

HOW TO REQUEST ETHICAL APPROVAL

All students who have passed proposal examination and submitted the completed proposal are to prepare documents to request ethical approval from the Faculty of Medicine's Human Research Ethics Committee according to the following steps:

Download documents from the following webpage:
<https://medinfo2.psu.ac.th/research/hrec/?q=node/5>

1. Submission form (according to your research type)
2. Protocol form (AP-002)
3. Clinical record form or questionnaire
4. Participant information sheet and informed consent form template (AP-026)
5. Informed assent form (Children aged 7-13 years) (AP-030)
6. Recruiting material (poster, script, web)

* Do not forget to insert page number and update the version after each revision *

Submit all the files to your advisor or academic staff:

Forms no.1-6
CV (ajarn&student)
GCP (ajarn&student)
RMIS form (see appendix 1)
Memorandum (has to be signed by you + your adviser Head of the Department)

Wait for 1-3 week (depend on the type of review)

Exempt (7 days)
Expedited (1 month)
Full board (> 1 month)

* Details of the review process in Table 1*

If revision is required, your ajarn / staff will send you an e-mail with details, please:

1. Respond to reviewers comments
(use AL- 009 response form, see appendix 2)
2. Hi-light the revised parts in all revised documents
3. Update version/date of all revised documents



**Submit response form and all revised documents
To your advisor or academic staff**



Wait for Certificate of Approval before starting data collection



After ethical approval if you wish to:

1. Change methods/documents: Submit the Amendment form
2. Extend the approval time (if your approval EC will expire before finishing data collection): Submit the Renewal Form at least 30 day BEFORE the expiration date
3. Finish data collection before the expiration date: Submit the Closing Form

Download the forms here:

<http://medinfo2.psu.ac.th/research/hrec/?q=node/5>

or contact academic officer for the ENGLISH version of the forms

(see Continuing Review – Amendment/ Progress Report/Renewal to EC /Closing)

Table 1 Ethics Committee Review Processes

Documents initially submitted for review through the RMIS system		
	↓	
Staff check for completeness of the submitted documents (1-3 Days)		
	↓	
Submit to the EC Secretary for Review (<1 week)		
Exempt	↓	Send comments to the investigator to revise the documents
Submit Certificate to be signed by the Committee President within 1 week		Investigator answer questions and submit the revised documents to the EC
	Expedited Review	Full Board Review
	Submit documents to 2-3 reviewers for review (2 weeks)	Submit documents to 3 reviewers for review (2 weeks) + notify investigators to prepare 14 sets of documents for the Full Board review.
	Staff summarize the results and inform the investigator (1 week)	Prepare to attend the Full Board review (1-2 weeks)
	Investigator answer questions and send the revised documents to the EC	Attend the Full Board Review
	Staff and Secretary review the revised version. If there is no more need to revise, the Certificate will be sent to the Committee President to sign and approve within 1 week	Staff summarize the results of the review and inform the investigator (1 week)
		Investigator answer questions and send the revised documents to the EC
		Staff and Secretary review the revised version. If there is no more need to revise, the Certificate will be sent to the Committee President to sign and approve within 1 week

Appendix 1

RMIS Form	
Project title in Thai	
Project title in English	
Name of researcher and Responsibility	1. Name.....Responsibility..... 2. Name.....Responsibility..... 3. Name.....Responsibility.....
Key word (2-5 words) in Thai	
Key word (2-5 words) in English	
Research type	
Starting date	
Ending date	
Amount of Budget (Baht)	
Source of Funding	
Name of funding	
Synopsis (≤ 500 words)	

Appendix 2

Response to Comments and Suggestions of the Ethics Committee		
Sequence, Date of review	:	Sequence....., Date:
Project ID	:	REC
Title (in Thai)	:	-
Title (in English)	:	
Project leader	:	
Work unit	:	
Date for return of response to EC	:	

1.Methodology		
	Comment	1.
	Response (if any)	
	Original points	
	Revised/amended points	
	Revision	(revised text).....{Please highlight revised text in the document}..... (revised document)..... (revised part/page)
2. Risks and benefits		
	Comment	
	Response (if any)	

	Original points	
	Revised/amended points	
	Revision	(revised text).....{Please highlight revised text in the document}..... (revised document)..... (revised part/page)
3. Consent form		
	Comment	
	Response (if any)	
	Original points	
	Revised/amended points	
	Revision	(revised text).....{Please highlight revised text in the document}..... (revised document)..... (revised part/page)

NOTE: Please see additional details according to the documents indicated by the Ethics Committee.