Appendix D:

Request for Waiver or Alteration of Authorization for Use or Disclosure of Individually Identifiable Data or Protected Health Information (PHI)

Project Title:

The Chicago Department of Public Health (CDPH) Institutional Review Board (IRB) may grant a waiver or alteration of authorization for use or disclosure of identifiable data or PHI if certain criteria are met. In cases where such waiver/alteration is granted, the IRB approves use or disclosure of individually identifiable data and waives or alters the usual requirement of obtaining an individual authorization from each affected individual to use or disclose his/her individual level data for research. The IRB must be satisfied that all three of the following criteria must be met in order for a waiver of authorization to be granted

Instructions:

In the spaces provided, use protocol-specific language to explain of how criteria A through C below are met. Following criteria A, B and C, provide the additional information requested in questions 1-5. This form should be completed by someone with knowledge and responsibility sufficient to make the assurance on page 2.

A. **The research involves no more than minimal risk to the privacy of individuals:**

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

a. *an adequate plan to protect the identifiers from improper use and disclosure;*

b. *an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is required by Illinois's Local Records Act or another law; and*

c. *adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule;*

Explain why the research involves no more than minimal risk to the privacy of individuals referring specifically to the criteria above.

B. The research could not practicably be conducted without the waiver or alteration:

Explain why the research could not practicably be conducted without the waiver or alteration to the normal process of obtaining authorization from the individual or the individual's personal representative. Impracticability is not inconvenience. Please explain in terms of reasons relating to practicability, feasibility, or workability, such as the size of the data set, lack of availability of the individuals to provide authorizations, geographic constraints, the nature of the research, etc.

C. It is not possible to conduct this research without access to or use of the PHI.

Explain why the specific identifiable records are necessary in order to conduct the research. Why couldn't the study be carried out with de-identified records? Are identifiers--even indirect identifiers--really necessary?

Additionally, please respond to each of the following items:

1. Provide a brief description of the identifiable records or PHI for which you believe use or access is necessary and without which the research could not practicably be conducted:
2. It is not practical to obtain signed authorization for this disclosure. Explain:
3. Identifiable information used or disclosed for this research will be protected from improper uses or disclosure. Explain:
4. When appropriate, the subjects will be provided with additional pertinent information after participation. Explain:
5. Explain when and how identifiable information used or disclosed for this research will be destroyed.

Assurance

I assure that all identifiable personal records and/or protected health information that are used or disclosed for this research will not be reused for other purposes, or disclosed to any other person or entity, except as specifically required or permitted by law and approved by the CDPH IRB; and no individual whose personal records or protected health information is used in this research will be identified in any written report resulting from this research.

Signature of Individual Completing this Form:

Signature	Date
Name	Position

For Use by the IRB Only

The IRB:

___✔ *is satisfied that the waiver or alteration satisfies criteria A, B and C above.*

___✔ *is* not *satisfied that the waiver or alteration satisfies criteria A, B and C above.*

IRB comments (list any additional information requests here):

Signature of IRB Chair or other IRB member designated by the Chair:

Signature	*Date*
Name	