



# SAINT LOUIS UNIVERSITY

## USE AND DISCLOSURES FOR RESEARCH

**Policy Number: OUC-052**

**Version Number: 2.0**

**Effective Date: 04/14/2003**

**Responsible University Official: Privacy Officer**

**Approved By: Executive Staff**

Legal and Compliance Committee

### 1.0 INTRODUCTION

Saint Louis University (hereinafter the “University”) is committed to provide services in compliance with all state and federal laws governing its operations, incorporating the highest levels of business and professional ethics. The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”. A covered entity may always use or disclose, for research purposes, health information which has been de-identified.

### 2.0 PURPOSE

The purpose of this policy is to provide guidance to workforce regarding the use or disclose information about individuals for research purposes.

### 3.0 PERSONNEL AFFECTED

This policy applies to all regular full-time and part-time faculty and staff and volunteers within all divisions of the University, including employees, professional staff members, residents, agents, representatives and consultants tasked with use and release of patient health information for research purposes.

### 4.0 DEFINITIONS

**Disclosure:** The release, transfer, provision of access to, or divulgence in any other manner, of patient protected health information to any individual or organization outside of Saint Louis University.

**Institutional Review Board (IRB):** A committee group comprised of Saint Louis University's personnel and community representatives with varying backgrounds and professional experience that review and approve the research protocol involving human subjects.

**Protected Health Information (PHI):** Individually identifiable health information transmitted or maintained in any form or medium, including oral, written, and electronic

communications. Individually identifiable health information relates to an individual's health status or condition, furnishing health services to an individual or paying or administering health care benefits to an individual. Information is considered PHI where there is a reasonable basis to believe the information can be used to identify an individual.

**Research:** a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Use:** With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within Saint Louis University.

## 5.0 POLICY

### General

When Saint Louis University uses or discloses an individual's information for research purposes, it must consider the following:

- Saint Louis University may use or disclose an individual's information for research purposes as specified in this policy.
- All such research disclosures are subject to applicable requirements of state and federal laws and regulations and to the specific requirements of this policy.

**Note:** *This policy is intended to supplement existing research requirements of the Common Rule, 45 CFR Part 46. The Common Rule is the rule for the protection of human subjects in research promulgated by the U.S. Department of Health and Human Services, and adopted by other federal governmental agencies, including the National Institutes for Health, for research funded by those agencies. In addition, some agencies have requirements that supplement the Common Rule that are applicable to a particular research contract or grant.*

- De-identified information may be used or disclosed for purposes of research, consistent with the University's policy for De-Identification of PHI.
- Saint Louis University may also conduct public health studies, studies that are required by law, and studies or analysis related to its health care operations.

## Uses and Disclosures for Research Purposes – Specific Requirements

Saint Louis University may use or disclose patient or participant information for research purposes with the patient's specific written authorization.

- Such authorization must meet all University uses and disclosure requirements and may indicate as an expiration date such terms as “end of research study,” or similar language.
- An authorization for use and disclosure for a research study may be combined with any other type of written permission for the same research study.
- If research includes treatment, the researcher may condition the provision of research related treatment on the provision of an authorization for use and disclosure for such research.

Saint Louis University may use or disclose patient or participant information for research purposes without the patient's or participant's written authorization provided that:

The University obtains documentation that a waiver of an individual's authorization for release of information requirements has been approved by the Institutional Review Board (IRB).

Documentation required of IRB when granting approval of a waiver of an individual's authorization for release of information must include:

- A statement identifying that the IRB has approved the waiver of an individual's authorization, and the date of such approval;
- A statement that the IRB has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:
  - The use or disclosure of an individual's protected information involves no more than minimal risk to the privacy of individuals, based on at least the following elements:
    - An adequate plan to protect an individual's identifying information from improper use or disclosure;
    - An adequate plan to destroy an individual's identifying information at the earliest 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; and

- 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 study, or for other research for which the use or disclosure of the protected information would be permitted under this policy;
  - The research could not practicably be conducted without the waiver; and;
  - The research could not practicably be conducted without access to and use of the Individual's protected information.
- A brief description of the protected health information for which use or disclosure has been determined to be necessary by the IRB;
- A statement that the waiver of an individual's authorization has been reviewed and approved under either normal or expedited review procedures, by the IRB, pursuant to federal regulations at 45 CFR 164.512(2);

In some cases, a researcher may request access to individual information maintained by Saint Louis University in preparation for research or to facilitate the development of a research protocol in anticipation of research. Before agreeing to provide such access to individual information, the University should determine whether federal or state law otherwise permits such use or disclosure without individual authorization or use of an IRB. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by an IRB and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, Saint Louis University will only provide such access if the University obtains, from the researcher, written representations that:

