



NKTI REC 4.4: FINAL REPORT

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *This form is required upon completion of the study or closure of study site. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission. Attach manuscript for all studies except for clinical trials*

NKTIREC CODE:		
STUDY PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
STUDY PROTOCOL APPROVAL DATE: <dd/mm/yyyy>		
Email:	Telephone:	Mobile:
STUDY SITE: <Name and address>		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	Telephone:	Mobile:
REPORT SUBMISSION DATE: (to be filled out by NKTIREC) <dd/mm/yyyy>		
1. Period of data collection: <dd/mm/yyyy> to <dd/mm/yyyy>		
2. Study Arms:		
3. Target Number of study participants in the beginning of the study:		
4. Number of participants at the end of the study:		
5. Number of participants who received the test articles:		
6. Summary of amendments to the original protocol (including dates of approval):		
7. Summary of SAE reported:		
8. Summary of SUSAR reported:		
9. Summary of participants' complaints or grievances documented regarding conduct of study:		
10. Summary of benefits documented:		
11. Summary of indemnifications (If Applicable):		
12. <i>Continuing Review Application Submission</i> dates with corresponding action (required for approval dates issued one year ago or earlier):		
13. Summary of study materials used (for non-clinical research):		
14. List of treatments or interventions:		
15. Summary of post-trial provisions (required for clinical trials):		
16. Summary of biobanking (including total number of samples included and withdrawn):		
17. Study dose(s):		
18. Duration of the study:		
19. Study objectives, summary of results, conclusion of the study		
20. List of informed consent form used (version/date) and attach most recent version, or report on outcome of waiver of informed consent (e.g., no follow-up of patients, anonymized data collection, and others):		
21. Report on outcome of data protection plan (e.g., reports of breach of privacy, and storage of identifiable information):		
DATE OF LAST REVIEW: <dd/mm/yyyy>		
SIGNATURE OF PI:		
DATE SUBMITTED: <dd/mm/yyyy>		



RECEIVED BY:

Name and signature of REC Secretariat

Date:

RECOMMENDATIONS (for NKTIREC use only)

COMMENTS OF PRIMARY REVIEWER (i.e., compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study)

RECOMMENDED ACTION:

- APPROVE
- REQUEST INFORMATION: (specify)
- RECOMMEND FURTHER ACTION: (specify)
- PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER

Signature _____

Date: <dd/mm/yyyy>

Name

<Title, Name, Surname>