

	Central Committee for the Ethics of Human Research Central Research Ethics Committee; CREC Telephone: 082-258-9529 E-mail: official@crecthailand.org	AP 04-S04
		V. 5.1 date 24 July 2024
		Page 1 of 4 pages

**Proposal for ethical consideration of human research
For Biomedical Research Projects (Submission Form for Biomedical
Research)**

Protocol Title: _____

Name of Sponsor: _____

Sponsor Protocol Code: _____

Please check category of research:

Target population

- ☐ Research involving only adults
- ☐ Research involving adults and children
- ☐ Research involving only children
- ☐ Not applicable

Type of Investigational Product

- ☐ Investigational new drugs
- ☐ Clinical investigation of medical device
- ☐ Not applicable

1. Principal Investigator	
Principal Investigator:	
Institution:	
Address:	
Tel:	
Fax:	
Email:	

	Central Committee for the Ethics of Human Research Central Research Ethics Committee; CREC Telephone: 082-258-9529 E-mail: official@crecthailand.org	AP 04-S04
		V. 5.1 date 24 July 2024
		Page 2 of 4 pages

2. Participating Investigators			
No	Name	Institution	Contact number E-mail
1			
2			
3			
4			
5			
4. Research Coordinator			
Name:			
Tel:			
Fax:			
Email			
5. Type of Study			
<input type="checkbox"/> Clinical trial <i>Please specify</i> <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Survey <input type="checkbox"/> Screening <input type="checkbox"/> Genetic study <input type="checkbox"/> Others <i>Please specify</i>			
6. Investigational New Drug (IND) or Medical Device (IDE)			
Is your study involved IND or IDE? <input type="checkbox"/> No <input type="checkbox"/> Yes, <i>please specify</i> <input type="checkbox"/> IND <input type="checkbox"/> IDE			

	Central Committee for the Ethics of Human Research Central Research Ethics Committee; CREC Telephone: 082-258-9529 E-mail: official@crecthailand.org	AP 04-S04
		V. 5.1 date 24 July 2024
		Page 3 of 4 pages

FDA number Date of FDA approval
7. Study Population
<input type="checkbox"/> Vulnerable <input type="checkbox"/> Patient <input type="checkbox"/> Healthy If VULNERABLE , please specify <input type="checkbox"/> Children under 18 years old <input type="checkbox"/> Cognitively or mentally impaired <input type="checkbox"/> Others specify.....
8. Special Resource Requirement / Procedures (check all that apply):
<input type="checkbox"/> Intensive Care <input type="checkbox"/> Isolation unit <input type="checkbox"/> Surgery <input type="checkbox"/> Pediatric Intensive Care <input type="checkbox"/> Transfusion <input type="checkbox"/> Prosthetics <input type="checkbox"/> Gene therapy <input type="checkbox"/> Gynecological services <input type="checkbox"/> Organ transplant <input type="checkbox"/> Substances (narcotics / psychotropics) <input type="checkbox"/> CAT scan <input type="checkbox"/> Ionizing radiation used (x-ray, radioisotopes, etc. <input type="checkbox"/> Others specify.....
9. Procedures Used in the Study
<input type="checkbox"/> None <input type="checkbox"/> Non-invasive <input type="checkbox"/> Invasive
10. COI Disclosure form (AP06-S04) has been submitted.
<input type="checkbox"/> No <input type="checkbox"/> Yes
11. Research Ethics Training
<input type="checkbox"/> ICH GCP <input type="checkbox"/> Human Research Subject Protection Course <input type="checkbox"/> Other..... Please indicate what training in the protection of human subjects (eg ICH GCP) the research team have completed: (Please attach copies of training certificate for members of each site)
12. FUNDING:
Source of funding (tick all that apply) <input type="checkbox"/> THAI Government /Department/ Faculty, please specify

	Central Committee for the Ethics of Human Research Central Research Ethics Committee; CREC Telephone: 082-258-9529 E-mail: official@crecthailand.org	AP 04-S04
		V. 5.1 date 24 July 2024
		Page 4 of 4 pages

<input type="checkbox"/> NGO (eg WHOTR, HSRI), please specify _____ <input type="checkbox"/> Private sector (eg pharmaceutical company), please specify _____ <input type="checkbox"/> Others
13. Signature of Principal Investigator
_____ (Date

More information (Please specify in Thai)

List of all data collection institutions in Thailand and the number of volunteers planning to study in Thailand, number of..... Number ofinstitutions include: 1. Number of volunteers persons 2. Number of volunteers persons	List of institutions requesting certification from CREC and number of volunteers requesting consideration Number of institutions including: 1. Number of volunteers persons 2. Number of volunteers persons
List of researchers at institutions that <u>collect all data in Thailand</u>	

****note**

	Central Committee for the Ethics of Human Research Central Research Ethics Committee; CREC Telephone: 082-258-9529 E-mail: official@crecthailand.org	AP 04-S04
		V. 5.1 date 24 July 2024
		Page 5 of 4 pages

- 1. This information is for staff to carry out administrative tasks such as preparing Local Issue submission letters and considering Reviewers for reviewing research projects.*
- 2. When submitting documents, in addition to submitting this document with the signature of the research project leader as a .pdf, please also submit this document as a .doc.*