

**MEMORANDUM**

**Department**...............................................................................................................................................................................

**MHESI** 0605. ……………................/........................................ **Date**....................................................................................

**Subject :**proposed a research project to considered an expedited review in order to request consideration of research ethics in humans

**To :** Chairman of the Committee on Ethics for Research in human, Mahasarakham University

Name............................................................ Affiliation..............................................................................

Staff Academic position .............................................................

Supportive officer

Student …………………………………………………….. (Bachelor, Master or Ph.D)

a research project titled

(Thai) ...............................................................................................................................................................................

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(English)...............................................................................................................................................................................

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request the Expedited review ethics by attaching the supporting documents in accordance with the Checklist

Please be informed accordingly.

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| Signature………………………………….………….…………… | Signature………………………………….………….…………… |
| (……………………………….……………………..…………….) | (……………………………….……………………..…………….) |
| Student / Project Leader  In the case of the research project leader is a student | Project Advisor |
| Signature ………………………………….………….…………… | |
| (……………………………….……………………..…………….) | |
| Dean Faculty | |

**Human Ethics (Expedited review) request form for research projects**

1. **Name of the research project in both Thai and English**

(ไทย) ………………………………………………………………………………………………………………………………………………………………………

(English)......................................................................................................................................................................................

**2. Student / Project Leader (In the case of the research project leader is a student)**

Name-Surname ………………………………………………………………………………………………………………………………………………………………………………..

Department .............................................................................. Faculty......................................................................................

Mobile phone number............................................................ e-mail ..................................................................................

Research location......................................................................................................................................................................

**Advisor**

Name-Surname …………………………………………………………………………………………………………………………………………………………………………………

Department ....................................................................... Faculty ............................................................................................

Mobile phone number............................................................ e-mail ......................................................................................

**3. Research participants and affiliated agencies Both Thai and English**

Name-Surname …………………………………………………………………………………………………………………………………………………………………………………

Department ...................................................................... Faculty ......................................................................................

Mobile phone number.................................................... e-mail ..........................................................................................

**4. Importance of research problems**

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**5.** **Project objectives**

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**6. Benefits of this project When completed, how would it be realized?**

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**7. preparation of this research project**

[ ] Consulted researchers or biographers

researchers or biographers’s name...........................................Signature...................…........................

[ ] Not consulted researchers or biographers

**8. Research Methodology**

* a forward study (Requires consent of volunteers and provide details in item 9.)

a study of existing information (answer item 9.4 or 9.6)

**9. Research projects is the intensive consideration process under item of announcement?**

🞎 **9.1 Research project with blood sample collection**

🞎 9.1.1 Piercing the fingertips / heels / ears And the collection of blood samples must not be more than 2 times per day

Blood collection are from fingertips / heels / ears .....................................................

1. Total blood sample times....................................................... per project
2. Amount of blood each time................. cc.
3. If take more than 1 time, each time are separated ........................ Minutes / hour / week / month

🞎 9.1.2 Adult intravenous blood samples are collected (Excluding pregnant women) and blood samples not exceeding 20 ml and blood samples must not be more than 2 times

1. Total blood sample times....................................................... per project
2. Amount of blood each time................. cc.
3. If take more than 1 time, each time are separated ........................ Minutes / hour

🞎 **9.2 A research project in which biological samples are collected by means of non-invasive methods and do not cause injury to volunteers. Methods for collecting biological samples from volunteers include**

* + Nails or hair or hair that are not ugly after sampling
  + urine, stool, sweat, mucus
  + Saliva that is not collected by tube insertion
  + placenta from birth
  + Amniotic fluid collected from prenatal / during giving birth
  + plaque and saliva stones above the gums and beneath the gums, the storage methods provided are not too intrusive to the teeth scaling as normal preventative measures, the completion process is in accordance with the accepted disease prevention methods
  + Baby teeth or permanent teeth that must be withdrawn from the dental service
  + oral epithelium By scraping the oral mucosa, mouthwash, or smearing
  + skin cells from scraping or getting smeared
  + sputum obtained from spit Or after saline mist nebulization

**Note : If not all those specified above. (Must be considered as normal board)**

🞎 **9.3 Research projects require data collection through non-invasive processes, that is normal practice in patient care. Must not use sedation or sleeping pills, not related to X-ray or microwaves ,medical equipment must be a tool that has been commonly used. Data collection by noninvasive procedures that are normally performed in patient care, including**

* Weigh, measure height, measure blood pressure, Body temperature, measurement Heart rate, Respiratory rate
* Sensor, that tracks the skin, such as measuring the amount of oxygen from the fingertips
* Testing or measuring the level of exposure (such as visual acuity, audiometry, algometry, smell test)
* Magnetic Resonance Imaging (MRI)
* Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow และ echocardiography
* Moderate exercise , muscle strength testing, evalute body composition and flexibility test that Suitable for the age, weight and health of the volunteers

**Note : If not all those specified above. (Must be considered as normal board)**

🞎 **9.4 a study that uses data from medical records / documents / records / audio / motion pictures / photos / prints Or specimens that are stored for other purposes, not a research (Such as regular care or routine diagnosis) and not studies related to Post marketing**

9.4.1 Specify the source of information (such as medical records, laboratory results, etc.),

the location and time period.

