# Application Form for Ethics Review

1. Title (English) …….
2. Full Name of principal investigator ……

   Position; Student/ Researcher/ Lecturer ……..

   Institution ……

   Telephone/Mobile phone ……

   E-mail Address: ……..
3. The protocol involving population/participants as human subjects: Population/sample group Is it a human being or a cell? Cell components, materials, specimens, tissues, secretions, genetic material, medical records, or health information.

   ☐ No (Not relevant to be considered for ethical approval of research in humans)

   ☐ Yes (relevant to be considered for ethical approval of research in humans)
4. The protocol involving the population/participants as human subjects is as follows.

   4.1 Vulnerable

   ☐ Psychosis ☐ Prisoner

   ☐ Younger than 18 years ☐ Pregnancy

   ☐ Senile dementia ☐ Dementia

   ☐ Disabled ☐ Mental retardation

   ☐ Refugee ☐ Drafted private

   ☐ Minority/different religion

   ☐ Having disease (specified) .....

   ☐ (Others) .....

   4.2 Non-vulnerable ……...
5. Number of places to collect data …….. (specified)

   …….

   Data storage location that has an ethics review committee. (specified) ……....

   ……
6. Funding Agency (specified)……..…

   ☐ Under consideration ☐ has been approved

   Amount/fund received …… Baht

7. Thesis proposal/research proposal that indicates its ethics application has been reviewed and approved by ……. (Date) …….

8. Other agencies/institutions for research study (jointed research)

……...

……

Thesis Name of other institutions (multi-centered study)

9. Trey of Approval

⬜ Exempted (Reasons).....

⬜ Expedited) (Reasons).....

⬜ Full board

10. Attached documents.

| | | Yes | No | Official used |
|---|---|---|---|---|
| 10.1 | Memorandum for thesis proposal submission (EC_SAU 01_01) / Research protocol (EC_SAU 01_02) | ⬜ | ⬜ | ⬜ |
| 10.2 | Application Form for Ethics Review (EC_SAU 01_03) | ⬜ | ⬜ | ⬜ |
| 10.3 | - Patient/ Participant Information sheet (EC_SAU 01_04)<br>- Consent Form for research participants (EC_SAU 01_05)<br>- Adolescent Assent Form for research participants aged between 12 and <18 years old (EC_SAU 01_06)<br>-Information Sheet and Assent Form for research participants aged between 7 and <12 years old (EC_SAU 01_07)<br>- Consent form for parents or guardians of research participants aged between 7 and <12 years old (EC_SAU 01_08)<br><br>**Note:** If there is a request to collect information from a foreigner Submit the local language version (non-Thai language) that has been authenticated for consideration as well | ⬜<br>⬜<br>⬜<br>⬜<br>⬜ | ⬜<br>⬜<br>⬜<br>⬜<br>⬜ | ⬜<br>⬜<br>⬜<br>⬜<br>⬜ |
| 10.4 | Work plan of every activity **including time requesting for research Ethics Review Board's approval** | ⬜ | ⬜ | ⬜ |
| 10.5 | Research Protocol; with details, including EC_SAU 01_02 | | | |
| | 10.5.1 Project Name | ⬜ | ⬜ | ⬜ |

