Explanations and Suggestions
for
Approval of Human Research Protocol

By

Office of The Human Research Ethics Committee,

Suranaree University of Technology

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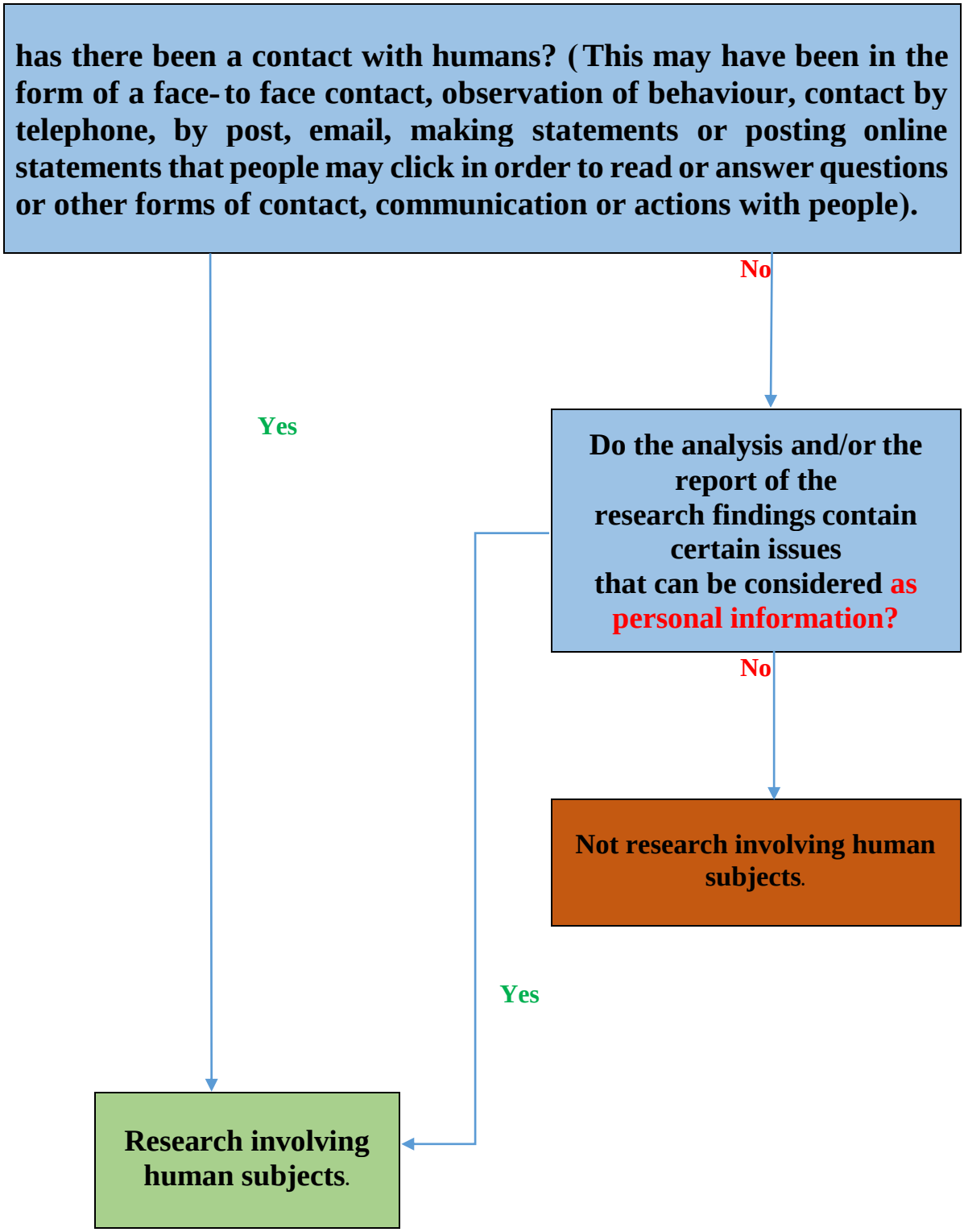
Does this research project require an ethics review for research involving human subjects?



Explanations and Suggestions for Approval of Human Research Protocol
The Human Research Ethics Committee, Suranaree University of Technology

Objectives

1. To comply with international standards in protecting those who are involved in human research, Suranaree University of Technology has appointed "The Human Research Ethics Committee" in accordance with the University's Regulations, Stipulating the Promotion of Ethics in Research Involving Human Subjects.
2. To protect of the rights and welfare of the research sampling population or participants so as to enable the research procedure to continue correctly according to ethics in research involving human subjects, which are accepted at the national and international levels.
3. To review research projects in Biomedical, social sciences, humanities, as well as other related fields in order to help to prevent faculty members, researchers and graduate students who conduct research for their theses from facing problems when they apply for research funding from outside sources or when they have their academic work published in national or international journals or when they apply for an academic appointment.

