**Patient/ Participant Information Sheet**

***Instruction:****Need to use simple/lay language, avoid technical terms. (If used, give explanation in lay language)*

 *Do not copy content of research proposal/thesis as information for participant.*

*The information must be consequently arranged as follows.*

**Title of research protocol** ……………………………………………………………………………………………….

**Principle researcher’s name** ……………………………………………………………………………………………

**Position** ……………………………………………………………………………………………………………………………….

**Office address** ………………………………………………………………………...…………………………………………

**Home address** …………………………………………………………………………...………………………………………

**Telephone (office)** …………………………………………………………………………………………………………...

**Telephone (home)** ……………………………………………………………………………………………………………

**Cell phone** ……………………………………….. **E-mail:** …………………………………………………………………

1. You are being invited to take part in a research protocol. Before you decide to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and do not hesitate to ask if anything is unclear or if you would like more information.
2. This research protocol involves………………………………….(What researcher intend to do ……………)
3. Objective (s) of the project.
4. Details of participant.
	* Characteristics, including inclusion and exclusion criteria.
	* Number of participants needed.
	* How to approach potential participants.
	* Reason why this person is invited.
	* Group allocation and number of participants in each group.
5. Procedure upon participants : who, will do what, how, when, where, how much time involved as indicated in the research proposal.

If collection of data involves personal data of participant, tape recording, taking picture, taking participant’s blood/tissue/urine etc., these procedures need to indicate explicitly and easy to understand, for lay person. For example: amount of

blood by tea spoonful, (not ml.). After the end of the project personal data e.g. **tape recorder will be deleted, blood will be destroyed. If it will be kept for future studies, should be stated in the information.**

1. Process of providing information which also be stated in the proposal.
	1. Who will provide information to potential participants and how.
	2. If potential participant is illiterate/can not write/can not speak native language, how the researcher will proceed with the process of informed consent.
	3. In vulnerable group e.g. psychosis, prisoner, mental retarded, person under eighteen years old, pregnant woman, dementia, disabled, minority, drafted private, very sick person, refugee, etc., how informed consent is handled?
2. If the process of screening potential participant found a person not meet inclusion criteria and in need of help/advice, researcher needs to state what will be done for that person. (If screening needs information in medical records, consent from hospital authority required)
3. If intervention and data collection intervene with treatments, permission from responsible physician is required.
4. Use of medical record.
	1. Research involving medical records only, permission to access to medical records required.
	2. If procedure done upon patient and need information in medical record, permission to access to medical record is required and patient’s consent is needed.
5. Indicate risk/harm procedure which may cause ill effect to physical, mental, social, economic, belief of participants. State how the researcher has any preventive/protective measures toward those consequences. In case an ill effect occurs, state guideline how to handle the situation to help that participant.
6. For benefit of the project, state clearly; what/how to individual/public/ academy. Do not exaggerate benefit.

If study’s results proved beneficial, state what kind of benefit(s) researcher will share with the control group/community.

12. Information will include “participation to the study is **voluntary** and participant has the **right to deny** and/or **withdraw** from the study at any time, no need to give any reason, and there will be no bad impact upon that participant.” (state explicitly eg. still receive the same usual services)

13. Information will include “if you have any question or would like to obtain more information, the researcher can be reached at all time. If the researcher has new information regarding benefit on risk/harm, participants will be informed as soon as possible.” This practice will provide an opportunity for participants to decide whether to stay/not stay with the project. (**Exception**, in case of one time interview and unable to re-contact participants.)

14. Information will include “Information related directly to you will be kept **confidential.** Results of the study will be reported as total picture. Any information which could be able to identify you will not appear in the report.

15. State explicitly whether there is any compensation for time loss/inconveniences transportation fee etc. The amount should be appropriate, not too high as if to “buy” or not too low as to take advantage of participants.

16. State that if researcher does not perform upon participants as indicated in the information, the participants can report the incident to the Human Research Ethics Committee of Thammasat University (Science), (HREC-TUSc), Room No. 110, Piyachart Building, 1st Floor, Thammasat University Rangsit Campus, Prathumthani 12121, Thailand, Tel: 0-2986-9213 ext.7358 E-mail: ecsctu3@tu.ac.th