**Informed Consent Form/Research Statement**

**(to aid volunteer’s decision making)**

**Research Project Title** …………………………………………………………………………………………………………………

Name of the Principal Investigator…………………………………………………………………………………………………………………

Research location …………………………………………………………………………………………………………………………….…………….

Sponsor(s) ……………………………………………………………………………………………………………………………………………………….

Before agreeing to participate in the study, you must be informed of the following:

|  |
| --- |
| * This is a research project NOT a treatment/data collection by a government unit. * You DO NOT need to participate in the study or MAY WITHDRAW at any time without losing any benefits to which you are entitled. * You may ask for further explanation from the research staff to help you fully understand all parts of this document. * You should be provided sufficient information and time to help you make the decision independently. You may bring this document to review further at home and consult with your family members, relatives, friends, physicians or health-related personnel in your personal life who can help you make the final decision whether to participate in this study. |

**(Blue texts are only sample texts to help guide researchers on how to write a statement and should be edited to best suit each individual project. Key information must include:**

**1) Risks and benefits**

**2) Use simple, non-technical, or English language. Offer illustration or diagram if appropriate.**

**3) Allow the volunteers independence in their own decision making including the alternatives should they wish to opt out.**

**● Provide brief description of the study**

Use simple, non-technical language to explain the problem that the study is trying to solve or include keywords used in the research.

**● Explain why the volunteer is invited to participate in the study**

* You are invite to join the study because …………………………………………………………………………..
* Duration of the study (months/years), total number of participants .................people

**● Explain how the data collected from this study is used?** (Use plain language to enhance understanding)

* The study aims to identify a new method that might be more efficient than the current one.
* Data collected shall be used toward resource management.

**● Methodology (drugs/substance/equipment/procedures) used in the research project** (some specific technical terms are allowed, otherwise use simple language to ensure clear understanding to those without any scientific background)

* There are two drug/substance used in this research including xxxx, manufactured by (company)………………………………………. and yyyyy manufactured by company zzzz. Drug/substance xxxx is approved by FDA of (name of country) ………………………………..….. while drug/substance yyyyy has been tested among (number) ### healthy volunteers and patients suffering from (number) ### individuals. Results prove that drug/substance xxxx serves an efficient treatment with manageable side effects.
* Equipment titled xxxxxx is designed to ………………………………………………………….
* Research method is …………... with purpose to ………………………………………………………………………..

**● Procedures for when you join the study (or how does this study relate to you)**

* Once you agree to join the project and sign the informed consent form, the researchers shall ask you to …………………..
* If the study involves drugs/substance/equipment/procedures, provide details such as frequency of appointments, number of times blood will be drawn, from which part of the body, amount of blood in teaspoon, tablespoon, how long is fasting required prior to the blood draw, will hospitalization be required, what position required when being examined by an equipment, for example.
* If a routine procedure is involved, specify routine vs research procedures.
* If a placebo is used, specify ratio between placebo recipients vs. drug/substance/equipment/procedure recipients (for example, this study organizes volunteers into two group through randomization – one is drug (avoid using the term “new drug” as it would entice the volunteers to use the drug) and placebo group (drug/substance/equipment/procedure that is similar to the testing drug/substance/equipment/procedure). The possibility for you to be in either group is 50-50 percent chance, like a coin toss). Explain how placebo group would be treated upon completion of the research.
* If interview is used, explain whether it is an interview or a questionnaire, duration of the interview or questionnaire, will there be any content that may cause the participant to feel awkward or uncomfortable.
* If risks of the drug/substance/equipment/procedure to pregnant women is unknown, a disclaimer should be provided such as: For female volunteers, should there be a possibility for you to become pregnant during the selection process, a blood test shall be conducted to confirm the pregnancy. You may not participate in the study if you are pregnant. Otherwise, you must seek advice on an acceptable birth control method. For male volunteers, if your partner cane become pregnant, you must agree to resort to at least two acceptable birth control methods including ……............................................................................

**● Benefits** (compensation is not included as benefits)

* You will not receive any direct benefit from the study but the data from your participation will contribute to develop new knowledge.
* Your symptoms/problems may respond well to drugs/substance/equipment/experiment and improve. However, it is also possible that the symptoms/problems may not improve or worsen.
* You will receive screening test results which will help you to seek early treatment for any problems you may discover.