Scope of Responsibility

The Human Research Ethics Committee, Suranaree University of Technology is assigned with the following responsibilities:

1. Considering full research proposals/full thesis proposals and reviewing the research procedure, with emphasis on the steps and methods used in collecting information from humans and the ethics in research involving human subjects as well as the researcher's readiness to conduct research projects submitted to the Committee.

2. Reviewing, at the appropriate time and at least once a year, the progress of the research and risks to the research sampling population/participants. The Committee also has the right to observe the consent process involving the research sampling population/participants as well as other processes related to their rights and welfare.

3. Imposing suspension, withdrawal or termination on the research project in cases where it might cause more risk to the research sampling population/ participants than had been expected or in cases where the research fails to comply with the ethical principles of research involving human subjects or fails to observe those principles in a consistent manner. Such a decision has to be made by the consent of a full board meeting of the Human Research Ethics Committee and evidence of this consent must be recorded in writing.

4. Limiting the scope of the research project or suspending the execution of certain parts of it in cases where the researcher fails to comply with the ethical principles of research involving human subjects according to those specified by the Committee, which are a condition required for the approval of the research project which may only be conducted after the researcher has complied with the said specifications and the principles.

Research Project Review Categories

There are three categories of review for full research proposals/full thesis proposals, namely, Exemption Review, Expedited Review and Full Board Review, details are as follow:

The First Category : Exemption Review

Research protocols that can be exempted from ethical review of the EC are mandatorily required to be under the following criteria:

1. Education researches that are conducted in accredited educational institutes and related to regular processes of education, and studies of new strategies in education administration according to the policy of the institutions, e. g. , researches on adjustment of teaching methods for school and university students of the entire class which may be done through comparison of scores or a study of efficiency of school and university students of the entire class in particular subject regarding the teaching method of the syllabus that has been adjusted, for syllabus evaluation or assurance of educational quality.
2. Applied research protocols on educational evaluation of cognitive, diagnostic, aptitude, achievement, survey on generalized public opinions, interviews or behavior observation of a specific group of people; the research protocols are exempted from ethical review under the following conditions:
   2. 1 Data collection process and the data are not related to any private information or not personally identifiable.
   2. 2 No part of the protocol leads to criminalization of or civil litigation against any subject or insecurity of job or carrier of a person.
3. Research on known results which are non-specific and non-identifiable to any person such as a retrospective study of the ten years cumulative pathological findings of biopsied kidney specimens.
4. Research related to micro-organisms that are cultured in laboratory or on micro-organisms that have been isolated from samples which are not related to any identifiable personal identity.
5. The research is related to the study of commercially available human related cell lines and laboratory isolated human cell, which product resulted from the study will not be used in human.
6. Research on policies, strategies which are commissioned under the approval of the institutes to search for new alternatives of organization reengineering, development of efficiency in work to achieve certain international standard that are not related to any identifiable personal data, and not against any rule of law.
7. Research on flavor, quality of food and consumer satisfaction in general, given that the food sample is safe and conformed to the standard of the Office of Food and Drug Administration.

Report Note.

1. The exemptions do not apply to research involving vulnerable participants. The CIOMS International Ethical Guidelines for Biomedical Research define "vulnerable persons" as "those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests"
2. Any research that is conducted specifically to a public group or candidates running for public offices, the research protocol is not exempted from ethical review.

The Second Category : Expedited Review

Research projects eligible for expedited review are those whose research process or research procedures are of a low level risk—meaning that the risk does not exceed the kind of risk that may affect people's daily lives in general and for which the researcher has appropriate measures and methods to prevent such low level risk. The research must not be conducted on a vulnerable/deprived group and research projects should comply with the characteristics of one of the following items:

1. Expedited review will be conducted by chair or an experienced board member appointed by chair.
2. Applicability:
   2.1 The research activities that present no more than minimal risk.
   2.2 If identification of the subjects or their responses place them at risk, the reasonable and appropriate protection must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
   2.3 Minor changes in previous approved research which no additional risks involved.
   2.4 Recruitment materials which the standard requirements of informed consent have been applied.
   2.5 Research activities that are not directly involved with living human e.g. study of donated organs or bodies.
3. Research activities that involve procedures listed in the following categories may be reviewed through expedited review process.
   3.1 Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from healthy, non-pregnant adults who weigh at least 50 kg (110 pounds). For these subjects, the amounts drawn may not exceed 550 ml in an 8 weeks period and collection may not occur more frequently than 2 times per week.
   3.2 Blood samples taken from volunteers other than 3.1, age, weight, and health condition of the volunteers must be considered. In general, 3 ml/kg body weight within 8 weeks and collection not occur more frequently than 2 times per week is possible; however, total blood quantity should not exceed 50 ml.
   3.3 Prospective collection of biological specimens for research purposes by noninvasive means e.g. hair or nail clipping in a non-disfiguring manner, teeth if routine patient care indicates a need for extraction, external secretion (include sweat), placenta removed at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, mucosal and skin cells collected by buccal swab or scraping or mouth washing, sputum collected after saline mist nebulization, etc.
   3.4 Collection data through noninvasive procedures routinely employed in clinical practice (exclude x-rays or microwaves) e.g. physical sensors that are applied either to amounts of energy into the subject or an invasion of the subject's privacy, magnetic resonance imaging, ECG, EEG, ultrasound, Doppler blood flow, echocardiography, moderate exercise, body composition measurement.
   3.5 Examining materials (data, records, documents, specimens) that have been collected or will be collected solely for non-research purposes (such as medical diagnosis or treatment).
   3.6 Collection of data from voice, video, digital, or image recordings made for research purposes.
   3.7 Research on individual or group behaviors or research employing survey, interview, oral history, focus group, program evaluation, or quality assurance methodologies.
   3.8 Continuing review of protocol previously approved without non-compliance/ deviation/ violation.
   3.9 Protocol amendment with which no additional risks have been identified.
4. Expedited reviewers can exercise all of the authorities of the board except disapproval. Expedited reviewers may approve the protocol or refer to the full board otherwise.
5. Case report

