NKTIREC FORM 3.4-A: PROTOCOL EVALUATION

I have been assigned as (Check one)
____ Medical/Scientific Reviewer
____ Non-Medical/Non-Scientific Reviewer

NKTI REC Protocol no.	
Protocol Title	
Principal Investigator	

Type of the Study			
☐ Intervention	☐ Epidemiology	☐ Observational study
☐ Document review	☐ Individual based	☐ Genetic
☐ Social Survey	☐ Others, specify	

Description of the Study in brief: Mark whatever applies to the study.

☐ Randomized	☐ Drug	☐ Use of Genetic Materials
☐ Double blind	☐ Medical Device	☐ Multicenter study
☐ Single blind	☐ Vaccine	☐ Global protocol
☐ Open label	☐ Diagnostics	☐ Sponsor Initiated
☐ Observational	☐ Questionnaire	☐ Investigator Initiated

Phase of the Study	☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4

Review Type	☐ Full Board Review ☐ Expedited Review

INSTRUCTIONS

To the Principal Investigator:	Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.
To the Primary Reviewer:	Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable by ticking the corresponding box. Write your comments/recommendations if there are any. Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

ASSESSMENT POINTS	To be filled out by the PI *Page and paragraph where it is found*	To be filled out by the Primary Reviewers. *Kindly check if the study protocol contains the specified assessment point.*						*Comments/ Recommendations (If any)*
I. SCIENTIFIC ISSUES								
1. Objectives of the Study			Clear		Not clear			
2. Background information/ Literature Review *Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials*			Clear		Not clear			
3. Methodology *Review of appropriateness of research design, sampling method and techniques.*			Clear		Not clear			
4. Sufficient Number of Participants? *Review of justification of sample size*			Sufficient		Not sufficient		N/A	
5. Control Arms *(Placebo, if any)*			Yes		No		N/A	
6. Data Analysis Plan *Review of appropriateness of statistical and non-statistical methods to be used and how data will be summarized*			Appropriate		Not appropriate			
7. Study Outcomes			Defined		Incomplete		Not defined	
8. Inclusion Criteria *Review of precision of criteria both for scientific merit and safety concerns; and equitable selection*			Appropriate		Not appropriate			
9. Exclusion Criteria *Review of criteria precision both scientific merit and safety concerns; and of justified exclusion*			Appropriate		Not appropriate			
10. Withdrawal Criteria *Review of criteria precision both scientific merit and safety concerns*			Appropriate		Not appropriate			
11. Data Collection Plan *Review of appropriateness of data collection, including description of personal data to be collected. For studies involving use of*			Appropriate		Not appropriate			

	database, review of database management and role of personal data collector, as well as authority of investigator to access database. (NEGHHR 2017)							
12.	**Specimen Handling** *Review of specimen storage, access, disposal, and terms of use, including appropriateness of biobank custodian and adherence to institutional guidelines for biobanking, including provision for sample and data removal and destruction for biobanked samples (NEGHHR 2017*			Appropriate		Not appropriate		N/A	
13.	**Are the qualifications and experience of the coordinating investigators/participating investigators, research team appropriate?**			Yes		No			
14.	**Suitability of Site** *Review of adequacy of qualified staff and infrastructures.*			Suitable		Not suitable			
15.	**Duration of participant involvement** *Review of length/extent of human participant involvement in the study*			Appropriate		Not appropriate		N/A	
16.	**Transparency and Conflict of interest** *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site (NEGHHR 2017)*			Yes		No			
17.	**Privacy, confidentiality, and data protection plan** *Review of measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators) (NEGHHR 2017). Review of appropriateness of processing personal data, storage of data, access, disposal, and terms of use (NEGHHR 2017; Data Privacy Act of 2012)*			Yes		No			

18. Informed consent process *Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done, who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances (NEGHHR 2017)*			Yes		No		N/A	
19. Waiver of informed consent *Review of justification for waiver of informed consent or waiver of documentation of consent with considerations to potential risk to participants, collection of data, and mechanisms to ensure confidentiality and anonymity (NEGHHR 2017)*			Acceptable		Not acceptable		N/A	
20. Justification for the involvement of vulnerable groups *Review of involvement of vulnerable study populations and impact on informed consent. Vulnerable groups include the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants (NEGHHR 2017)*								
21.1 Involvement of vulnerable participants			Yes		No		N/A	
21.2 Protection of vulnerable participants			Appropriate		Not appropriate		N/A	
21. Justification for involving minors (less than 18 years old) *Review of involvement of minors and impact on informed consent. Research involving minors must always be assessed in the context of the protocol and the participants.*			Yes		No		N/A	
22. Assent *Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children: 0-under 7: No assent*			Yes		No		N/A	

	7-under 12: Verbal Assent *12-under15: Simplified Assent Form* *15-under18: Co-sign informed consent form with parents (NEGHHR 2017)*							
23.	**Consent for continued participation** *For research involving children and adolescents, review of process for obtaining consent if the participant reaches legal age during the research. (CIOMS 2016)*			Yes		No		N/A	
24.	**Recruitment** *Voluntary, non-coercive recruitment of participants*			Yes		No		N/A	
25.	**Level of Risk**			Low		Medium		High	
26.	**Risk Mitigation in the Protocol**			Appropriate		Not appropriate		N/A	
27.	**Benefits of the Participants in Protocol**			Appropriate		Not appropriate		N/A	
28.	**Safety monitoring plan** *Review of appropriateness of measures to assess risk and burdens to the participants and precautions taken to minimize negative impact of the study on the well-being of the participants (NEGHHR 2017)*			Appropriate		Not appropriate		N/A	
29.	**Post-trial access** *Review of provision of clinical trials for post-trial access*			Yes		No		N/A	
30.	**Incentives or compensation for study related injury.** *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses. Review of amount and method of compensations for study-related injuries, including treatment entitlements, or certificate of insurance for clinical trials.*			Appropriate		Not appropriate		N/A	
31.	**Community considerations** *Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study*			Yes		No		N/A	

32. Collaborative study terms of reference *Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building*			Yes		No		N/A	
33. Dissemination/data sharing plan/statement *Review of appropriateness in sharing research results which may have significant implications on the well-being of the participants and the community and in relation to achieving social value. (NEGHHR 2017)*			Appropriate		Not appropriate		N/A	
34. Other issues *Review of issues not subsumed in the issues covered by the above items.*			Yes		No			

RECOMMENDED ACTION

☐ APPROVE
☐ MINOR MODIFICATIONS
☐ MAJOR MODIFICATIONS
☐ DISAPPROVE
☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

JUSTIFICATION FOR RECOMMENDED ACTION

PRIMARY REVIEWER Signature _____

Date: <dd/mm/yyyy> Name <Title, Name, Surname>