**● Risk and discomfort and preventive measure/solution prepared by the researchers**

To help volunteers to make an informed decision, researchers must provide sufficient information, including any possible severe adverse events, risk mitigation plans and solutions.

* The possible risks associated with blood drawing are pain, minor bleeding, bruising that may last 3-4 days, infection (rare), and fainting. To minimize these risks, the researchers employ skilled nurse practitioners to perform the task.
* Drug/substance/equipment/experiment tested on #### of healthy volunteers show that the most common side effect is (XX %), second is (YY %), lastly is (xxx %). These side effects may improve over time or can be treated with …………………….. or by using ………………………..………….
* Multiple side effects should be listed using bullet points or in tables for easy reading. Technical terms must be simplified such as …………………………….

**● Your responsibilities as a participant**

* You must record ……………………………….in your notebook.
* If you can conceive a child, you must use birth control measure during the participation. Acceptable birth control options include ……………………………………………………………………………………………..
* You must report any abnormal symptoms the researchers.

**● How will your personal information will be stored, used, or shared?**

* Your data shall be recorded on a form which is securely kept inside a locked cabinet (Electronic filing shall be kept on a password-protected computer).
* On the research forms, your privacy is preserved using Identification number instead of your full name. Moreover, only the general research results may be published but without any identifiable information. None of your data can be transferred without your permission.
* Research project auditors and the PSU Human Research Ethics Committee, Prince of Songkla University may examine the record keeping system to ensure compliance.

**● You may withdraw from the project at any time**

* You may stop your participation at any time by notifying the individuals indicated in the document. Your decision to withdraw has no impact on the benefits you may receive. In any case, it is advisable to not stop the participation on your own without notifying the research staff. In some cases, sudden termination without proper monitoring may impose danger to your health.
* Once your participation is terminated, you may not return to the research project in the future. Upon termination, your data will no longer be added but other pre-termination data may be used to assess the overall research result.

Volunteers should be allowed to skip or stop answering any questions that make them feel uncomfortable.

* You may ask to skip any questions (or stop the interview altogether) should they make you feel uncomfortable.

**● You may be asked to leave the project without your agreement**

Volunteers may be asked to leave the project for some reasons such as

* Researchers may end your participation to protect your safety or when the research sponsors terminate the project due to the following instances:
* You are not able to follow the protocols.
* You violate the protocols.

**● Is there any fees to participate in the project?**

Itemized expenses and indicate clearly whether the participant is or is not responsible throughout the project participation.

* The research team is responsible for any research-related expenses such as medical fees, lab fees, travel fees.
* Even though you may not be responsible for expenses related to drug/substance/equipment/experiment that are utilized in the research, including ……………………………….…… However, you are responsible for any fee involved in any medical service you receive prior to joining the project.
* You are not compensated for joining the project but you will be reimbursed for travelling (or time) to be examined at the rate of xxx THB per trip.

**● What happens should your participation impose danger on your health?**

* You must immediately report to the research staff should you experience any adverse events or injuries as a direct result of participating in the research so to receive proper interventions. The research team (or the research sponsors) take full responsibility for any medical expenses or compensation according to the laws.

**● What happens when new information is discovered during the research?**

* You should be promptly notified upon any new discovery about the drug/substance/equipment/experiment that may have impact on your safety. You may use the information to decide further whether to continue your participation.

Should you have any concerns regarding the research protocols or experience adverse events, please contact **(Name responsible individual)........................................................... at (office address)………………………………….…………..Telephone number ……………………..…… (office hours) and (Cell phone ………..…………….………..) at any time.**

Should the researchers not follow the protocols as stated in this document, please report to PSU Human Research Ethics Committee at Telephone number 0-7428-6955 or E-mail: arunwan.s@psu.ac.th.

|  |
| --- |
| **IMPORTANT NOTICE:**  - You must be provided with a copy of the research statement and informed consent. Please keep it for your record and review when you may have any questions.  - The informed consent form must have 1) your signature 2) Signature of the individual who explained the document and 3) date of signature written by each person |