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9.4.2 Specify the information that will be used in the research (such as gender, age, results of biopsy pathology, Radiographic examination, Bone density examination, etc.)

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9.4.3 There is a physician who works as a researcher, including................................................

🞎 **9.5 A study that uses data in the form of audio, animation, photos, prints, questionnaires / tests, surveys, interviews, discussion groups, tests.**

9.5.1 Data type

🞏 Audio

🞏 animation

🞏 images

🞏 Print image

* Questionnaire / measurement form

🞎 Survey

🞎 Interview

🞎 Group discussion

🞎 Pre or post test

🞎 Other (specify).........

9.5.2 Specify data collection methods and data collection period.

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🞏 **9.7 A study of specimens remaining from normal diagnostic tests (leftover specimen/surplus blood) or research in laboratories that use the same specimen from the project that has already been certified in ethical research.**

9.7.1 The biological samples in the study are..................................................................................

🞏 obtained from normal service, specify organization.........................................................

method of acquisition............................................................................................................

(attaching a document to use biological samples from the hospital director)

🞏 The remaining samples from previously approved research projects

Research Name.............................................................................................................................

Project has been certified by the ethics committee Project number ...........................

(Attach the letter certifying permission to use the remaining samples from the project by the original research project leader and the volunteer explanation document form of the original research project)

9.7.2 Biological samples in the study contain information that can be directly or indirectly linked to the volunteer such as name / surname / identification number. / Medical record number / Social Security Number / Various identification cards

🞏 No data associated to volunteer

🞏 Some are associated to volunteer, I will encrypt the patient data and extract the information, so that there is no connection later.

9.7.3 What are the research methods for encrypting the patient data, keep the secret excerpts the connection of patients or data owners. Both in the process of research and the presentation of the research results.

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**10. Methods of study and the population.**

10.1 Detailed study process

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* 1. Population / Sample group
     1. Total number of volunteers or samples
     2. Specify details of the number of volunteers / samples /show a sample calculation formula

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* + 1. Volunteer Inclusion criteria ***if any***

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* + 1. Volunteer Exclusion criteria ***if any***

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* + 1. Any method to reach the target population to persuade them to participate in the project (such as publicizing signs on print media, radio, or requesting cooperation from physicians, etc.), ***if any.***

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**11. How to invite to join the project by signing, consenting, or verbally (Please specify clearly) if relevant**

* Sign in a document (As the volunteer statement form and consent form)
* Verbally , please attach the request for exception form (ECMSUU-Waiver of Consent)

(attach the volunteer statement form)

**12. Explain the volunteer consent process. If relevant**

12.1) Who requests consent from volunteers? (The applicant for consent should be a person who does not influence for volunteer to participate in the research project) ..........................................................................................................................

12.2) When would you ask for volunteer consent? (Volunteers have sufficient opportunities and time to ask questions and understand about being a volunteer in a research project) ...............................................................................................................

12.3) he place to request the consent of the volunteers (Places that are private and do not reveal the identity of volunteers And easy to understand and ask questions about being a volunteer in a research project) should be clear.......................................................................................

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**13. Is this a Multicenter study? If so, please name the institution. And a list of researchers from that institution As well as project sponsors (Only in Thailand) such as pharmaceutical / chemical manufacturing companies, etc., if relevant**

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**14. What are the research methods for being secret? keep the secret excerpts the connection of patients or data owners, both in the process of conducting the research and the presentation of the research.**

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**15. Budget details of all research projects**

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**16. The relationship of the researcher and the company sponsoring the research project, such as**

* Holding the shares of the sponsoring company Please specify the number of shares.
* owner of copyrights of drugs or medical devices
* Received a salary of ........................... Baht / month is consulting fees
* guest speaker of the company or being support to attend academic conferences abroad during the past year, please inform the details …………………………………………………
* Other (specify) .........................................................................................................................................
* Not relevant

**17. Experience in ethics of research in humans**

The researcher and the research team have completed training in research ethics as follows Please specify individually and attach evidence.

**1. )**Name of researcher.......................... Course/ training subject.......................... the year of study...............

**2.)** Name of researcher.......................... Course/ training subject.......................... the year of study...............

**3.)** Name of researcher.......................... Course/ training subject.......................... the year of study...............

**18. This research project**

18.1 is expected to begin the data collection in ……….…….……… (Month/Year) expected to finished in …….………(Month/Year)

18.2 Expected collection time ……………………. Year…………….…..Month

**19. Consideration of research methods from faculty**

* Considered by the Faculty Thesis Examination Committee at the faculty of .........................................

Date .............. Month ...................................................... Year.......................................

* Research funding program Date .............. Month ...................................................... Year.......................................
* Other....................................................................................................................................................................

**20. Wishes to receive a certificate** ( ) Thai ( ) English

**I certify that the above statements are true. And understand the meaning clearly in all respects**

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| ………………………………….………….…………… | ………………………………….………….…………… |
| (……………………………….……………………..…………….) | (……………………………….……………………..…………….) |
| Project Advisor  In the case of the research project leader is a student | Student / Head of Research Project  ..........................................................  (...................................................................)  Research project participants  ..........................................................  (...................................................................)  Research project participants |
| **This research project has been approved by the faculty.**  (……………………………….……………………..…………….) | |
| Dean Faculty | |