| | | Yes | No | Official used |
|---|---|---|---|---|
| | 10.5.2 Principal Investigators/Co-Investigators including percentage of workloads | ☐ | ☐ | ☐ |
| | 10.5.3 Rationales/Background of the problem | ☐ | ☐ | ☐ |
| | 10.5.4 Research objective | ☐ | ☐ | ☐ |
| | 10.5.5 Scope of Study | ☐ | ☐ | ☐ |
| | 10.5.6 Conceptual Framework | ☐ | ☐ | ☐ |
| | 10.5.7 Research Methodology and Study Design | ☐ | ☐ | ☐ |
| | 10.5.8 Contact method details/ How to access research volunteers | ☐ | ☐ | ☐ |
| | 10.5.9 Research Schedule throughout the project (Timetable in each month identified all research steps including ethical review committee submission) | ☐ | ☐ | ☐ |
| | 10.5.10 Human Subjects Protection | ☐ | ☐ | ☐ |
| | 10.5.11 Expected Benefits | ☐ | ☐ | ☐ |
| | 10.5.12 References | ☐ | ☐ | ☐ |
| | 10.5.13 Appendix<br>1) Research instruments (such as questionnaire, interview guidelines, and evaluation form)/ experimental program/ teaching plan/ teaching manual/ training program were approved by experts)<br>2) etc.. | ☐<br>☐ | ☐<br>☐ | ☐<br>☐ |
| 10.6 | Curriculum vitae (EC_SAU 01_02) | ☐ | ☐ | ☐ |
| 10.7 | A copy of the Certificate of Ethics Attendant / GCP Training for the principal investigator.)<br>Other documents e.g.: Advertising leaflet for potential participants etc., Specified …….....…… | ☐ | ☐ | ☐ |
| 10.8 | The CD contains the information included in (10.1) - (10.7) | ☐ | ☐ | ☐ |

11. Disclosure of Conflicts of Interest

☐ No ☐ Yes (explain details) ……..

12. I am willing to abide by the conditions of the subcommittee as follows:

12.1 The researcher is aware that it is unethical if the research data has been collected before receiving approval from the Human Research Ethics Subcommittee.

12.2 If the research is not completed according to the certified deadline (1 year), the renewal of the certification, along with the research progress report (document form EC_SAU 01_09) must be requested and submitted, respectively, at least 1 month in adv.

12.3 The researcher(s) must strictly carry out the research activities as mentioned in the proposal.

12.4 Use the information sheet for research volunteers (document form EC_SAU 01_04), the letter of consent to participate in the research (document form EC_SAU 01_05/ EC_SAU 01_06/ EC_SAU 01_07/ EC_SAU 01_08), the tools used in the research. and the invitation to participate in research (if any) **only with the seal of the subcommittee.**

**12.5 If the violence results in a fatality, the research activities must be stopped immediately, and the report must be presented to the subcommittee within 24 hours from the date of the unusual event occurring with the research subjects.**

12.6 If there is any change in the research operation, the revised research project to the subcommittee for approval before proceeding (document form EC_SAU 01_10), must be submitted.

12.7 Research projects are accredited for no more than 1 year at a time.

12.8 Upon completion of the research project, the researchers must submit a report summarizing the research results (document form EC_SAU 01_11) along with one electronic file within 30 days. For a thesis research project, the same report must be submitted.

13 Intention to receive the certificate (Choose one)

⬜ Thai

⬜ English

(Name in English) ……

| | |
|---|---|
| …… | …… |
| (……) | (……) |
| Principal advisor (if applicable) | Principal Investigator/Student |
| Date ……../……/……. | Date ……../……/……. |

Approval of request for ethics review

……

(……)

Date ……../……/…….

# Attached documents (1)

**1. Research proposals that can be exempt from research ethics consideration: Exemption**

Including a research outline that has one of the following characteristics:

**1.1 Educational research project**

1.1.1 Carry out in an institution or a place where education is accepted **and**

1.1.2 It is research related to teaching and learning according to educational standard practices **and**

1.1.3 Involves evaluating the effectiveness of teaching techniques, curriculum assessment, classroom management methods, and education quality assurance.

**1.2 Research projects that use educational test results or projects that use survey methods. or interview or observe public behavior.**

1.2.1 If educational test results or data recording forms of the agency are used consent from the person responsible for the information must be received first.

1.2.2 Data recording cannot trace the identity of the owner of the data. or reveal the identity of the owner of the information **and**

1) Research data is not related to sensitive issues such as sexual behavior or attitudes, alcohol or drug addiction other immoral or legal acts, mental illness, or infectious diseases that are not socially accepted such as HIV and AIDS, tuberculosis, etc., **and**

2) Disclosing the results of individual responses does not create a person's risk of punishment, or damage to the body, mind, reputation, career, and financial status, and any benefits and rewards that should be given to the person who owns the information or the institution.

