Instructions for Document Preparation of Research Ethical Application

*Only for those using the Google Docs Templates

1. Copying the Google Docs Template การทำสำเนา Template Google Doc Duplicate the Google Docs template.

2. Turning On/Off Outline การปิดเปิด Outline Enable or disable the document outline as needed.

3. Navigating Different Sections การไปยัง Section ต่างๆ Move between various sections in the document.

4. Managing Comments; Check the comments, view checked comments, and reopen comments as necessary. การ จัดการ Comments

5. Copying Choices from Comments to the Document
การ Copy ตัวเลือกจาก Comment มาใส่ในเอกสาร Transfer selections from comments to the main document.

6. Inserting Rows/Deleting Rows การแทรกแถว การลบแถว Add or remove rows as required.

7. Deleting Document Preparation Instructions
การลบหน้า คำชี้แจงการเตรียมเอกสาร Remove unnecessary instructions from the document.

8. Electronic Signing
    8.1 Signing (Electronic Signature) into the Google Doc
การลงนาม electronic by drawing your signature.
    8.2 Inserting a Signature Image into the Google Doc
การแทรกรูปลายเซ็นต์ Add your signature image to the document.

9. Saving Google Docs to PDF การ Save Google doc เป็น PDF Convert and save the Google Doc as a PDF file.

NU-NRE	Naresuan University Network Research Ethics	Research Ethical Application (Intervention Study)

Protocol title (TH)	.....	
Protocol title (ENG)	.....	
Sponsor	.....	
Has this research been reviewed and approved by any other institution's research ethics committee?		.....
- If you have been 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 I Section J Section K Section L Section M Section N Section O

1. Principal Investigator			
Name - Surname	.....		
Department	.....		
Faculty	.....		
Expertise	.....		
Research Responsibility	.....		
2. Co-Investigator(s) (if applicable)			
Name - Surname	.....		
Department	.....		
Faculty	.....		
Expertise	.....		
Research Responsibility	.....		
3. Number of Research Assistants	.....	people	If applicable, please specify names and roles/responsibilities.

Name - Surname Human Research Ethics Training	1. ..... Roles / Responsibilities ....

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)

.....

2. Literature Review

.....

3. Has this research been conducted on humans before? .....

If conducted on humans before, please provide a summary of the study results. .....

If conducted on humans before, why must the study be repeated? .....

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

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

4. Research Questions/Objectives/Hypothesis/Delimitation

- Research Questions (if any) (If yes, please specify)

  .....
- Objectives

  .....
- Hypothesis (if any) (If yes, please specify)

  .....
- Delimitation

  .....

5. Keywords (specify 3 – 5 words)

Thai	.....
English	.....

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

1. Type of study	.....
Study Design	.....
2. Number of Study sites	.....
Study site	.....
3. Has this research study been registered for a clinical trial?	.....
If registered, please provide the Clinical Trial registration number or specify the registration status.	.....

4. Research Population	
Population (Please specify)	.....
Total Population	.....
Blinding Process	.....
If applicable, please specify details of the blinding process.	

5. Sample Group			
Number of Sample Group	.....	Group	
• Group 1	.....	Total	sample
Age Range	.....		
Type of Sample Group	.....	Ability to speak, listen, read, and write	.....
• Group 2	.....	Total	sample
Age Range	.....		

Type of Sample Group	.....	Ability to speak, listen, read, and write	....
Sample size determination	.....		
Selection procedures and random sampling or distribution techniques.	.....		
.....			
Details of the sample calculation	.....		
.....			

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?	
2. Details for Participant Group 1	
2.1 Initial Contact with Potential Participants	.....
• Channel of Contacting Potential Participants	Channel 1 .....
	Channel 2 .....
	Channel 3 .....
• Location for Contacting Potential Participants	.....
*Please specify the channel used and provide details when contacting potential participants via online channels	
• Person(s) responsible for contacting potential participants	.....
2.2 Process of Informed Consent	.....
• Consent Process	.....

*If the investigators choose a consent process that is not written consent, please state the reasons.	.....
• Person(s) who need to request consent	.....
• Person(s) responsible for providing research information to participants	.....
• Person(s) responsible for obtaining consent from participants	.....
- Does the investigator or team have a power relationship with the participants? For example, teacher-student, doctor-patient, etc.	..... 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. .....
• Location of Consent Request	.....
2.3 Compensation for participants' travel expenses and time loss.	.....
• Indicate the compensation (Baht)	Number of times: ..... times Amount per time: ..... Baht Total amount: ..... Baht
• Souvenir (Specify the type of souvenir or any other items to be given to participants)	.....
3. Details for Participant Group 2 (If there is only one participant group, remove item 3)	
3.1 Initial Contact for Participant Selection	.....
• Channel of Contacting Participants	Channel 1 .....
	Channel 2 .....

