**Recommendations for writing an inform consent for research participants**

* The Informed consent form has been adapted from the "SIDCER" model designed to cover the required elements of Good Clinical Practice, the US Code and Regulations (45 CFR 46) and the Helsinki Declaration (2013) in a concise and easy-to-read format.
* Slanted text in large parentheses is the text that the researcher wrote.
* Some information in the "SIDCER" format may not be necessary for certain types of research, for example, alternatives to the treatment approach in Frame 2 may not be necessary for research in healthy participants. on the contrary, research in certain contexts may require additional information, such as regulatory information or national or local laws. In addition, consent forms may need to be adapted according to the nature of the research, for example, research involving vulnerable subjects may require the signature of a legitimate representative. Researchers must consider the data and elements relevant to their studies and adapt consent documents according to the format of "SIDCER" to suit the research.
* In the case of research projects conducted in children between the ages of 7≤13 years, the researcher shall produce an additional data sheet for children’s research participants (ScF 05\_04) using words that can be easily understood by the child.

**Suggestions:**

To make the inform consent for research participants easier to read and better understanding. After the researcher finished writing this document, researchers are encouraged to test the understanding from the lay person before submitting to EC. Researchers can also provide additional details in the attachment (if necessary).

**Note:**

Researcher can adjust the color or format as appropriate.

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| **Information Sheet for Research Participants**  **Title in English** *[Specify name of the research in English]*  **Title in Thai** *[Specify name of the research in Thai, if applicable]*   |  | | --- | | **Researchers***[Name all investigators, academic placement and qualification are not required]*  **Contact address** *[Specify the researcher's contact address with phone number /mobile phone/email address, for students using the address of the institution]*  **Research advisor***[Specify name of the advisor in the case of the thesis]*  **Contact address** *[Specify the advisor's contact address with phone number /mobile phone/email address]*  **Research funding source** *[Specify source of the research funding. If not, indicate that there is none or that the grant application is pending]* | |  | | |

You were invited to participate in this research project because you…. *[Specify the qualifications of the participants in this project, in summary]* The total number of suitable candidates to participate in this project is ……*[Specify the required number of participants]*

Before you decide whether to participate in this research project or not. Please take the time to read this document carefully. This will help you understand the things you will be involved in and you can always ask for more information or unclear information. We would like to emphasize that the decision to participate in this research project is voluntary (see frame 1). If you do not voluntarily participate in the project, it will not affect your medical care or rights. You will receive *[specify treatment options (if applicable) or standard treatment]* (see frame 2).

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| **Frame 1 The participation in this research project is voluntary**   * You can choose not to participate in this research project**.** * You may withdraw (withdraw consent) from this research project at any time, without affect to*[treatment rights and other related matters]***.** |

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| **Frame 2** Treatment options in case you do not participate in this research   |  |  | | --- | --- | | *- [Specify alternative treatment (if applicable)]* | *[Briefly* *explain the pros and cons of this treatment approach.]* | |

**Study-related information**

*[Summarize the principles and reasons for the research in a simple way for the lay person to understand. Avoid using technical terminology and copying from research outlines without editing.]*

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| **Frame 3** Research Method/Data Collection Method  *[Show the research methods in an easy – to-understand chart, including how to grouping the participants, how many groups, how many participants in a group (if any) and also specify the main processes of research]*  **Writing examples**  Divided into 2 groups  By randomized method  **Writing examples**   * This research use questionnaires to collect data from only one group of 150 participants. * This research was divided into two groups:  1. A group of 50 workers collected data using a questionnaire. 2. A group of 10 executives collected data through in-depth individual interviews. |

This study lasted approximately…. *[indicating participants' length of participation].* If you decide to participate in this study. We ask you to follow the study schedule (see frame 4).

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| **Frame 4 Procedures for conducting research in participants**   * *[Please specify a time table or chart by specifying part of the experimental process, such as how often and when of the appointments will be made, what kind of actions will be taken for each time, such as answering questionnaires, blood draws, urine collection, etc., by specifying the number of times, frequency, processing time, as well as the amount clearly indicated. In understandable units, such as teaspoons, tablespoons, cups, etc.]*   **Writing examples**  Exercise by swinging your arms in the morning and in the evening every day for 20 minutes for 4 months |

This research project aims to … *[Specify the objectives or briefly describe the research model]*

The side effects/risks and prevention/treatment from participating in this research project is summarized in Frame 5.

