



NKTIREC FORM 4.1A: SERIOUS ADVERSE EVENT/S REPORT

Whenever there is any SAE event in any research approved by the NKTIREC, it has to be reported by the principal investigator (PI) to the REC. Section 1 of this form should be filled out by the PI.

SECTION 1

Principal Investigator:	
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Study Title:	
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NKTIREC Protocol No.:	
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Name of the study drug/device:

Report Date:
<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up
Onset Date:

Sponsor:

Date of first use:

Title of the Report

Date of the report

Subject's initial/number: _____ Age: _____

Male Female

Subject's history:

Laboratory findings:

SAE:

Treatment:
Outcome: <input type="checkbox"/> Resolved <input type="checkbox"/> On-going

Seriousness:

Relation to

Death Life Threatening Drug Device Study

Hospitalization: Not related

Initial Prolonged Possibly



- | | |
|--|---|
| <input type="checkbox"/> Disability/Incapacity | <input type="checkbox"/> Probably |
| <input type="checkbox"/> Congenital Anomaly | <input type="checkbox"/> Definitely related |
| <input type="checkbox"/> Others | <input type="checkbox"/> Unknown |

Note: PI should attach SAE REPORT FORM (NKTIREC FORM (4.1B) to this REC form.

SECTION 2 (to be filled out by the designated REC Primary Reviewer)

Document receipt by the REC

Name (REC Secretariat)	Signature	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>

Changes to the protocol recommended. No Yes
 Comments:

Changes to the informed consent form recommended. No Yes
 Comments:

REC Final Action: <input type="checkbox"/> Request changes to the protocol <input type="checkbox"/> Request changes to the informed consent form <input type="checkbox"/> Request further information <input type="checkbox"/> Suspend or terminate the study <input type="checkbox"/> Take note and no further action is needed <input type="checkbox"/> Others	Type of review: <input type="checkbox"/> Expedited review <input type="checkbox"/> Full board review Date of meeting _____
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Name of Member- Secretary:	Signature	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>

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