	Channel 3 ……..
● Location for Contacting Participants	……..
*Please specify the channel used and provide details when contacting potential participants via online channels ……..	
● Person(s) responsible for contacting participants	……..
3.2 Process of Informed Consent	……..
● Consent Process	……..
*If the investigators choose a consent process that is not written consent, please state the reasons.	……..
● Person(s) who need to request consent	……..
● Person(s) responsible for providing research information to participants	……..
● Person(s) responsible for obtaining consent from participants	……..
- Does the investigator or team have a power relationship with the participants? For example, teacher-student, doctor-patient, etc.	…….. 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. ……..
● Location of Consent Request	……..
3.3 Compensation for participants' travel expenses and time loss.	……..
● Indicate the compensation (Baht)	Number of times: …….. times Amount per time: …….. Baht Total amount: …….. Baht
● Souvenir (Specify the type of souvenir or any other	……..

items to be given to participants)	

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 …….. 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. ……..
2. ……..

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. ……..
2. ……..

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. .....
2. .....

***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. .....
2. .....

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

.....

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?

.....

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. ……
2. ……

***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	……
……	
2. Control group/Comparison group	……
……	
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……..

3.1.1 Investigational Product ……..

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

Type of Intervention	……
Generic Name	……
Trade Name	……

Manufacturing facility/Organization	……..
GMP certification of Manufacturing sites for Pharmaceutical Production	……..
Person(s) responsible for preparing the investigational drug	……..
Indication	……..
	Has this indication been approved by the Food and Drug Administration? ……..
	If certified, indicate the institution that has approved the indications ……..
Dosage Strength	……..
Instructions for Use	……..
Dose rationale	……..
Efficacy information	……..
Adverse Reaction	……..
Precaution	……..
Person(s) responsible for managing investigational product	……..
Product storage	……..
Registration	…….. Registration number..... (if any)
Production Procedure (if applicable)	……..
If the product has not been released in the market, specify the details regarding its components, quantities, and/or the functions of its components.	
……..	
Current medical practices related to the treatment of the specific disease or symptoms indicate the use of this investigational product.	
……..	

Image of the label for an investigational product already released to market.	……
(Insert image) If not applicable, please remove this row.	
Image of the label for an investigational product not yet released to market	……
(Insert image) If not applicable, please remove this row.	
Should the participant take this investigational product back home for personal use?	……
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?	……
…… (Provide additional details, such as the containers for packaging, quantities, person(s) responsible for packaging, and the location for the packaging process.)	
Other Information ……	

***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…… If there is no control group, remove the table below.

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

Generic Name	……
Trade Name	……
Manufacturing facility/Organization	……

Good Manufacturing Practice (GMP) certification for the drug manufacturing facility.	……..
Person(s) responsible for preparing placebo or drugs used in the control group.	……..
Indication	……..
	Has this indication been approved by the Food and Drug Administration? ……..
	If certified, indicate the institution that has approved the indications ……..
Dosage Strength	……..
Instructions for Use	……..
Dose rationale	……..
Efficacy information	……..
Adverse Reaction	……..
Precaution	……..
Person(s) responsible for managing the placebo or products used in the control group	……..
Product storage	……..
Registration	…….. Registration number..... (if any)
Production Procedure (if applicable)	……..
If the product has not been released in the market, specify the details regarding its components, quantities, and/or the functions of its components.	
……..	
Current medical practices related to the treatment of the specific disease or symptoms indicate the use of this investigational product.	

.....	
Image of the label for a product already released to the market	.....
(Insert image) If not applicable, please remove this row.	
Image of the label for a product not yet released to market	.....
(Insert image) If not applicable, please remove this row.	
Does this product need to be divided or repackaged?	.....
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?	.....
..... (Provide additional details, such as the containers for packaging, quantities, person(s) responsible for packaging, and the location for the packaging process.)	
Other Information	

***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 .....

3.2.1 Investigator product .....

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

Type of Intervention	.....
Generic Name	.....
Trade Name	.....
Indication	.....
Instructions for Use	.....

