NKTIREC FORM 3.4-B: INFORMED CONSENT EVALUATION

NKTI REC Protocol no.	
Protocol Title	
Principal Investigator	

INSTRUCTIONS

To the Principal Investigator: Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF). 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 elements outlined below have been appropriately addressed by the informed consent form (ICF), 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 informed consent form contains the specified assessment point.*						*Comments/ Recommendations (if any)*
1. Who will give consent? ☐ Subject ☐ Parent/Legally Authorized Representative Was this defined in the informed consent form?			Yes		No		N/A	
2. Is the age of subjects detailed? If so, what is the age range of the subjects?			Yes		No		N/A	
3. Does subject selection appear appropriate for the study? Who will be enrolled? ☐ Men			Yes		No		N/A	

☐ Women ☐ Children ☐ Healthy Volunteers ☐ Minorities ☐ Vulnerable populations								
4. Does the recruitment plan allow for equitable selection of subjects?			Yes		No			
5. Does the Informed Consent document contain comprehensive and relevant information?			Yes		No			
6. Is the language in the Informed Consent Form understandable?			Yes		No			
7. Is the Informed Consent Form translated into the local language/dialect?			Yes		No			
8. Is the information provided in the protocol consistent with those in the consent form?			Yes		No			
9. Is there clear distinction between research and standard of care?			Yes		No			
10. Are the exams, history taking, laboratory tests, etc. adequate to monitor subject safety?			Yes		No			
11. Is there is a period when treatment will be withheld? Are there adequate safeguards for subjects?			Yes		No			
12. Is there monetary compensation to be provided for subjects? Is the amount detailed appropriate? (Not coercive)			Yes		No		N/A	
Does the consent form contain all of the required elements of informed consent?								
1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration			Yes		No		N/A	

	of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.							
2.	A description of any reasonably foreseeable risks or discomforts to the subject.			Yes		No	N/A	
3.	A description of any benefits to the subject or to others which may reasonably be expected from research			Yes		No	N/A	
4.	A description of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject? Is there post-study access to the study products or intervention that have been proven safe and effective			Yes		No	N/A	
5.	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained			Yes		No	N/A	
6.	Is there provision for treatment or compensation for study-related injuries?			Yes		No	N/A	
7.	Anticipated expenses, if any, to the participant in the course of the study			Yes		No	N/A	
8.	Is there a statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefits to which the subject is entitled?			Yes		No	N/A	
9.	Statement that the participant or participant's legally acceptable			Yes		No	N/A	

representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participate								
10. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury			Yes		No		N/A	
11. Statement that the NKTI REC has approved the study and may be reached through the following contact information regarding rights of study participants, including grievances and complaints. Name of NKTI REC Chair Address: 3rd Floor, Annex 1 bldg. National Kidney and Transplant Institute Email:nktiresearchethics@gmail.com Tel: (02) 8981-0300 loc.2158			Yes		No		N/A	
RISK/BENEFITS								
1. Is this a greater than minimal risk study? (See definition) ***Risk.*** *There is a probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.* ***Minimal Risk.*** *A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinary encountered in daily life or during the performance of routine physical or psychological examinations*			Yes		No		N/A	

or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.								
2. Is there a prospect of direct benefit to the subjects?			Yes		No		N/A	
3. Are the risks/benefits justifiable and adequately defined?			Yes		No		N/A	
4. Are the risks minimized?			Yes		No		N/A	
5. Based on the degree of risk to subjects, is the standard one year and subsequent continuing review appropriate?			Yes		No		N/A	
6. If the study involves interventions that may have adverse effects on a fetus, are pre-enrollment and follow-up pregnancy tests included?			Yes		No		N/A	
7. Are women (and men) of child-bearing potential advised to practice medically accepted methods of birth control?			Yes		No		N/A	
PRIVACY AND CONFIDENTIALITY								
1. Is there an appropriate procedure for protecting the subject's privacy and confidentiality? *Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality*			Yes		No		N/A	

2. Description of data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage) (*NEGHHR 2017)*			Yes		No		N/A	
3. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant			Yes		No		N/A	
4. Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study			Yes		No		N/A	
PEDIATRIC STUDIES								
1. Are Assent forms appropriate for the study participants?			Yes		No		N/A	
2. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study			Yes		No		N/A	
HANDLING OF BIOLOGICAL SPECIMEN								
1. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming			Yes		No		N/A	

participant's right to refuse future use, refuse storage, or have the materials destroyed								
2. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development			Yes		No		N/A	
DEVICES								
1. Is this an investigational device study? If yes, has an Investigational Device Exemption (IDE) been filed with PFDA? What is the appropriate classification? ☐ Significant Risk ☐ Non-Significant Risk			Yes		No		N/A	
2. Is the device classification appropriate?			Yes		No		N/A	
OTHERS COMMENTS NOT ADDRESSED IN THE ABOVE ITEMS								

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>