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| **Appendix D**  **Request for Waiver of Authorization for Use or Disclosure of**  **Identifiable Records or Protected Health Information (PHI)**   |  |  | | --- | --- | | **Project Title:** |  |   The Illinois Department of Public Health (IDPH) 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. Then check the Appendix D box on the *Application Coversheet.***  **All three of the following criteria must be met in order for a waiver of authorization to be granted. Briefly describe the identifiable personal records or protected health information for which the waiver is requested1:** |
| 1. **The research involves no more than minimal risk to subjects** (OCR HIPAA Privacy; December 3, 2002 Revised April 3, 2003).  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:   * 1. *an adequate plan to protect the identifiers from improper use and disclosure;*   2. *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 otherwise required by law; and*   3. *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 this subpart.*   Every research project could potentially incur some risk to subjects. Explain the potential risk(s) to subjects specific to the proposed research. Explain why research risks are minimal. Explain procedures to lessen the possibility that the risk(s) would occur. |
| 2. **This research is of sufficient importance to outweigh the intrusion into the privacy of subjects that will result from the disclosure of his/her identifiable records and/or protected health information** (December 28, 2000 - HIPAA Privacy Rule Final Rule; Section 164.512(i)—Uses and Disclosures for Research Purposes (3) (iv)).  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? |
| 3. **It is not possible to conduct this research without use or disclosure of identifiable records or PHI** (December 28, 2000 - HIPAA Privacy Rule – Final Rule; Section 164.512(i)—Uses and Disclosures for Research Purposes (3) (v)).  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:** |
| 4. The waiver of authorization will not adversely affect the rights and welfare of the subjects participating in the research. Explain: |
| 5. It is not practical to obtain signed authorization for this disclosure. Explain: |
| 6. Identifiable information used or disclosed for this research will be protected from improper uses or disclosure. Explain: |
| 7. When appropriate, the subjects will be provided with additional pertinent information after participation. Explain: |
| 8. Explain when and how identifiable information used or disclosed for this research will be destroyed. |
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| **If you are requesting a waiver of authorization, provide your signed assurance:**  I assure that the *Data Use Agreement* for all identifiable personal records and/or protected health information that are used or disclosed for this research will be in place prior to data release; the *Data Use Agreement* will specify that the data 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 IDPH IRB; and that the *Data Use Agreement* will specify that 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. |
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