Participant Information Sheet

(For Participants Aged 13 - 17 years)

Naresuan University
Institutional Review Board

Protocol title

……
……

Investigator

Name
……
……
Address
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Office Tel No. ……..…Mobile Phone……..……..……..…
……
E-mail……
……

Co-Investigator

Name
……
……
Address
……
……

Office Tel No. ……..…Mobile Phone……..……..……..…… E-mail…… ……

Sponsor

…… ……..……

In case of any emergencies or if you require additional information related to the research study, you can contact the Investigator at ……., phone number ……, available 24 hours.

Dear all participants

You are invited to participate in this research study because you are a ……..... (specify the reason for the invitation to participate in the research)…… In this research study, there will be a total of ……. (specify the total number of participants)……. participants

Before you decide to participate or not participate in this research study

- Please read this document carefully for you to know the reasons and details of the research
- You can ask for advice on participating in this research from your family, friends, personal doctor, or others as you wish. Take your time to ensure you have sufficient time to make an independent decision.
- If you have any questions, please ask [Specify the You decline to participate in the research, name of the research doctor, co-research doctor, or research team].

Participation in this study must be voluntary

- You can refuse to participate in this project.

- Even after participating in this research study You can withdraw at any time. without any impact on you

Other options if you decide not to participate in the research study

(For Example)

- You decline to participate in the research study.
- You will receive standard medical care as provided by the hospital.

"Drugs/products/medical devices/programs" that participants will be tested in this research.

(For Example)

- Exercise program for Fitness training
- Training program combined with aerobic dancing
- Assessment of Physical Examination, including resting heart rate, percentage of body fat, waist circumference, hip circumference, waist-to-hip ratio, and blood pressure etc.
- Self-assessment
- Survey or Questionnaires
- Any other devices/tools/equipment

1. Why is this research being undertaken?

2. What is the purpose of this research?

3. What activities will you have to participate in?

After you voluntarily agree to participate in this research, you will be invited to meet the research team on the appointed date and time.

The location of this research is …… You must come and meet all the research team …… times. Each time it

takes approximately ……. (minutes/hours). In total, you will be participating in the research for a duration of …… (number of days/months/years).

- **The 1st appointment** will take approximately ..... minutes/hours. You will undergo a screening process to assess your eligibility for participation in the research. This process includes the following steps:

- .....Specify the activities that the participant will need to do.....

- **The 2nd appointment** will take approximately ..... minutes/hours.

- .....Specify the activities that the participant will need to do.....

- **The 3rd appointment** will take approximately ..... minutes/hours.

- .....Specify the activities that the participant will need to do.....

- **The 4th appointment** will take approximately ..... minutes/hours.

- .....Specify the activities that the participant will need to do.....

4. If you participated in this research study, what risks might you encounter?

(For Example) (The investigator specifies the risks associated with medication/research products, other medications/products received, tools/equipment used in the research, medical procedures, blood sampling, data collection/interviews/questionnaire responses, and any other information or predictions regarding potential outcomes that may arise from interactions with research participants at each stage of the research process)

You may experience abnormalities from……. (Specify the medication/research products, other medications/products received, tools/equipment used in the research, medical procedures, blood

sampling, data collection/interviews/questionnaire responses, and any other information or predictions regarding potential outcomes that may arise from interactions with research participants at each stage of the research process)

(For clinical research)
Commonly observed abnormal symptoms: such as nausea, vomiting, hand numbness, dizziness, headache, itching rash, pain, bleeding, bruising from blood sampling, swelling in the area of blood sampling, etc. …….
Less frequently observed but severe abnormal symptoms: such as bleeding in the stomach, infection, severe allergic rash, seizures, coma……...

(For social or survey research)
The potential risks that you may encounter include
……..

In addition to the risks mentioned, you may experience symptoms or discomfort that are unusual and not covered in this document. These symptoms are unprecedented.

If you need more information or have any concerns about the risks associated with participating in the research, you can inquire with the investigator at any time.

