NKTIREC FORM 3.6: APPROVAL LETTER

Date _____

This is to certify that the following protocol and related documents have been granted approval by the NKTI REC for implementation

REC Protocol No.		Sponsor Protocol No	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			
Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From (date) To	Frequency of continuing review

REC Chair	Name	Signature	Date

**** The NKTI-REC has been organized and currently operates in compliance with ICH-GCP Guidelines and according to the applicable national/local laws and regulations.***

INVESTIGATOR RESPONSIBILITIES AFTER APPROVAL (IF APPLICABLE):

- Pharmaceutical – Effective as of 10/12/2017; Please coordinate with CTRU for Clinical Trial Agreement Approval prior to Study initiation
- Submit document amendments for REC approval before implementing them
- Submit SAE and SUSAR on-site reports to the REC **within 7 calendar days**
- Deaths on-site must be reported to the REC **within 48 hours** after its occurrence
- Submit progress report **every 6 months**
- Submit final report after completion of protocol procedures at the study site
- Report all protocol non-compliance/deviation/violation at the soonest possible time
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research

---

Received by: _____

Name _____

Signature _____ Date _____