The Third Category: Full Board Review

A research work involving human subjects might present risks at a high level—that is risks that are higher than those that happen in people's daily lives. Also, this applies to a research project involving human subjects belonging to a vulnerable/deprived group, which requires special care and, especially, experimental or semi-experimental research and research conducted through workshops or complicated research; all have to go through the full board review.

"The Vulnerable Group" and the "Deprived Group" consist of 1) neurosis patients, 2) children under 18 years of age, 3) the elderly with memory deficiency, 4) patients with dementia, 5) waiters/waitresses in night entertainment venues and massage parlors, 6) people with mental deficiency or with a short attention span, 7) patients with seriously infectious diseases, 8) minority groups from different racial/religious backgrounds, 9) inmates/the accused/defendants in criminal cases, 10) gamblers/ waiters in gambling houses, 11) the crippled, 12) men /women who sell sexual services, 13) people of an alternative sex,14) pregnant women, 15) immigrants/displaced persons/transnational laborers, 16) conscripts, 17) drug addicts.
Some of the people in items (1) to (17) are not considered to be vulnerable or deprived, for example, pregnant women who are asked to answer online questionnaires about their purchasing behavior or normal children of 15 years of age, being asked to answer online questionnaires about their reading behavior.

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World Health Organization (WHO). 2011. Standard and Operational Guidance for Ethics Review of Health-related Research with Human Participants.

Steps in Applying for an Ethics Review of Research Involving Human Subjects

Document List*	Social/Anthropological studies	Clinical/Biomedical
1. Protocol form	AF/01-08/02.0	AF/17-08/02.0
2. Conflict of interest form	AF/03-08/01.0	
3. Participant information sheet	AF/21-08/01.0	AF/20-08/01.0
4. Informed consent form	AF/23-08/01.0	AF/19-08/01.0
5. Waiver of consent form	AF/16-08/02.0	
6. Memorandum	AF/15-08/02.0	
7. Progress/renew	AF/01-12/01.0	
8. Amendment	AF/01-11/01.0	
9. Protocol Deviation/Violation Report	AF/01-14/02.0	
10. Adverse Event and Problem Report (Investigator Initiated)	AF/03-17/02.0 AF/02-17/02.0	
11. Suspect Adverse Reaction Report (CIOM Form)	AF/01-17/02.0	
12. Final report	AF/01-13/01.0	
13. Clarification on questions or suggestions of the committee	AF/22-08/02.0	

* specify version and dated

The officers of the Human Research Ethics Committee will accept a full proposal together with other related documents in the first submission. The documents that the principal investigator (PI) is required to submit consist of the followings:

1. A letter stating the PI's intention to submit the research project for the Human Research Ethics Committee (AF/14-08/02.0 or AF/15-08/02.0 (for student))
2. A research protocol form requesting an ethics review of research involving human subjects. Either (AF/01-08/02.0 or AF/11-08/02.0) should be selected for the research project depending on the suitability.
3. Documents providing participants information for the research sampling population/ participants. In cases where the research participants are 8 -17 years of age, they must be provided with documents and information written in a simple language that is easy to understand and appropriate for their age. Either (AF/21-08/01.0 or AF/20-08/01.0) should be selected for the research project depending on the suitability.
4. A consent letter from the research sampling population/participants. Either (AF/23-08/01.0 or AF/19-08/01.0) should be selected for the research project depending on the suitability.

