



SAINT LOUIS UNIVERSITY

Policy on Research Records and Biological Specimens: Ownership, Retention, Transfer, and Destruction

Policy Number: RC006

Version: 2.0

Classification: Research Compliance

Effective Date: November 5, 2012

Responsible University Official: Vice President for Research

1.0 INTRODUCTION

The mission of Saint Louis University (SLU) includes the pursuit of knowledge to further the many fields of science and to enhance human life. Therefore, the University encourages faculty, staff, and students to engage in research that has the potential for scientific discoveries that will lead to the increased health and wellbeing of people throughout the world.

2.0 PURPOSE

This policy describes the ownership, retention requirements, and circumstances under which Research Records and specimens may be removed from the University or destroyed. Under most circumstances, Research Records and biological specimens become the property of SLU when those records and specimens are developed or obtained by faculty, staff, or students of the University. The University is responsible for retention of Research Records. Research Records, particularly those related to human subjects research, are subject to requirements imposed by funding agencies, federal regulatory agencies (e.g., FDA/DHHS), the Health Insurance Portability and Accountability Act (HIPAA), and others. This policy is intended to ensure that records are held, retained, and destroyed in compliance with all regulations, and that all legal, regulatory, contractual, and policy obligations are met.

3.0 PERSONNEL AFFECTED

This policy applies to all faculty, staff, and students who are engaged in research at Saint Louis University.

4.0 DEFINITIONS

Consent Form: A written document, signed by a Research Participant (or his/her representative) that indicates understanding of the project, the risks involved, and the use of the data and specimens to be collected.

Data: Information obtained during the course of a research project or clinical trial, including but not limited to technical data, computer software, laboratory worksheets, memoranda, and notes or copies that result from original observation and activities and are necessary for replication and evaluation of the study.

Human Subject/Research Participant: Any living individual about whom an investigator gathers data directly (e.g., through intervention or interaction with that individual) or indirectly (e.g., through access to identifiable private information). This includes any living person who participates in research involving drugs or devices.

Principal Investigator: The individual who has direct and full responsibility for the design, conduct, and reporting of research.

Research: A systematic investigation or clinical procedure that is expected to contribute to generalizable knowledge which may include research and development or testing and evaluation.

Research Record: Any information regarding a research project or clinical procedure that is made permanent by preservation in a paper, electronic or other format. This includes, but is not limited to, research proposals, protocols, grant applications, related publications, and other related reports. Research Records also include, but are not limited to, data, tissue and blood specimens obtained from human or animal subjects, or identifying information regarding human subjects. Research Records may also include, but are not limited to, case history records, study protocols, synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, DNA sequences, mapping information, plants, animals, and spectroscopic data.

5.0 POLICY

5.1 RESEARCH RECORD AND DATA OWNERSHIP AND RETENTION

It is the Policy of Saint Louis University that all Research Records and data obtained or developed by SLU faculty, staff, or students remain the property and possession of SLU unless otherwise authorized by the University through a Data Transfer Agreement (DTA), Memorandum of Understanding (MOU), Memorandum of Agreement (MOA), Materials Transfer Agreement (MTA), or other appropriate documentation. This includes records and data obtained through clinical trials, projects sponsored by an external agency, research sponsored by the University, or investigator-initiated, unsponsored research undertaken by a SLU agent, in SLU facilities or using SLU equipment.

Research Records (data and specimens) must remain in the University's possession or held in trust for SLU (in cases of records transfer) for a period of no less than three (3) years past the end of the research project, or for the period of time based on sponsor guidelines or regulatory requirements if longer (e.g., HIPAA requires record retention for up to six years). Records will be retained in

accordance with all legal and regulatory requirements and/or contractual requirements. Should the Principal Investigator or other key personnel involved in the research or clinical project leave the University, unless otherwise authorized, the Research Records must remain at the University under the protection of another designated Investigator. The Department Chair and/or Dean of the College/School will determine who will take possession of the Research Records. Notification of this change to the appropriate University officials (Vice President for Research or designee) and appropriate oversight offices (e.g., Institutional Review Board, Institutional Animal Care and Use Committee, Office of Environmental Health and Safety) must occur prior to the Principal Investigator or key personnel leaving the University.

