



NKTIREC FORM 3.11: CHECKLIST FOR EXEMPTION FROM ETHICAL REVIEW

STUDY PROTOCOL INFORMATION

NKTIREC Code:	
Study Protocol Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date:	<dd/mm/yyyy>

INSTRUCTIONS

To the Primary Reviewer: Please evaluate how the exemption criteria outlined below apply to the study protocol by confirming the submitted information and putting your comments in the space provided under “REVIEWER COMMENTS.” Finalize your review by indicating your conclusions under “RECOMMENDED ACTION” and signing in space provided for the primary reviewer.

CRITERIA FOR EXEMPTION	To be filled out by the Primary Reviewer		REVIEWER COMMENTS
	Indicate if the assessment point applies to the study protocol		
1. PROTOCOL ASSESSMENT	YES	NO	
1.1. Does this research involve human participants?			
1.2. Does this research involve use of non-identifiable human tissue/ biological samples?			
1.3. Does this research involve use of non-identifiable publicly available data? <i>*Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHR 2017)</i>			
1.4. Does this research involve interaction with human participants?			
1.5. Type of research 1.5.1. Institutional quality assurance 1.5.2. Evaluation of public service program 1.5.3. Public health surveillance 1.5.4. Educational evaluation activities 1.5.5. Consumer acceptability test			



<p><i>*These 5 have been identified in the NEGHR as exemptible, as long as it does not involve more than minimal risk.</i></p>			
<p>1.6. What is/are the method/s of data collection (please tick appropriate box)</p> <p>1.6.1. Surveys and/or questionnaire, Interviews, or observations of public behavior</p> <p>1.6.2. Audio/video recordings of public behavior</p> <p>1.6.3. Research which only uses existing data</p> <p><i>*These have been identified in the NEGHR as exemptible, as long as anonymity and/or confidentiality is maintained.</i></p>			
<p>1.7. Will the collected data be anonymized or de-identified?</p>			
<p>1.8. Is there a data protection plan? Measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators) (NEGHR 2017); Plan on processing personal data, storage of data, access, disposal, and terms of use (NEGHR 2017; Data Privacy Act of 2012)</p>			
<p>1.9. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHR 2017)</p> <p><i>*Please refer to section 2. Risk Assessment, prior to answering this item</i></p> <p><i>*If YES, then this protocol does not qualify for exemption</i></p>			
<p>2. RISK ASSESSMENT</p>	<p>YES</p>	<p>N/A</p>	
<p>2.1 Does this research involve the following (please select all that apply):</p>			
<p>2.1.1 Any vulnerable</p>			



groups?			
2.1.2 Sensitive topics that may make participants feel uncomfortable (<i>i.e. sexual behaviour, illegal activities, racial biases, etc.</i>)			
2.1.3 Use of drugs			
2.1.4 Invasive procedure (e.g. blood sampling) and specify			
2.1.5 Physical stress/distress, discomfort			
2.1.6 Psychological/mental stress/distress			
2.1.7 Deception of/or withholding information from subjects			
2.1.8 Access to data by individuals or organizations other than the investigators			
2.1.9 Conflict of interest issues			
2.1.10 Or any other ethical dilemmas			
2.1.11 Is there any blood sampling involved in the study?			
RECOMMENDED ACTION: <input type="checkbox"/> QUALIFIED FOR EXEMPTION <input type="checkbox"/> NOT QUALIFIED FOR EXEMPTION			
SUMMARY OF RECOMMENDATIONS: 1. 2. 3. 4. 5.			
JUSTIFICATION FOR RECOMMENDED ACTION 			
PRIMARY REVIEWER		Signature _____	
Date: <dd/mm/yyyy>		Name <Title, Name, Surname>	