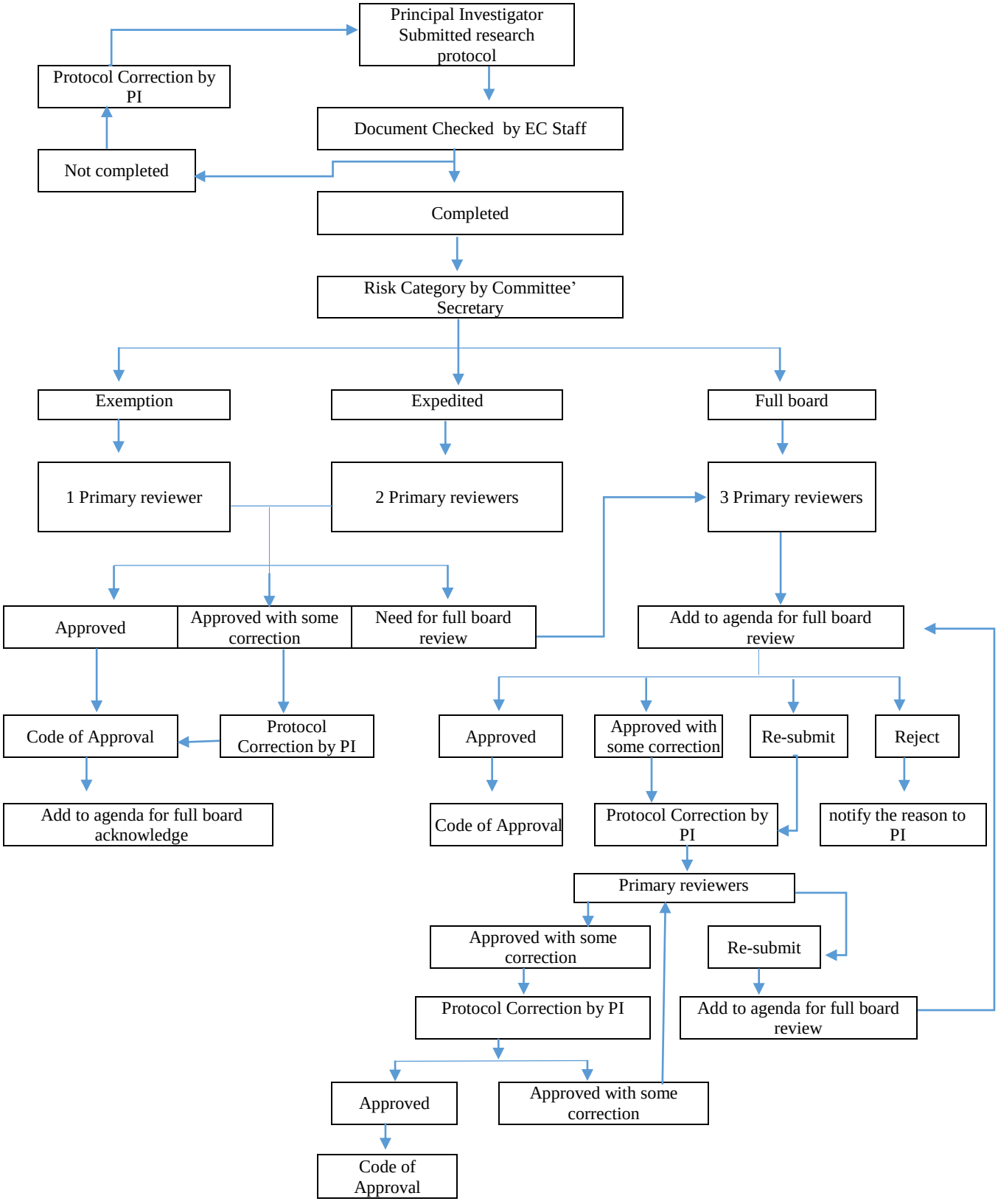
Note:

1. In cases where the research participants are 8 -17 years of age a consent form must be co-signed by their parent(s) or their guardian(s).
2. The researcher may request for exemption from a consent form in cases where the risk of the research is at a low level, for example, a research project that uses questionnaires that do not state the names of responders, a research that collects information from telephone interviews, a research about human subjects that uses secondary information for analysis or where signing the consent form may cause damage because it is a way of revealing confidential information about the participants, for example, collecting information from drug addicts, from HIV infected patients, from those who have sexually transmitted diseases and from service women.

5. The Certificate for human subject protection training of the PI and research team members.
6. The CVs of the PI and research team members to show their experience and their readiness to conduct the research. (Sign the document)
7. A full research proposal/full thesis proposal that page being provided with a page number.
8. Other documents related to the research project, namely, detailed programs of activities, questionnaires, posters for advertising, leaflets and brochures.
9. Conflict of interest form (AF/03-08/01.0)
10.Fee for review (if any)

Note:
The documents about the research project and other related documents that the PI must submit at the First Submission to the Ethics Review Committee will be completed :
1. When all the documents of a research project have been submitted to the Office of the Human Research Ethics Committee, be sure to following the 1-10 list above.
2. When all the documents have been signed by the researcher and all the involved persons.
3. Specify the document number from Institute.
4. When the research related documents have been signed by the research supervisor, in the case of a postgraduate research.
5. When all the documents have been uploaded in the online submission system at https://ec.sut.ac.th/index.php
6. When a hard copy of all the documents has been submitted at the office of Human Research Ethics Committee, Institute of Research and Development

Flow chart for review



The Research Documents and Related Documents to Be Submitted when Corrections are needed

When there are corrections to the research documents and related documents, the Principal investigator has to re-submit the following research documents and related documents for the Committee to review:

1. A letter showing the intention to submit the documents for a review (AF/22-08/02.0).
2. A chart showing corrections that have been made in detail (AF/22-08/02.0).
3. A copy of the notification of the result of the first review from the Office of the Human Research Ethics Committee.
4. The documents (version 2.0) that have been corrected according to the notification of the result of the review from the Office of the Human Research Ethics Committee.