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| **Frame 5 Possible side effects or risks associated with participating in the study**  **and the prevention/treatment guidelines**   |  |  | | --- | --- | | **Side effects/Risks** | **Prevention/Treatment** | | *- [Identify the major or common side effects of the medication or study (if any).]*  *- [Identify risks such as physical, mental, social, or economic status and beliefs of the participants]* | *- [Identify the guidelines for prevention, assisting or treatment of the side effects/risks]* | |

The benefits of participating in the research project is summarized in Frame 6.

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| **Frame 6 Expected benefits from participating in this research project**   |  |  | | --- | --- | | **Direct benefits** | **Indirect benefits** | | *- [Identify direct benefits to participants (if any) If not, indicate that you may not directly benefit from participating in this research project.]* | *- [Identify indirect benefits to participants or the overall project benefits]* | |

The guidelines of treatment or care for the situations that may arise during the research is summarized in Frame 7.

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| **Frame 7 Situations that may arise during research**   |  |  | | --- | --- | | **Situations** | **Guidelines** | | If you withdraw your consent during the research | *[Explain how to treat participants after they withdraw their consent, such as requesting to store their blood for further research/destroying their data immediately.]* | | When there is new and important information that may influence your decision-making. | The researcher will inform you as soon as possible. You can decide whether you will continue to participate in this research project or not.  *[****Exception:*** *the guidelines must not be specified when the research conducts for answering a single interview, study only one time, or no longer able to contact participants.]* | | *[Identify the termination criteria for participation (if any)]* | *[Describe the incident management approach.]* | |

After completing the study, you will.. [explain how participants will receive care or guidance from the researcher. If not, indicate that the participants will receive standard care.]. Your information related to the study will be kept confidential. Presentations of the study results at any conferences or any scientific journals will not include your name. However, the Human Research Ethics Committee, Regulatory Authorities and Thai FDA (if applicable) will be granted direct access to your data for verify data and research procedures.

[This section specifies the handling of data or storage of the biological samples, such as questionnaires, voice recorder files, recording strips, blood, urine, etc. Once the research is completed, how will the researcher proceed? (specify one of the following)

1. Destroy data/samples according to standard methods as soon as research is completed. Clearly specify the type of data/sample.
2. To retain data/samples for......e.g. re-examination to confirm the accuracy of the results for a period of time.....(specify the exact time) by clearly specifying type of data/sample
3. We would like to retain data/samples for future research on the subject of ...........for (how many) ……. Years (by clearly specifying the type of data/sample. Identify how the retention process will be linked to participants' identities. Where to store and who can access to the samples) and states that before conducting the research, the research outline must be proved from the Ethics Committee.)]

Summarization the fare, cost of waste time and expenses in participating in the research are shown in Frame 8

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| **Frame 8 Fare, cost of waste time and expenses for participating in the research**   * *[Specify the providing of the fare, cost of waste time for participating for each time of visits in details (if not, indicate that the participation in the research does not provide the fare and cost of waste time to the participants).]* * *[Clarify the details of the expected costs for the participants (if any) and the costs that the researcher will be responsible for the research project]* * *In the case if you get harm or illness related to the research. We will… [explain the management/care/responsibility] by the researcher.* |

If you have any questions either before or during the study, or if any side effects occur during your participation. You can inquire from the persons in Frame 9

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| **Frame 9 persons to contact for more information**  1. *[Specify the person’s name]*  Telephone *[provide both work and mobile phone numbers]* Email *[Specify]*  2. *[Specify the person’s name]*  Telephone *[provide both work and mobile phone numbers]* Email *[Specify]* |

If you have not been treated that indicated in the Information sheet for research participants, the complaints can be made to the Human Research Ethics Committee of Thammasat University (Science), Room No. 112, 1st Floor, Dome Administrative Building, Thammasat University, Rangsit Campus Tel. 02-564-4440 ext. 7358 Email ecsctu3@tu.ac.th

You will receive a copy of the Information sheet for research participants and a copy of the Consent Form for research participants with both signature and date.

*[This section the researcher(s) can disclose the conflicts of interest related to the research project (if any).]*