



**NKTIREC FORM 4.2: PROTOCOL AMENDMENT REVIEW**

REC Protocol Number:			
Study Title:			
Principal Investigator:		Sponsor:	
Approval Date			

<p><b>AMENDMENT TO RESEARCH STUDY (Choose all that apply)</b></p> <p><input type="checkbox"/> Change(s) to research protocol (<i>attach tracked versions of protocol</i>)</p> <p><input type="checkbox"/> Change(s) to Informed Consent Forms (<i>attach clean and tracked version of document(s)</i>)</p> <p><input type="checkbox"/> Change to study population</p> <p><input type="checkbox"/> Addition of study site</p> <p><input type="checkbox"/> Change to sample size</p> <p><input type="checkbox"/> Initiation of new study phase</p> <p><input type="checkbox"/> Changes of recruitment materials, data collection forms, instruments, questionnaires/surveys (<i>attach tracked version of revised documents with new version number</i>)</p> <p><input type="checkbox"/> Change to drug or device information for FDA regulated study</p> <p><input type="checkbox"/> Change in conflict of Interest</p> <p><input type="checkbox"/> Other change/s (<i>describe below</i>)</p>
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Describe changes to the **PROTOCOL**. Explain in detail in the space below the reasons for requesting these changes and which part(s) of the approved document will be amended. Please highlight changes in the revised document.

List of Amendments	Reasons
1.	
2.	
3.	

Describe changes to the **ICF/assent form/recruitment advertisement, etc.** Explain which sections of these items are being changed. Please highlight changes in the revised document.

List of Amendments	Reasons
1.	
2.	
3.	



Submitted by:

*Signature over Printed Name of Principal Investigator/ Date  
(Signature of co-investigator or study staff is not acceptable)*

Received by:

*Signature over Printed Name / Date*

*To be filled up by REC*

**Recommendations:**

- Approve
- Request an amendment to the protocol or informed consent form
- Request further information
- Disapprove amendment

**Type of Review:**

- Expedited review
- Full board review

Date of Meeting:

\_\_\_\_\_

Primary Reviewer:

\_\_\_\_\_  
*Signature over Printed Name / Date*

Approved by REC Chair:

\_\_\_\_\_  
*Signature over Printed Name / Date*