C I T Y O F P H I L A D E L P H I A

DEPARTMENT OF PUBLIC HEALTH
INSTITUTIONAL REVIEW BOARD
STRAWBERRY MANSION HEALTH CENTER
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www.phila.gov/health/units/irb/

IRB Waiver or Alteration of Consent or HIPAA

Complete this form if requesting waiver or alteration of informed consent or waiver of HIPAA authorization. Check all areas that you believe apply to this proposal. Requests for waiver of HIPAA authorization require a determination by the full IRB.

Study Title:_____
_____
_____

Principal Investigator:_____

Contact Information: _____

_____

1		**Waiver of Informed Consent is requested, or**
		Alteration of Informed Consent is Requested: describe alteration (verbal consent, telephone consent, etc.)
		(A) **Demonstration or government program – Both** sections below must apply
		(1) 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
		(2) the research could not practicably be carried out without the waiver or alteration.
		(B) Other proposals – all sections below must apply
		(1) the research involves no more than minimal risk to the subjects:
		(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
		(3) the research could not practicably be carried out without the waiver or alteration; and
		(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2		**Waiver of documentation of informed consent – One section below must apply NOTE:** In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
		(A) 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
		(B) 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.
3		**Waiver of HIPAA Authorization –** Sections A, B and C must **all** apply
		(A)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:
		(1) An adequate plan to protect health information identifiers from improper use and disclosure.
		(2)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.)
		(3)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.
		(B) The research could not practicably be conducted without the waiver or alteration.
		(C)The research could not practicably be conducted without access to and use of the PHI.

DO NOT WRITE BELOW THIS LINE – FOR IRB USE ONLY	
	I agree waiver of informed consent is acceptable as documented above
	I agree that alteration of informed consent is acceptable as documented above
	I agree that waiver of documentation of informed consent is acceptable as documented above
	I agree that waiver of HIPAA authorization is acceptable as documented above
	I disagree with:
Date:	Signature of Reviewer Printed Name of Reviewer: