

**CHECKLIST FOR EXEMPTION FORM\* (Form 3.4)**

IRB Protocol Code: Date (D/M/Y):

Protocol Title: Sponsor:

Principal

Investigators:

**A. CRITERIA FOR EXEMPTION REVIEW**

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|  | **To be filled out by the IRB Chair/Member-Secretary** | | |
| **CRITERIA FOR EXEMPTION** | Indicate if the Criteria for Exemption applies to the study protocol | | **REVIEWER COMMENTS** |
| **PROTOCOL ASSESSMENT** | **YES** | **NO** |  |
| 1. Does this research involve human participants |  |  |  |
| 1. Does this research involve use of non-identifiable human tissue/biological samples? |  |  |  |
| 1. Does this research involve the use of non-identifiable publicly available data?   *\*Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGRIHP 2022)* |  |  |  |
| 1. Does this research involve interaction with human participants? |  |  |  |
| 1. Type of research    * + Institutional quality assurance      + Evaluation of public service program      + Public health surveillance      + Educational evaluation activities      + Consumer acceptability test   *\*These 5 have been identified in the NEGRIHP as exemptible, as long as they do not involve more than minimal risk.* |  |  |  |
| 1. What is/are the method/s of data collection (please tick appropriate item)    * + Surveys and/or questionnaire, interviews, or observations of public behavior      + Audio/video recordings of public behavior      + Research which only uses existing data   *\*These have been identified in the NEGRIHP as exemptible, as long anonymity and/or confidentiality is maintained.* |  |  |  |
| 1. Will the collected data be anonymized or de-identified? |  |  |  |
| 1. 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 and 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)(NEGRIHP 2022); Plan on processing personal data, storage of data, access, disposal, and terms of use (Data Privacy Act of 2012)* |  |  |  |
| 1. Does this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHHR 2022)   *\*Please refer to Section 2. Risk Assessment, prior to answering this item.*  *\*If YES, then this protocol does not qualify for exemption.* |  |  |  |
| **RISK ASSESSMENT** | **YES** | **NO** |  |
| 1. Does this research involve the following *(please select all that apply):*  * Any vulnerable groups? |  |  |  |
| * Sensitive topics that may make participants feel uncomfortable (*i.e., sexual behavior, illegal activities, racial biases, etc.)* |  |  |  |
| * 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 |  |  |  |
| * Any other ethical dilemmas |  |  |  |
| * Is there any blood sampling involved in the study? |  |  |  |

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**B. Recommendations**

**Decision:** QUALIFIED FOR EXEMPTION NOT QUALIFIED FOR EXEMPTION

**Summary of Recommendations:**

**1.**

**2.**

**3.**

**4**

**5.**

**Comments**

(Identify items

For revisions)

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**Name & Signature of IRB Chair: Date:**

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