NEW YORK CITY DEPARTMENT OF

HEALTH AND MENTAL HYGIENE

Mary T. Bassett, M.D., M.P.H.

Commissioner

Office of Vital Statistics – DOHMH Internal Data Use Protocol Form

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General Information

Project Name:

Estimated project Start date: **Estimated project end date:**

If your end date is unknown / indefinite, leave the end date blank and check here:

> **PROTOCOL ORIGINAL**
> (If you have never completed this form before for this project, select ORIGINAL)

> **PROTOCOL AMENDMENT**
> (If an amendment, please only complete project name section, and the sections where information has changed.)

Project Description

Background - Please provide a paragraph (3- 5 sentences) on the background for this work.
Example.: this is part of a 3 year grant funded by CDC to look at X; or: This is part of ongoing surveillance conducted by Bureau Y for mandatory surveillance of Z to New York State.

Objective - Please provide a paragraph on what this work aims to accomplish.
Example: This research project aims to answer the question of X. or: The purpose of this surveillance activity is to reconcile deaths from any cause with cases of X disease investigated by our bureau.

Benefits - Please provide a few sentences on the specific populations or processes this work will benefit.
Example: This work will benefit the following New York City communities; this work will contribute to a policy action; this work will evaluate the impact of a program designed to help the following subpopulations.

Project Primary Contact

Please list the name of the person who will serve as the project administrator. This person will be responsible for updating Vital Statistics with changes to the protocol and with additions / deletions to the data users list for this project.

Project Data Users

Please use the Vital Statistics Data User template to list all data users for the project.

Data Sharing Parameters

Data Types and Frequency
VS Datasets used for this project:

Years of data used for this project:

As a part of your data project, will the Bureau of Vital Statistics need to extract data one time or on a recurring basis?

> One-time, or,

> Recurring

If recurring, how often/ at what intervals will you need the data to be extracted for you by Bureau of Vital Statistics? (e.g., periodically as needed; twice a year for the next four years, quarterly over the next year, etc.)

If recurring, please describe any modifications you know of at this time that would apply to future requests related to this data project. (e.g., each year at the beginning of the year, this project would require data to be extracted for the most current available year of data.)

Transfer and Access
Please provide details on how you expect to receive / match / transfer data. Provide names or titles of people in your unit or Vital Statistics who will play specific roles, wherever known.
Example: Matching of datasets will be conducted by the Bureau Z under the direction of Dr. Smith. Transfer of OVS data to the Bureau Z occurs securely and routinely through existing procedures. The Data Unit of Bureau Z will create a master, de-identified analytic dataset. Access to the de-identified analytic dataset will be limited to only staff involved in the analysis.

Required Data Elements

Please **list** specific variables needed for your project:

1. **Matching:** Please describe any matching required for your project. Reference specific variables used in matching.

2. **Stratifications:** (list purpose and variables – if no stratifications are required list N/A)
   Example: In order to examine demographic risk factors associated with (birth, death, etc.) in New York City, the following variables are needed:
   - *Sex (M,F)*
   - *Race (NH White, NH Black, Hispanic, Asian/Pacific Islander, Other)*
   - *Etc.*

3. **Inclusions and Exclusions**

   Please list all steps in your inclusion and exclusion criteria.
   Example 1:
   Include all mothers who gave birth in New York City between YYYY-YYYY.
   Exclude women who gave birth to infants who died.
   Example 2:
   Include all homeless shelters in the following ZIP codes (can attach lists)

4. **Weighted Sampling / Oversampling**
   If your project involves a weighted sample or oversampling, please specify details. If not, note N/A.

IRB Approval

   Does this project require IRB approval?   Yes   No

If yes, please provide the IRB protocol number:

Please also check here to indicate that you have attached a copy of the approval letter: