



CHECKLIST FOR EXEMPTION FROM REVIEW (Form 2.7)

STUDY PROTOCOL INFORMATION

Protocol Code:	
Study Protocol Title:	
Principal Investigator:	
Contact details and email address:	
Study Site:	
Study Protocol Submission Date:	

INSTRUCTIONS

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 “EVALUATOR’S COMMENTS.” Finalize your review by indicating your conclusions under “RECOMMENDED ACTION” and signing in space provided.

	To be filled out by Evaluator		
CRITERIA FOR EXEMPTION			REVIEWER COMMENTS
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 (NEGRIHP 2022)</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 <i>*These 5 have been identified in the NEGRHP 2022 as exemptible, as long as it does not involve more than minimal risk.</i>			
1.6. What is/are the method/s of data collection • Surveys and/or questionnaire, Interviews, or observations of public behavior • Audio/video recordings of public behavior • Research which only uses existing data			
1.7. Will the collected data be anonymized or de-identified?			
1.8. Is there a data protection plan? <i>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)); Plan on processing personal data, storage of data, access, disposal, and terms of use (; Data Privacy Act of 2012)</i>			
1.9. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? <i>*Please refer to section 2. Risk Assessment, prior to answering this item</i> <i>*If YES, then this protocol does not qualify for exemption</i>			



2. RISK ASSESSMENT	YES	N/A	
Does this research involve the following (<i>please select all that apply</i>):			
Any vulnerable groups?			
Sensitive topics that may make participants feel uncomfortable (<i>i.e. sexual behavior, illegal activities, racial biases, etc.</i>)			
Use of drugs			
Invasive procedure (e.g. blood sampling) and specify			
Physical stress/distress, discomfort			
Psychological/mental stress/distress			
Deception of/or withholding information from subjects			
Access to data by individuals or organizations other than the investigators			
Conflict of interest issues			
Or any other ethical dilemmas			
Is there any blood sampling involved in the study?			
RECOMMENDED ACTION: <input type="checkbox"/> QUALIFIED FOR EXEMPTION <input type="checkbox"/> NOT QUALIFIED FOR EXEMPTION			
TYPE OF REVIEW <input type="checkbox"/> Expedited <input type="checkbox"/> Full Board			
SUMMARY OF RECOMMENDATIONS: 1. 2.			



中華崇仁總醫院暨醫學中心
CHINESE GENERAL HOSPITAL
AND MEDICAL CENTER
EXCEPTIONAL CARE WITHIN REACH



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3.

4.

5.

JUSTIFICATION FOR RECOMMENDED ACTION

EVALUATOR

Signature

Date: <dd/mm/yyyy>

Name

<Title, Name, Surname>