Criteria for an Ethics Review of Research Involving Human Subjects

There are three criteria for an ethics review of a full research proposal/full thesis proposal as follows:

1. Research Procedure and Management of the Research Project

1) The submitted research procedure must be correct and appropriate in accordance and in accordance with the research objectives.
2) The criteria for selecting the research participants show that everyone is equally treated.
3) The criteria for selecting people to join the research project, for excluding them, and for withdrawing them from the project are appropriate.
4) Preventative and cautious measures for risk, illness, inconvenience or unsafe situations that may affect the research participants are appropriate.
5) Proportion between risks and benefits expected to be gained from the research is appropriate
6) Research participants should not be coerced, deceived or inappropriately persuaded to join the research project; they have the right to reject or withdraw from the research at any time without losing the benefits to which they are entitled.
7) There should be specific guidelines for keeping information about the research participants confidential.
8) There should be sufficient supporting reasons for bringing the vulnerable/the deprived into the research project and there should be logical measures for danger prevention.

2. Protection of the Rights of the Research Participants

1) Documents providing information for the research sampling population/ participants (AF/21-08/01.0 or AF/20-08/01.0), with sufficient information that is comprehensive, concise and written in language that is easy to understand.
2) A letter of consent from the research sampling population/participants with statements describing the characteristics of the research project, what the research participants have to do, the duration of their participation, their willingness to take part in the research project and how to keep information about the research participants confidential. (AF/23-08/01.0 or AF/19-08/01.0)
3) Providing the research sampling population/ participants with a photo copy of documents that provide information for them and a photo copy of their letter of consent, to be kept as evidence thereof.

3. Review of the Researcher and Things Used for Conducting the Research

1) The researcher's knowledge and abilities, experience and readiness to conduct the research.
2) Sufficient facilities/objects/instruments.
3) An appropriate budget for administering the research project according to the plan (This can be the researcher's own budget or the budget allocated by the source of financial support).

Results of an Ethics Review of Research Involving Human Subjects

1. The First Category : Exemption Review
2. The Second Category : Expedited Review
3. The Third Category: Full Board Review

The review results come in 4 types as follows:

The 1st type (A) - Approved The proposal is approved or certified without requiring any corrections. The Office of the Human Research Ethics Committee will notify the result of the review and issue a certificate within seven days.

The 2nd type (B) - Approved with some corrections The proposal requires corrections even though the research procedure and different research stages are appropriate. However, certain issues concerning ethics in research involving human subjects still need to be improved; for example, an unclear framework or concepts, random sampling, random sampling techniques, research instruments (for example, questionnaires, statistics used for analyzing a research work that depends on statistics), different stages of checking while collecting the information and risk prevention having been not sufficiently secure. All these may affect the risk for the research participants. The Office of the Research Ethics Review Committee will notify the review result to the researcher within seven working days.

The 3rd types (C) -Resubmission The proposal requires corrections and to resubmission because the research procedure and different research stages are not adequately appropriate or certain issues concerning ethics in research involving human subjects need to be more improved. After the proposal has been corrected, the researcher must submit a copy of the research proposal/thesis proposal for full board review. If there is no problem, the Office of the Human Research Ethics Committee will notify the review result to the researcher within two weeks after the meeting.

The 4th type (D) -Reject The research proposal cannot be approved or certified because the research procedure and the steps in the research procedure are totally inappropriate, and the research contains many issues that contradict the ethics of research involving human subjects. This may have a negative impact on or cause harm to the research sampling population/ participants that belong to a vulnerable/deprived group.

*** The Office of the Human Research Ethics committee will notify the review result to the researcher within two weeks after the full board meeting of the Committee.

Notes

1. In cases where the research proposal/thesis proposal needs corrections— whether it be major or minor correction— the researcher can contest this if he/she does not agree with the review result or the opinions and suggestions of the Committee.
2. In some cases, the Committee may invite the researchers for discussions in order to make the corrections more convenient and rapid.
3. The researcher must make corrections within the deadline specified in the document notifying the review result. Failure to proceed with the corrections will be taken as his/her decision not to receive certification from the Human Research Ethics Committee.
4. If the researcher does not correct the research proposal/thesis proposal and resubmits the uncorrected version for the Committee to review, whether it be the 2nd or the 3rd category of review, the Office of the Human Research Ethics Committee will proceed with those steps which have been taken during the first review.