Formula/Recipe (Components, Quantities, and/or Functions of Substances) for each formulation (Specify for each formulation) for both the control and placebo products.	
……..	
Dose rationale	……..
Product Efficacy information	……..
Adverse Reaction	……..
Precaution	……..
Product storage	……..
Registration	…….. Registration number..... (if any)
Manufacturing facility/Organization	……..
GMP certification of Manufacturing sites	……..
Quality Assurance	…….. (In case the manufacturing facility has not yet been GMP certified.)
Production Procedure (if applicable)	……..
Person(s) responsible for preparing the investigational product.	……..
Person(s) responsible for managing the investigational product.	……..
Image of the label for an investigational product already released on the market.	……..
(Insert image) If not applicable, please remove this row.	
Image of the label for an investigational product not yet released to market	……..
(Insert image) If not applicable, please remove this row.	
Should the participant take this product back home for personal use?	……..

***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?	……..
…….. (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.	……..

***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 …….. If no control group, please remove the table below

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

Type of Intervention	……..
Generic Name	……..
Trade Name	……..
Indication	……..
Instructions for Use	……..
Formula/Recipe (Components, Quantities, and/or Functions of Substances) for each formulation	……..

(Specify for each formulation) for both the control and placebo products.	
Dose rationale	……
Product Efficacy information	……
Adverse Reaction	……
Precaution	……
Product storage	……
Registration	…… Registration number..... (if any)
Manufacturing facility/Organization	……
GMP certification of Manufacturing sites	……
Quality Assurance	…… (In case the manufacturing facility has not yet been GMP certified.)
Production Procedure (if applicable)	……
Person(s) responsible for preparing the investigational product.	……
Person(s) responsible for managing the investigational product.	……
Image of the label for an investigational product already released on the market.	……
(Insert image) If not applicable, please remove this row.	
Image of the label for an investigational product not yet released to market	……
(Insert image) If not applicable, please remove this row.	
Should the participant take this product back home for personal use?	……

***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?	……..
……. (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.	……..

***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) ……..

3.3.1 Trial Group ……..

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

Type of Intervention	……..
Details of the medical procedure/treatment procedure	
……..	
Person(s) responsible for providing the intervention	……..
Indications or objectives for	……..

providing the intervention	
Efficacy information for this intervention	……..
Adverse reactions to this intervention	……..
Precautions/Practices	……..
Other Information	……..

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

3.3.2 Control group …….. If no control group, please remove the table below.

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

Type of Intervention	……..
Details of the medical procedure/treatment procedure for control group ……..	
Person(s) responsible for providing the intervention	……..
Indications or objectives for providing the intervention	……..
Efficacy information for this intervention	……..
Adverse reactions to this intervention	……..
Precautions/Practices	……..
Other Information	……..

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

3.4 Device …….. 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 ……..

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

Type of Intervention	…….. If it is a medical device (Specify the type) ……..

Classification of Risk for Medical Devices	.....
Device Name	.....
Trade Name	.....
Registration	..... Registration number..... (if any)
Manufacturing facility/Organization	.....
Functioning principles	.....
Instructions for Use	.....
Precautions	.....
Effectiveness/User Experience Information in Humans	.....
Safety Information	.....
Device Images	
(Insert image of Device)	
Specification of Device	.....
Sensitivity of Device	.....
Safety-related Testing, such as Electrical Testing, Weight Endurance Testing, etc.	
(Specify Details).....	
For other Information, please remove this row if not applicable	.....

***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 …….. 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	…….. If it is a medical device (Specify the type) ……..
Classification of Risk for Medical Devices	……..
Device Name	……..
Trade Name	……..
Registration	…….. Registration number..... (if any)
Manufacturing facility/Organization	……..
Functioning principles	……..
Instructions for Use	……..
Precautions	……..
Effectiveness/User Experience Information in Humans	……..
Safety Information	……..
Device Images	
(Insert image of Device)	
Specification of Device	……..
Sensitivity of Device	……..
Safety-related Testing, such as Electrical Testing, Weight Endurance Testing, etc.	
(Specify Details)……..	
For other Information, please remove this row if not applicable	……..

***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

……..

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 .....

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

Type of Intervention	..... If it is a medical device (Specify the type) .....
Classification of Risk for Medical Devices	.....
Name of the program/application/ device related to clinical patient assessment	.....
Trade Name	.....
Company/Organization/Copyright Owner	.....
Functioning principles	.....
Instructions for Use	.....
Precautions	.....
Effectiveness/User Experience Information in Humans	.....
Safety Information/Precautions	.....
Participant's Practice	.....

