คณะกรรมการกลางพิจารณาจริยธรรมการวิจัยในคน
Central Research Ethics Committee; CREC
โทรศัพท์ 02- 579- 0117

แบบประเมินรายงานความก้าวหน้าของการวิจัย

Assessment of Progress Report

PROTOCOL No.:	CREC No:
PROTOCOL TITLE:	
Principal Investigator:	Institution:
Sponsor:	
Last Date of Approval: _____/_____/_____	Date of Expiration: _____/_____/_____

Date of Progress Report Submission: _____/_____/_____

Submission:

□ More than 30 days before the expiration date

□ Within 30 days before the expiration date

□ After expired date

Type of continuing review

□ **Expedited review**	□ **Full board review**
- Qualified for expedited review at the time of initial review. - Previously approved in full board but at this time of continuing review: (a) Where *(i) the research is permanently closed to the enrollment for new subjects;* *(ii) all subjects have completed all research-related interventions; and* *(iii) the research remains active only for long-term follow-up of subjects; or* (b) Where no subjects have been enrolled and no additional risks have been identified; or (c) Where the remaining research activities are limited to data analysis - Previously approved in full board but meets the following conditions ▪ *Research not conducted under and investigational new drug (IND) or investigational device exemption (IDE);* ▪ *Research involves no greater than minimal risk to the subjects; and* ▪ *No additional risks have been identified.*	Not eligible for expedited review

Issues to review

Tri	1. Recruitment rate (difference between the actual and expected rates of enrollment) is appropriate / reasonable.	□ YES	□ NO	□ NA

a l p r o g r e s s	*If no, please write a comment.*			
	2. The number and reasons of subject withdrawal is reasonable. *If no, please write a comment.*	□ YES	□ NO	□ NA
P r o t o c o l	3. All amendment of the research protocol and related documents have been reviewed by CREC without major concerns *If no, please write a comment.*	□ YES	□ NO	□ NA
R i s k	4. Risks to subjects are minimized. *If no, please write a comment.*	□ YES	□ NO	□ NA
	5. Risks to subjects are reasonable in relation to anticipated benefits *If no, please write a comment.*	□ YES	□ NO	□ NA
E q u i t y	6. Selection of subjects is equitable. *If no, please write a comment.*	□ YES	□ NO	□ NA
I n f o r m e d c o n s e n t	7. The site is using the most recently approved version of informed consent document *(date stamps to indicate an approved version).* *If no, please write a comment.*	□ YES	□ NO	□ NA
	8. The informed consent document contains accurate, up-to-date information about the study. *If no, please write a comment.*	□ YES	□ NO	□ NA
	9. Informed consent is sought from each subject or the subject's legally authorized representative appropriately. *If no, please write a comment.*	□ YES	□ NO	□ NA
O t h e r s	10. Where appropriate, the research adequately monitors the data collected to ensure the safety of the subjects. *If no, please write a comment.*	□ YES	□ NO	□ NA
	11. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. *If no, please write a comment.*	□ YES	□ NO	□ NA
	12. Appropriate additional safeguards are included to protect vulnerable subjects. *If no, please write a comment.*	□ YES	□ NO	□ NA

Decision	**For decision: approval**	
☐ Acknowledgement	Date of approval	

☐ Approval ☐ Require correction/ more information to secure approval ☐ Suspension of Prior Approval (please define) ☐ Suspend enrollment ☐ Suspend administration of investigational new drug/device ☐ Suspend all research activity ☐ Termination of Prior Approval	Date of expiration	
	Frequency of continuing review	☐ 6 months ☐ 1 year

REVIEWER'S SIGNATURE:_____ DATE: _____

(_____)