**1.3 Research projects in public services**

1.3.1 It is a demonstration project. or survey project or a work system assessment project that has been approved by the supervisor or person responsible for the organization **and**

1.3.2 The objective is to evaluate efficiency. or study alternatives or develop work systems or policies, **and**

1.3.3 No personal names or personal information of project volunteers will be disclosed.

**1.4 Food, products, and services satisfaction survey projects**

1.4.1 Food products or products or services do not contain any ingredients that are addictive or harmful to humans. or environment **or**

1.4.2 The food or products or services do not cause any harm to the health of consumers that have passed safety certification from the Food and Drug Administration. or related agencies.

**1.5 Research projects in the laboratory** include:

1.5.1 Project that uses microorganisms isolated from specimens (Isolated microorganisms) and cultivated in the laboratory as strains. and there is no information linked to the owners **or**

1.5.2 Project that uses cultured cells from human tissue that have been conditioned into cell lines.

1.5.3 Projects using samples from skeletons or the corpse of the headmaster of the Faculty of Medicine (Cadaver) or teeth that have been extracted in the normal course of dental work.

1.5.4 Projects that search for chemical contaminants, pathogens, or biological substances that do not directly affect volunteers.

**1.6 Meta-analysis or systematic review that cannot trace the individual owner of the data. or reveal the identity of the owner of the information.**

The research project must not involve prisoners, pregnant women, in vitro fertilization, fetuses, deception, forgery, identifiable student academic records, an interview with a teacher about a particular student, or interviewing children under 18 years of age and observing behavior in public places where the researcher engages in that behavior.

**2. Research proposals that can be considered for expedited review: Expedited**

Including a research outline that has the following characteristics.

**2.1** The research method has little risk to the volunteers (minimal risk*), meaning the risk is no greater than the risks in everyday life.

**2.2** This is research that was not conducted among weak and vulnerable people (Vulnerable subjects) **

**2.3** If there is a risk of invasion of privacy and may reveal the secrets of the volunteers, the researcher has implemented appropriate prevention methods so that the risk is no greater than "minimal risk."

**2.4** The research that does not directly affect the volunteer's body, such as studying blood samples or biopsy samples that are already in the laboratory.

**2.5** Collection of blood samples using a Piercing needle on fingertips, heels, ears, or venipuncture of healthy, non-pregnant adult volunteers. The amount of blood drawn must not exceed 550 ml within 8 weeks up to twice a week.

**2.6** Collection of biological specimens or biological specimens in advance for research using noninvasive methods such as cutting hair and nails in a way that does not cause disfigurement or teeth obtained from extractions during normal treatment, or external secretions

such as sweat and placenta from giving birth, amniotic fluid obtained from the rupture of the amniotic sac or during childbirth, skin cells collected by scraping, cheek mucosal cells collected by doing a buccal swab, mouth washing, collected sputum after spraying with saline, etc.

**2.7** Collection of data on routine treatment without invasive procedures such as MRI, ECG, EEG, ultrasound, doppler blood flow, echocardiography, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of an individual, etc. This does not include treatment or procedures that require anesthesia or sedation, X-rays, or microwaves.

**2.8** Research involving materials (data, documents, reports, or samples) that have already been collected or are about to be collected for purposes other than research, such as disease diagnosis. or treatment of disease.

**2.9** Research proposal with interviews or questionnaires and the collected information is not confidential information. or sensitive information such as sexual preferences, family violence, illegal behavior, destroying the beliefs of the community, etc., and not causing damage to the status or rights of the individual and not offending the sensitivities of the community concerned.

**2.10** Collecting data from audio recordings, video recordings, or images for research purposes.

**2.11** Behavioral research for a single person or group of people or survey research, history interview, focus group, program evaluation, or methods of quality assurance.

**2.12** Research on medical devices with insignificant risks (non-significant risk) and clear indications accepted according to standards.

**3. Definition**

* **Minimal risk** refers to the chance and size of the danger. or the discomfort expected from the research that is not beyond what happens in everyday life.

** **Vulnerable Subjects** refer to individuals who may be easily influenced to participate in clinical research with the hope that the benefit from participating in the research might be received whether it is reasonable or not or agreed to participate in the research due to the fear of being harassed by a superior against refusal.