- Use or disclosure is sought solely to review an individual's protected information needed to prepare a research protocol or for similar purposes to prepare for the research project;
- No patient information will be removed from Saint Louis University by the researcher in the course of the review; the patient information for which use or access is sought is necessary for the research purposes;
- Researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;

- Researcher and his or her agents agree not to publicly identify the information or contact the individual whose data is being disclosed; and
- Applicable federal or state law may require such other terms or conditions

In some cases, a researcher may request access to individual information maintained by Saint Louis University about individuals who are deceased. The University should determine whether federal or state law otherwise permits such use or disclosure of information about decedents without individual authorization or use of the IRB. There may be instances where it would be inappropriate to disclose information, even where the individual subject of the information is dead – for example, individuals who died of AIDS may not have wanted such information to be disclosed after their deaths. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by the IRB and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, Saint Louis University will only provide such access if it obtains the following written representations from the researcher:

- Representation that the use or disclosure is sought solely for research on the protected information of deceased persons;
- Documentation, if requested, of the death of such persons; and
- Representation that the Individual's protected information for which use or disclosure is sought is necessary for the research purposes;
- Researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;
- Researcher and his or her agents agree not to publicly identify the information or contact the personal representative or family members of the decedent; and
- Applicable federal or state law may require such other terms or conditions.

### **Public Health Studies and Studies Required by Law**

When Saint Louis University is operating as a Public Health Authority, it's authorized to obtain and use individual information without authorization for the purpose of preventing injury or controlling disease and for the conduct of public health surveillance, investigations and interventions. In addition to these responsibilities, Saint Louis University may collect, use or disclose information, without individual authorization, to the extent that such collection, use or disclosure is required by law. When information is used to conduct studies pursuant to such authority, no additional individual authorization

is required nor does this policy require IRB waiver of authorization based on the HIPAA Privacy rules. Other applicable laws and protocols continue to apply to such studies.

### **Studies Related to Health Care Operations**

Studies and data analyses conducted for the University's own quality assurance purposes and to comply with reporting requirements applicable to federal or state funding requirements fall within the uses and disclosures that may be made without individual authorization as University health care operations. Neither individual authorization nor IRB waiver of authorization is required for studies or data analyses conducted by or on behalf of Saint Louis University for purposes of health care operations, including any studies or analyses conducted to comply with reporting requirements applicable to federal or state funding requirements. "Health Care Operations" as defined in 45 CFR 164.512 include:

- Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalized knowledge is not the primary purpose of any studies resulting from such activities;
- Conducting population-based activities relating to improving health care or reducing health care costs, protocol development, case management and care coordination, contacting health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;
- Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, and conducting training programs, and accreditation, certification, licensing or credentialing activities;
- Underwriting, premium rating, and other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits;
- Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
- Business planning and development, such as conducting cost-management and planning related analyses related to management and operations, including improvement of administration or development or improvement of methods of payment or coverage policies; and
- Business management and general administrative activities of Saint Louis University, including management activities related to HIPAA implementation and compliance; customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers; resolution of internal grievances; and

- Creating de-identified information or a limited data set consistent with the University policies.

**Exception:** HIV-AIDS information may not be disclosed to anyone without the specific written authorization of the individual. Re-disclosure of HIV test information is prohibited, except in compliance with law or with written permission from the individual.

## 7.0 RELATED POLICY AND DOCUMENTS

Authorization for Use or Disclosure  
 Authorization for Disclosure (form)  
 Authorization to Use or Disclose Patient Image (form)

## 7.0 SANCTIONS

Individuals who fail to comply with this policy and the procedures associated with it will be subject to disciplinary actions guided by the University's Staff Performance Management Policy, Faculty Manual, or Student Guidelines.

Non-compliance in this Policy can result in disciplinary action, including but not limited to, restricted incentive payments, suspension or termination. It may also result in the enforcement of a corrective action plan, as well as notification of the suspected misconduct and/or violation to government regulatory agencies.

This Policy does not limit the University's ability to impose greater sanctions or impose immediate action against serious violations. Disciplinary actions appropriate to the severity of the infraction will be carried out as needed.

## 8.0 CHANGES TO THIS POLICY

Changes to this policy may be necessary from time to time. At a minimum, the policy and all other program policies, procedures and guidelines will be reviewed on an annual basis.

## 9.0 RELATED POLICIES & DOCUMENTS

- Authorization for Use or Disclosure Policy
- Authorization for Disclosure (Form)
- Authorization to Use or Disclose Patient Image (Form)

## REVISION HISTORY

EFFECTIVE DATE	VERSION NUMBER	MODIFICATION
4/14/2003	1.0	New Policy
7/01/2008	1.1	Review & Change Format
3/01/2015	1.2	Review & Change Format
	2.0	Ownership Shifted from Provost to General Counsel