Conditions after the Research Proposal Is Approved

1. The applicant for a certificate (a faculty member, a researcher or a graduate student) must note that it is unethical if he/she collects information for the research before the application for an ethics review has been approved or certified by the Human Research Ethics Committee.
2. If the certificate of the research project expires but the collection of the information in/with/from human subjects has not yet finished, the researcher must halt the collecting process and re-apply for approval. This has to be done one month or thirty days in advance before the expiry of the certificate, together with the submission of a research progress report (Renew or Progress Form, AF/01-12/01.0). If the research only requires compiling the information results, analyzing the information or writing a research report, the researcher does not have to apply for a new ethics certificate.
3. The researcher must conduct the research strictly in accordance with what is specified in the full research proposal/ the thesis proposal. If you have Protocol Deviation/Violation Report use AF/01-14/02.0
4. The researcher must only use documents that provide information for the research sampling population/participations, their letters of consent and the letters inviting them to take part in the research (if any), which have been endorsed with the seal of the Committee.
5. If any seriously untoward incident happens to the place where the research information, which has requested the approval of the Committee, is kept, the researcher must report this to the Committee within five working days. Adverse Event and Problem Report (Investigator Initiated), AF/03-17/02.0 or AF/02-17/02.0) or Suspect Adverse Reaction Report (CIOM Form), AF/01-17/02.0.
6. If there is any adjustment or change in the research procedure, the researcher must submit the adjustment or change for review by the Committee before he/she can continue with his/her research (Amendment Form, AF/01-11/01.0).
7. For a research project of less than one year, the researcher must submit a report of the research termination and an abstract of the research outcome within one month or thirty days of the research being completed (AF/01-13/01.0). For a research project which is a thesis, the researcher must submit an abstract of the research outcome within one month or thirty days of the research project being completed and the thesis being submitted.

Notes

1. The officers of the Human Research Ethics Committee will affix the seal of the Human Research Ethics Committee, the number of the research project, the date of certification and the expiry date on the documents that provide the information for the research sampling population/participants, their letters of consent, instruments and other related documents that are used to accompany the research; for example, publicizing documents.

2. The researcher must use those aforementioned documents whose contents match the ones bearing the seal of the Committee. When such documents are legitimately used, the researcher must submit a set of the documents to the Office of the Human Research Ethics Committee will affix the seal of the Human Research Ethics Committee, to be kept as evidence.

Where to Apply for an Ethics Review

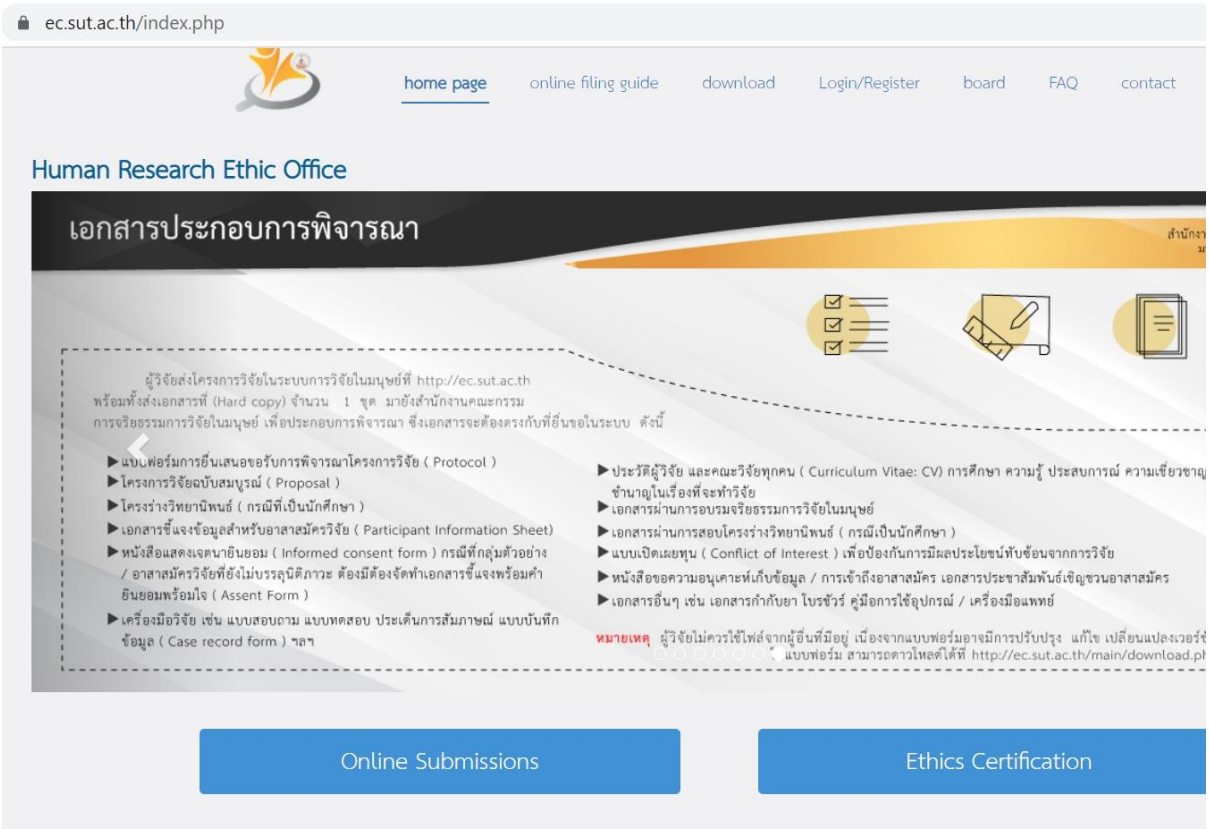
1. Online Submission
Submit and download research documents at https://ec.sut.ac.th/index.php

