



## NKTIREC FORM 4.6: EARLY STUDY TERMINATION

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *This form is required to apply for premature termination or suspension of a study and refers to ICH-GCP Section 4.12: PREMATURE TERMINATION OR SUSPENSION OF A TRIAL. Obtain an electronic copy of this form and encode all information required in the space provided. Print the application in A4 size paper; then date and sign this form before submission.*

<b>NKTI REC CODE:</b>		
<b>STUDY PROTOCOL TITLE:</b>		
<b>PRINCIPAL INVESTIGATOR:</b>		
<b>INITIAL APPROVAL DATE:</b>		
<b>DATE OF LAST CONTINUING REVIEW APPROVAL:</b> <dd/mm/yyyy>		
<b>Version and date of latest approved protocol:</b>		
<b>Version and date of latest approved ICF:</b>		
<b>Email:</b>	<b>Telephone:</b>	<b>Mobile:</b>
<b>STUDY SITE:</b>		
<b>STUDY SITE ADDRESS</b>		
<b>SPONSOR:</b>		
<b>SPONSOR CONTACT PERSON:</b>		
<b>Email:</b>	<b>Telephone:</b>	<b>Mobile:</b>
<b>REPORT SUBMISSION DATE:</b> (to be filled out by NKTIREC) <dd/mm/yyyy>		
<b>1. START DATE:</b>		
<b>2. PROPOSED TERMINATION DATE:</b> <dd/mm/yyyy>		
<b>3. PARTICIPANTS ENROLLED TO DATE:</b>		
<b>4. BRIEF SUMMARY OF PROTOCOL:</b>		
<b>5. SUMMARY OF RESULTS TO DATE:</b>		
<b>6. REASON FOR TERMINATION with JUSTIFICATION:</b>		
<b>7. PLAN FOR THE FOLLOW-UP OF PARTICIPANTS WHO ARE STILL PART OF THE STUDY:</b>		
<b>SIGNATURE OF PI:</b>		
<b>DATE OF REPORT:</b> <dd/mm/yyyy>		



**RECOMMENDATIONS (for NKTIREC use only)**

**Comments of Primary Reviewer** (i.e., implication on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants)

**RECOMMENDED ACTION:**

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

\_\_\_\_\_  
*Name and Signature Primary Reviewer*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Name and Signature of REC Chair*

\_\_\_\_\_  
*Date*