5.2 TRANSFER and SHARING OF RESEARCH RECORDS AND DATA

No Research Records, either original or copied, are to be removed from Saint Louis University premises or shared with other investigators without appropriate approval and compliance with federal and University regulations. Principal Investigators who leave the University and desire to take originals or copies of Research Records with them must go through the appropriate channels and obtain approvals before that may take place. No transfer of Research Records may be made prior to obtaining these approvals. Transfers or copies may be made only after all of the following steps have been taken.

1. A protocol detailing the change in venue and justification has been submitted and approved by the University's appropriate oversight committee/office (e.g., IRB, IACUC) and the Vice President for Research or his/her designee.
2. Approval for the transfer or copying has been granted by the funding agency or sponsor.
3. When appropriate, the Offices of Research Development and Services and Sponsored Programs Administration have approved the transfer of related grants or contracts.
4. Oversight committee (IRB, IACUC, etc.) approval from the receiving institution has been obtained to guarantee appropriate use and storage of the records and/or data.
5. When appropriate, steps have been taken to ensure that intellectual property rights of the University and research team are protected. (See Policy Regarding Intellectual Property and Patents, <http://www.slu.edu/x19062.xml>).
6. Any use or disclosure of Protected Health Information must be in accordance with HIPAA.
7. Saint Louis University's IRB must be consulted for transfer of human subject Research Records, and will determine whether a transfer of these materials or copies thereof is appropriate and allowable.
 - A. For human subjects Research Records, the IRB will determine whether Research Participants must be notified of the transfer, and whether they must give their consent and/or HIPAA authorization for a change in venue for their Research Records.

- B. In the case of anonymous data or specimens, the Principal Investigator must ensure that there is no possible way to identify the source of the data or specimens.
- C. In the case of clinical trials, continuation of patient care is ensured.
8. Hazardous materials (e.g., chemicals, radioactive materials, biohazards, or select agents) must be cleared for transfer by the Office of Environmental Health and Safety (OEHS).
 9. Laboratory animal transfers must be cleared through the University's Institutional Animal Care and Use Committee (IACUC).
 10. A Materials Transfer Agreement (MTA), Data Transfer Agreement (DTA), Memorandum of Agreement (MOA), or Memorandum of Understanding (MOU), or other documentation as appropriate, must be signed and approved by the Vice President for Research or his/her designee.

Transferred Research Records must be returned to the University if requested. In addition, during the required retention period, Research Records must be available to representatives of SLU, external sponsors or designated governmental officials, as appropriate.

5.3 DESTRUCTION OF RESEARCH RECORDS

When Research Records in the possession of the University have satisfied regulatory, legal and policy requirements, and are deemed no longer useful, they must be destroyed in accordance with University policies and/or biological specimen procedures (University Records Management and Retention Policy, dated June 5, 2007). Principal Investigators must keep documentation of the destruction of these records.

6.0 RESPONSIBILITIES

Principal Investigators are responsible for compliance with this policy and for the secure and proper use, storage, and destruction of Research Records.

Saint Louis University (ORDS, OSPA, IRB, IACUC, OEHS) is responsible for reviewing requests for transfers and ensuring that proper approvals are obtained prior to transfer.

7.0 SANCTIONS

Failure to comply with this policy may result in refusal of the University to transfer Research Records. Accordingly, research may be halted if a PI leaves the University. Funding agencies or sponsors may stop or delay the research or clinical project.

Any disputes regarding requests for original data, copies of data, or transfer of data will be referred to the Vice President for Research or his/her designee for resolution.

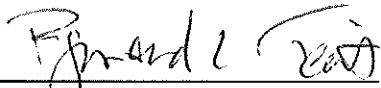
8.0 REFERENCES

University Records Management and Retention Policy, dated 6/5/07,
(http://www.slu.edu/Documents/provost/policies_procedures/Record_Management_Retention_Policy.pdf)

Policy Regarding Intellectual Property and Patents, <http://www.slu.edu/x19062.xml>

APPROVAL SIGNATURES

This policy was approved by:



Raymond C. Tait, Ph.D.
Vice President for Research

11/05/2012

Date

REVISION HISTORY

EFFECTIVE DATE	VERSION NUMBER	MODIFICATION
May 1, 2012	1.0	New Document
November 5, 2012	2.0	Modification #1

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