If new information is discovered that may affect your safety while participating in the research, the investigator will immediately inform you so that you can decide whether to continue in the research or request withdrawal.

If you feel uncomfortable or experience any unusual symptoms, please do the following:

(For example, in clinical research)

- Notify the investigator immediately. You can contact the investigator, ...(Specify the doctor's or investigator's name and phone number)..... available 24 hours a day.
- If necessary, please come to see a doctor at .....(Specify the responsible hospital or the nearest hospital)..... even if it is outside the scheduled appointment. This is to allow the doctor to assess your abnormal symptoms and provide appropriate treatment immediately.

(For example, in social science research)

- Notify the investigator immediately. You can contact the investigator, ...(Specify the investigator's name and phone number).....available 24 hours a day.
- Consult with the experts at ……(Specify the name or organization related to the field)……..at…. (Phone number).....available 24 hours a day.

5. The Investigator has safety measures or care procedures in place in case of any harm during the research. How will you be taken care of in case of harm during the research?

Measures to prevent harm and reduce risks (Please specify measures that align with the research)

- Investigators have organized a team of……(specify roles such as doctors or nurses)…….. to take care of you during……..(medication/surgery or other relevant procedures) to prevent……(specify risks)…….. or to ensure prompt care in case of……..(injuries or any adverse events for which the investigators should adapt as needed).....
- Investigators have organized a team of……(specify roles such as nurse/staff……..) experts in…….. (specify, such as mental health, developmental experts or any other experts) will be available at all times during data collection. This is to

prevent……(specify the risk)…….. to ensure that they can promptly attend to you in case of……..(psychological distress or other adverse events related to which the investigators should adjust as appropriate).....

- Investigators have organized a team of……(specify roles such as doctors or nurses)…….. to take care of you during……..(medication/surgery or other relevant procedures) to prevent……(specify risks)…….. or to ensure prompt care in case of……..(injuries or any adverse events for which the investigators should adapt as needed).....
- If a participant experiences danger or injury during……(study/testing/surgery/data collection, or other, please specify it by the research) you will receive initial first aid by……(specify the responsible person).....If the condition does not improve, you will be referred to…… (or specify the name of the nearby medical facility)
- If you have already followed the recommendations provided by the research team, the investigators/supporters of the study will willingly take responsibility for covering your medical expenses.
- If you feel uncomfortable or anxious, you can call the emergency hotline……(provide the contact numbers of relevant organizations or hotlines)…….. at…(provide the phone number)..... or consult with experts in …… at…….. (specify the field and contact number)
- To allow you to freely and confidentially fill out the questionnaire, the investigators have implemented…… (describe the process of managing confidentiality)……

*Signing the document of consent does not imply that you have waived your legal rights as normally possessed.

6. Will you receive insurance coverage for participating in the research study or not?

(For example)
This research study does not provide insurance coverage for research participants.

7. Participation in this research study, what benefits will you receive?

(For example)
You will not receive any benefits from participating in this research. However, the study findings may be used to contribute to future developments in areas …….. (such as improving the care of patients with heart disease).....

8. When participating in this research, what responsibilities will you have?

(Example: Adjust as needed to align with the research)

- Please follow the investigator's instructions carefully.
- Please notify the investigator immediately of any abnormalities that occur during your participation in the research.
- Please provide your medical information honestly, both past and present to the investigator.
- Please consult and inform the investigator before using any medication/herbs/products other than those provided or authorized by the investigator.
- Please refrain from using any medication/herbs/products other than those provided or authorized by the investigator.
- If you need to receive vaccines or other medications/herbs/products, please consult with the investigator in advance.
- Please inform the investigator immediately if you receive any medication/herbs/products other than those provided or authorized by the investigator.
- Please bring all the remaining medications/herbs/products and containers used in your study for (consumption/application) to the investigator every scheduled appointment.

9. What expenses will you incur to participate in the research study?

(For example)
You do not have to incur any expenses for participating in this research.

10. Will you receive compensation for participating in the research study?

(For example)
You will not receive compensation, travel expenses, or compensation for time spent participating in this research.

