assessment	Click or tap here to enter text.
Trade Name	Click or tap here to enter text.
Company/Organization/Copyright Owner	Click or tap here to enter text.
Functioning principles	Click or tap here to enter text.
Instructions for Use	Click or tap here to enter text.
Precautions	Click or tap here to enter text.
Effectiveness/User Experience	Click or tap here to enter text.
Information in Humans	
Safety Information/Precautions	Click or tap here to enter text.
Participant's Practice	Click or tap here to enter text.
Operating System, Login/Logout Procedures, Installation/Uninstallation of the Application	
Click or tap here to enter text.	
Structure of the Program/Application	
Click or tap here to enter text.	
(Draft) Content of the Program/Application/Device Related to Clinical Patient Assessment	
Click or tap here to enter text.	

Images, Videos, Audio Clips, or Other Devices	เลือกรายการ
Assessment Validity of Content	Click or tap here to enter text.
Assessment of the Validity of the Program/Application/Device Related to Clinical Patient Assessment	
Click or tap here to enter text.	
Data Security of the Program/Application	Click or tap here to enter text.
Other information	Click or tap here to enter text.

***Note**:

1. In addition, investigators can provide any additional information beyond the specified requirements.
2. 'Significant risk medical device' refers to equipment with a high level of risk, meaning devices that pose a significant risk of death or permanent disability when used, may require surgery or the use of certain medications to prevent death, and/or disability resulting from the use of such devices (Ethical Guidelines for Human Research in Thailand, B.E.2550 (2007), page 42).

----------Section J - 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 Section N Section O

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. Scientific Instruments	Choose an item.
Click or tap here to enter text. Click or tap here to enter text.	
5. Reviewing and Considering Safety During Research Operations	
5.1 By the Independent Committee, such as the Data Safety Monitoring Board (DSMB) Choose an item.	
Specify the frequency of meetings of the Independent Committee Click or tap here to enter text. Month/Year	
5.2 Initial Interim Analysis Plan Choose an item.	
Specify the data analysis plan Click or tap here to enter text. Frequency Click or tap here to enter text. Month/Year	
6. Outcomes	
Click or tap here to enter text.	
7. Data Analysis and Statistics	
Click or tap here to enter text.	

----------Section K - 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.
- Process of obtaining consent for sample collection for future research: Click or tap here to enter text.
- Other relevant details (specify): Click or tap here to enter text. If not applicable, please remove this row

----------Section L - 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 Section N Section O

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 M - 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 Section N Section O

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 N - 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 O - 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

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	