(government) .....

phone. ..... Fax .....

No. SorThor .....

Date ..... month ..... B.E. .....

Subject

Propose a research project to be considered for ethics certification in human research from the committee.

Center for research ethics in human subjects

Dear Chair of the Central Committee on Human Research Ethics

With me ..... Affiliation .....

I would like to propose a research project Study Code: … for consideration and approval from the committee on human research ethics, with research project documents as per the attached document.

Please be informed accordingly.

sign.....

(.....)

Research Project Leader

Attachment (List of documents for consideration)

	Applied Document Book/
1	Note Submission of a research proposal*
2	Proposal for Ethics Review for Biomedical Research Program (AP 04-S04)*
	Approval documents : Research protocol
3	Complete Research Outline*
4	Thai abbreviated research project
	Approval documents : Informed Consent Documents
5	Document explaining information about research participants / letter of consent (in the case of Master in English)
6	Document explaining information about research participants / letter of consent (separate documents by institution)
	Approval documents : Case Record Form
7	data record form
	Approval documents : Investigator's Brochure
8	Investigational Drug: Investigator's Guide
9	Investigational Drug: Certificate that the drug has passed the FDA
10	Investigational Drug: Drug invoice in case it is a drug that has been registered with the FDA.
11	Medical Device: Technical file for medical device research projects (AP 01-S07).
12	Medical Device: Description and characteristics of the medical device as specified by the manufacturer. Functional test results Safety test in humans and animals according to the attachment attached to the announcement.
13	Medical Device: Manual for using medical devices 14
	Documents outlining details and characteristics of medicinal plants or medicinal plant products in vitro activity test data, toxicity data (related cave)
	Approval documents : Others Document
15	Questionnaires or interviews
16	notebooks
17	Materials for research invitations, such as brochures, posters, promotional scripts.
18	Other documents applicable to research subjects/participants
19	Other documents that require certification
	Approval documents : Acknowledge Document
20	Research injury compensation insurance documents Other
21	documents
	Documents for consideration
22	(Draft) Material transfer agreement (MTA)
23	(Draft) Research Project Budget

	Approval documents : Investigators
24	Approval letter from the primary supervisor* (separate documents by institution)
25	CV & Evidence of Ethics Training / GCP (If there is no researcher in the system)
26	Conflict of Interest Form of the principal investigator and co-investigator (AP 06-S04)* (separate documents by institution)
27.	Checking the completeness of the research project AO 01-S04
28.	AP02-S04 for PI for clinical trial phase I / II
29	Evidence of payment of fees