

IRB Waiver of Alteration of Informed Consent or HIPAA Authorization

Summary Information Sheet

Waiver or Alteration of Informed Consent: For alteration – please describe and justify.

- 1) For Demonstration or government programs, Informed Consent may be waived IF
 - a. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; **and**
 - b. the research could not practicably be carried out without the waiver or alteration.
- 2) For all other proposals, all of the below must apply:
 - a. The research involves no more than minimal risk to the subjects;
 - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c. The research could not practicably be carried out without the waiver or alteration; and
 - d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Waiver of documentation of informed consent – Note: In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement (informed consent without signature) regarding the research.

- 1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; **or**
- 2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Waiver of HIPAA Authorization. City Government data that is covered by HIPAA: Ambulatory Health Services, Public Health Laboratory, Philadelphia Nursing Home, EMS, Group Health Plan {employee benefits} and DBHHS. **All below items must apply:**

- 1) The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
 - a. An adequate plan to protect health information identifiers from improper use and disclosure.
 - b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so.)
 - c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
- 2) The research could not practicably be conducted without the waiver or alteration.
- 3) The research could not practicably be conducted without access to and use of the PHI.