

ST. LUKE'S UNIVERSITY HEALTH NETWORK

IRB POLICIES AND PROCEDURES MANUAL

600 Informed Consent (IC)

Policy IC 606: Waiver of Informed Consent and HIPAA Authorization

1. PURPOSE

To describe the procedures by which an IRB may waive documentation of informed consent or authorization to use and/or disclose protected health information.

2. RESPONSIBILITY FOR EXECUTING THE POLICY

IRB Medical Director; IRB Associate Directors; IRB Administrative Support; IRB Chair; IRB Vice-Chair; IRB Members and Subcommittees

3. POLICY STATEMENT

The IRB has the authority to waive the requirement for the investigator to document the informed consent process with an IRB-approved signed consent form. The IRB also has the authority to waive authorization for the use and/or disclosure of protected health information.

4. PROCEDURE

4.1: Waiver of Informed Consent

45 CFR 46.116(c) states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- 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
- The research could not practicably be carried out without the waiver or alteration.

Or that [45 CFR 46.116(d)]:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

When the IRB waives the requirement for informed consent, the IRB must document the specific criteria required by federal regulations in the minutes of the appropriate convened IRB meeting. This is not required for exempt studies.

If the research protocol meets the requirements for expedited review, the same documentation requirement holds when the waiver is granted through the expedited procedure.

FDA regulations have no provision for the waiver of informed consent, the alteration of the elements of informed consent, or the waiver of written consent. Therefore, if a study is FDA-regulated, these waivers are not permitted.

4.2: Waiver of Authorization to Use and/or Disclose Protected Health Information

Investigators at SLUHN may use and/or disclose protected health information of the covered entity for research purposes without prospective authorization, provided that they request such a waiver from

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the IRB by completion of a Request for Waiver of Subject Authorization. The following criteria must be adequately addressed:

- The use or disclosure of the protected health information involves no more than minimal risk to the privacy of individuals based on:
 - The provision of an adequate plan to protect the identifiers from improper use and disclosure.
 - The provision of an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
 - The provision of 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 law.
 - The research could not be practicably conducted without the waiver or alteration.
 - The research could not be practicably conducted without access to and use of the protected health information.

4.3: Documentation of Waiver of HIPAA Authorization

The IRB shall provide the following documentation for all waivers of HIPAA Authorization approved under Section 4.2 above:

- Identification of the IRB and the date on which the alteration or waiver was approved;
- Statement that the IRB determined that the alteration or waiver of HIPAA Authorization, in whole or in part, satisfied the criteria of Section 4.2 of this policy;
- Brief description of the protected health information for which use or access was determined to be necessary by the IRB;
- Statement that the alteration or waiver of HIPAA Authorization was reviewed and approved under expedited or full IRB review procedures; and
- Signature of the Director/Associate Director of the DHSP or other designated authority of the IRB as described in Policy GA 110.

5. TOOLS

SLUHN Request for Waiver of Subject Authorization

Approved by:

Senior Vice President for
Medical and Academic Affairs

Date: _____

Medical Director, IRB

Date: _____