11. Under what circumstances can you withdraw from this research study?

(For example)

The investigator may withdraw you from participating in the study for reasons related to your safety, or if the research sponsor terminates the study or in the following circumstances:

- You are unable to follow the investigator's recommendations.
- You consume medications, herbs, or dietary supplements not permitted for use in this research.
- You use products not authorized for use in this research.
- You become pregnant during participation in this research.
- You experience side effects or abnormalities in laboratory results from the medication used in this research.
- You suffer a severe injury, or the investigator assesses that you cannot continue to participate in the study.
- You have allergies to medications or products used in this research.
- You are required to change the treatment with medications not authorized by this research, etc.

(In addition, the investigator may adjust the withdrawal criteria as appropriate and in line with the research.)

12. How will your confidential information be protected?

The research data will be stored in a computer, with access protected by encryption, limited only to the research team. Specific information that could lead to your identification will be kept confidential and not disclosed to the public. In the case that research findings are published, your name and address will always be kept confidential, using only the project's research code. Your data will be stored for a total of ... years. The storage location is…….. and will be destroyed within…... years.

From your signature of consent, the investigator, other persons on behalf of the research sponsor, the Human Research Ethics Committee, and the Food and Drug Administration may be allowed to inspect and process your information. This will be done solely for the purpose of verifying the accuracy of the information. They may access and review your research records and medical information even after the research study has finished. If you wish to revoke this permission, you can notify or submit a written request for withdrawal of consent to .....(Name of Principal investigator and address in Thailand).....

If you request to withdraw your consent after participating in the research, your personal information will not be further recorded. However, other data related to your participation may be used for research evaluation purposes. It is important to note that you will not be able to rejoin this project in the future, as the essential data required for the research has not been documented.

By signing this consent form, you allow the investigator to disclose details about your participation in this research study to your treating doctor.

13. If there are blood samples or other specimens obtained from the participant's body, how will the investigator manage the remaining samples?

(For example)

- Not Applicable

or

1. Destroy immediately according to standard procedures upon completion of the research, by .....
2. Request to retain the samples for retesting to confirm the accuracy of the experimental results for a period of.....(specify an exact time, not exceeding 1 year)....
3. Request to keep the samples for future research purposes for 10 years, specifying the method of storage, whether it will be linked to the participant's information, the storage location, and who will have access to the samples. Any future research must be related to the approved main research study, such as studying genes related to absorption, decomposition, drugs, or substances studied in the main research. Before conducting the research, a draft proposal must be submitted for approval by the Research Ethics Committee before proceeding.

14. What rights do you have as a research participant?

As a research participant, you have the following rights:
adjusted to align with the research study*

1. You will be informed about the nature and objectives of this research.
2. You will be provided with an explanation of the medical research procedures, including drugs and equipment used in this research.
3. You will be explained about the risks and discomfort that may arise from the research.
4. You will be informed about the potential benefits you may gain from the research.
5. You will be disclosed about the treatment alternatives, medications, or equipment that may have benefits and risks.
6. You will receive guidance on treatment in case of complications arising after participating in the research.
7. You will have the opportunity to ask questions about the research or related processes.

8. You will be informed of your consent to participate in this research study. You can withdraw from the study at any time. Participants in this research can withdraw from the study without any consequences.
9. You will receive documents, including the participant information sheet and a copy of the signed and dated consent form.
10. You have the right to decide whether to participate in the research without the influence of coercion, threats, or deception.

If you do not receive compensation for injuries or illnesses directly resulting from the research, or if you are not treated as outlined in this participant information sheet, you have the right to file a complaint with the Research Ethics Committee at Naresuan University. The contact details are provided below.

Thank you for your cooperation

If you have decided to participate in this research, please sign the consent form for this research study.

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	

Note*: If you wish to retain the remaining biological samples for future research, please attach document AF 04-10, the Participant Information Sheet for Research Study, to Request permission for the future use of

remaining biological samples (additional to the main research study).
Additional information as per the attached link.