2. Submission of a hard copy

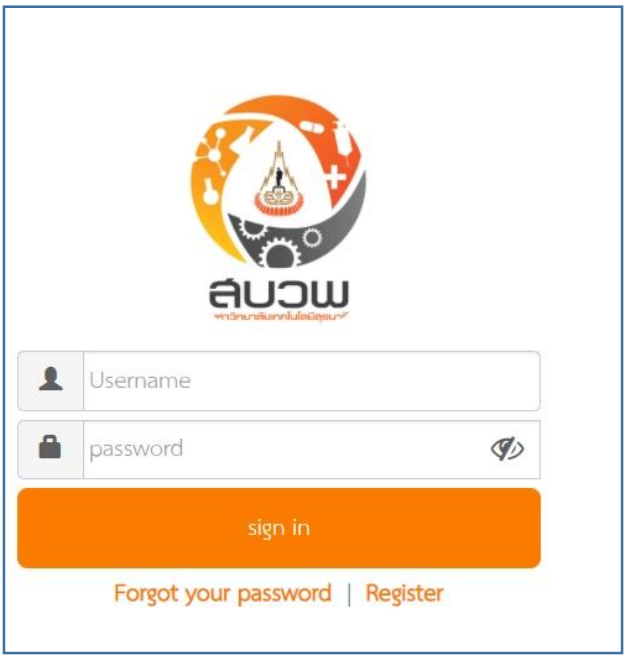
The Office of the Human Research Ethics Committee, Suranaree University of Technology
Institute of Research and Development
Suranaree University of Technology
111 University Avenue, Suranaree Sub-District, Muang District, Nakhon Ratchasima 30000
Telephone 044 224757
E-mail: ecsut@sut.ac.th

How to Submission online

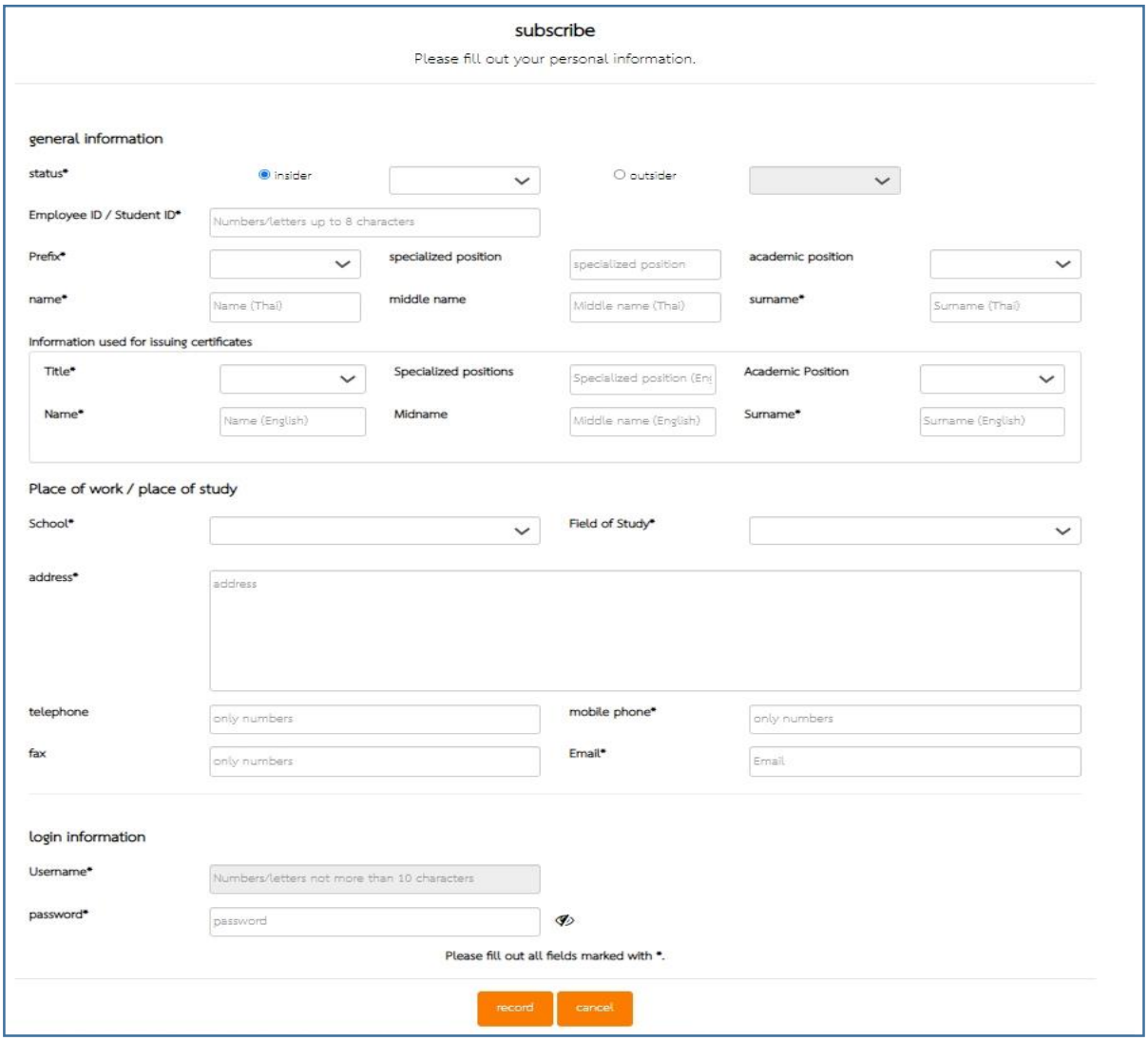
1. Submit and upload research documents at https://ec.sut.ac.th/index.php



