NKTIREC FORM 3.3: PROTOCOL SUMMARY SHEET

Protocol Summary

NKTIREC Protocol No.	
Title	
Principal Investigator	
Sponsor	
Rationale/Purpose/Significance of the Study	
Objectives	
Study Design/Methodology *Describe the source of data and the data collection procedures*	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Vulnerable subjects *In this study involves vulnerable subjects, describe additional safeguards included in the protocol to protect the rights and welfare of these subjects*	☐ No ☐ Yes, describe
More than Minimal Risk of Harm *If the research involves more than minimal risk of harm to subjects, describe the provisions for monitoring the data to ensure the safety of subjects*	☐ No ☐ Yes, describe
Benefits *Assess the potential benefits to science and/or society which may occur as a result of this research. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits*	
Study Outcomes	

General Study Information

Participants Recruitment Numbers: Estimated Study Duration Start Date: _____ End Date: _____	Participant Ages (Please Check) ☐ 0-7 (parental permission and child assent) ☐ 7-11(parental permission and child assent) ☐ 12-17 (parental permission and child assent) ☐ 18-65 ☐ 65+

Will this study involve long term follow-up with participants ☐ YES ☐ NO
If YES, please describe:

_____
Signature over Printed Name of PI
Date: _____

Received by:

_____
Signature over Printed Name
REC Secretariat Staff
Date: _____