Operating System, Login/Logout Procedures, Installation/Uninstallation of the Application	
.....	
Structure of the Program/Application	
.....	
Draft Content of the Program/Application/Device Related to Clinical Patient Assessment	
.....	
Images, Videos, Audio Clips, or Other Devices	.....
Assessment Validity of Content	.....
Assessment of the Validity of the Program/Application/Device Related to Clinical Patient Assessment	
.....	
Data Security of the Program/Application	.....
Other information	.....

***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 ..... 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	..... If it is a medical device (Specify the type) .....
Classification of Risk for Medical Devices	.....
Name of the program/application/	.....

device related to clinical patient assessment	
Trade Name	……..
Company/Organization/Copyright Owner	……..
Functioning principles	……..
Instructions for Use	……..
Precautions	……..
Effectiveness/User Experience Information in Humans	……..
Safety Information/Precautions	……..
Participant's Practice	……..
Operating System, Login/Logout Procedures, Installation/Uninstallation of the Application	
……..	
Structure of the Program/Application	
……..	
Draft Content of the Program/Application/Device Related to Clinical Patient Assessment	
……..	
Images, Videos, Audio Clips, or Other Devices	……..
Assessment Validity of Content	……..
Assessment of the Validity of the Program/Application/Device Related to Clinical Patient Assessment	
……..	
Data Security of the Program/Application	……..

Other information	.....

***Note**:

1. In addition, Investigators can provide any relevant 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)	
.....	
2. Data collection tools	.....
1.	
Details	
2.	
Details	
3. Research tools and Validity/reliability	.....
The qualification of experts	1. .....
	2. .....
	3. .....
Number of experts	.....
Method for testing tool's quality	.....
Details of the Method for testing the tool's quality	.....
Acceptance Criteria for Tools (IOC with references)	.....
4. Scientific Instruments	.....
.....	
.....	
5. Reviewing and Considering Safety During Research Operations	

5.1 By the Independent Committee, such as the Data Safety Monitoring Board (DSMB) ……..

Specify the frequency of meetings of the Independent Committee …….. Month/Year

5.2 Initial Interim Analysis Plan ……..

Specify the data analysis plan …….. Frequency …….. Month/Year

6. Outcomes

……..

7. Data Analysis and Statistics

……..

Section K - Storage and Future Use of Unused Samples

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

Storage of Biological Samples for Future Research ……..

- Details of the biological samples collected for future research ……..
- Storage location: …….. Duration of preservation: …….. years
- Scope of future research using these biological samples: ……..
- Sample Collection Process: ……..
- Sample Destruction Process: ……..
- Process of obtaining consent for sample collection for future research: ……..
- Other relevant details (specify): …….. 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.
……
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).
……
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.
……
4. Specify any potential risks or concerns that participants may face by participating in this research study.
……
5. Specify how the investigator will implement measures to ensure participant safety.
……
6. Describe how the investigator will implement measures to ensure participant well-being if any unexpected incidents occur.
……
7. Specify how the investigator/sponsor will take responsibility for unexpected incidents or harm to participants.
……
8. Explain the principles for determining the 'Inclusion Criteria' (characteristics of research participants) to ensure equal opportunities for research participation.
……
9. Explain the principles for determining the 'Exclusion Criteria,' considering safety and the prevention of potential harm to participants.
……
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).
……

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

……..

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

……..

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).

……..

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

……..

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.

……..

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. ……..												
2. ……..												
3. ……..												
4. ……..												
5. ……..												

Section N - References

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1. .....
2. .....
3. .....
4. .....
5. .....

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 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	(Insert Electronic Signature) (.....)	Date .....
Co-Investigator	(Insert Electronic Signature) (.....)	Date .....
Co-Investigator	(Insert Electronic Signature) (.....)	Date .....
Co-Investigator	(Insert Electronic Signature) (.....)	Date .....
Co-Investigator	(Insert Electronic Signature) (.....)	Date .....

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

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

ที่อยู่ สำนักงานคณะกรรมการจริยธรรมการวิจัยในมนุษย์เครือข่ายมหาวิทยาลัยนเรศวร			
กลุ่ม 4			กองการวิจัยและนวัตกรรม งานจัดการมาตรฐานและเครือข่าย คณะกรรมการจริยธรรมการวิจัยในมนุษย์ ชั้น 4 อาคารมหาธรรมราชา มหาวิทยาลัยนเรศวร เลขที่ 99 หมู่ 9 ตำบล ท่าโพธิ์ อำเภอเมือง พิษณุโลก จังหวัดพิษณุโลก 65000
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