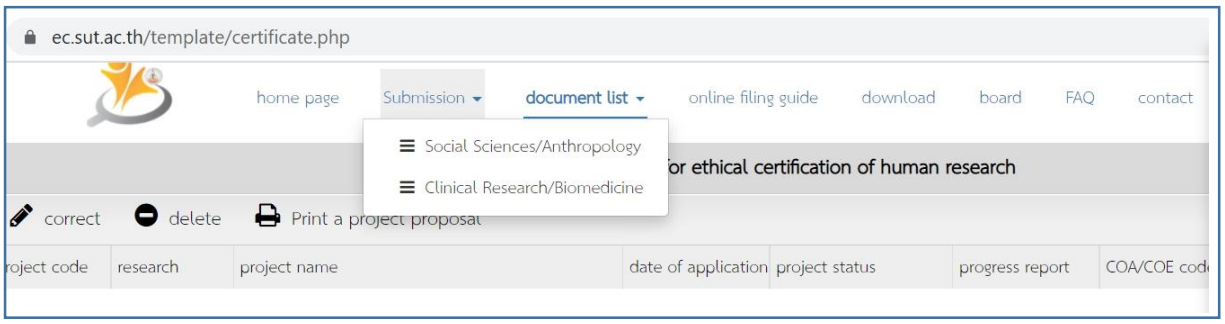
2. Log in



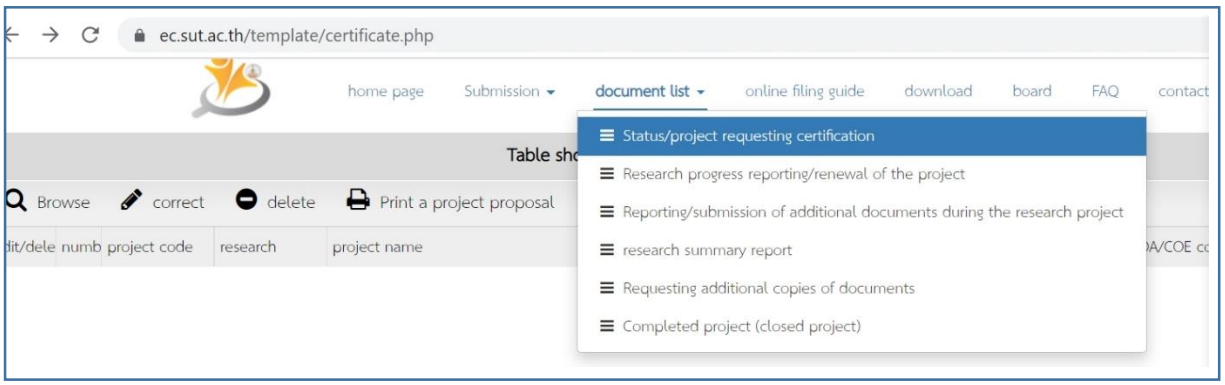
3. Register



4. Submission



5. Status



Annex Form

Document List	Social/Anthropological studies	Clinical/Biomedical
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4. Informed consent form	AF/23-08/01.0	AF/19-08/01.0
5. Waiver of consent form	AF/16-08/02.0	
6. Memorandum	AF/14-08/02.0 or AF/15-08/02.0	
7. Progress/Renew	AF/01-12/01.0	
8. Amendment	AF/01-11/01.0	
9. Protocol Deviation/Violation Report	AF/01-14/02.0	
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11. Suspect Adverse Reaction Report (CIOM Form)	AF/01-17/02.0	
12. Final report	AF/01-13/01.0	
13. Clarification on questions or suggestions of the committee	AF/22-08/02.0	

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