



INSTITUTIONAL REVIEW BOARD

Request for Waiver of Authorization for Use or Disclosure of Identifiable Records or Protected Health Information (PHI)

Project Title: _____

The Chicago Department of Public Health (CDPH) Institutional Review Board (IRB) may grant a waiver(s) of authorization (HIPAA) for disclosure or use of identifiable records or PHI if specified conditions are met. Use protocol-specific language to complete A through C below.

All three of the following criteria must be met in order for a waiver of authorization to be granted.

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;

Provide a strong scientific rationale for conducting the research. What would this research contribute to scientific knowledge or alleviation of a social/public health problem? In what ways would the importance of research findings justify intrusion into subject privacy?

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?

Briefly describe the identifiable personal records or protected health information for which the waiver is requested:



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Additionally, respond to each of the following items:

- 1. The waiver of authorization will not adversely affect the rights and welfare of the subjects participating in the research. Explain:

- 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.

If you are requesting a waiver of authorization, provide your signed 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.

Principal Investigator/Print Name & Provide Signature

Date

CDPH Sponsor/Print Name & Provide Signature

Date

Submit to:
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