

Saint Louis University

Office of Compliance & Ethics

Winter 2019 Newsletter

Happy Holidays from the Office of Compliance & Ethics

The Importance of Privacy

As a University Community, SLU Employees are obligated to maintain privacy among the student population, as well as the patient population.

As a reminder, The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record.

The Health Insurance Portability and Accountability Act (HIPAA) requires health care providers and organizations, as well as their business associates, to develop and follow procedures that ensure the confidentiality and security of protected health information (PHI) when it is transferred, received, handled, or shared.

If you need guidance regarding these regulations, contact Ron Rawson, the Privacy Officer at 314-977-5884.

If you are aware of a violation of either of these regulations, please contact the SLU Integrity Hotline at slu.edu/integrityhotline.

The SLU Integrity Hotline is
available 24/7 at
slu.edu/integrityhotline



Are You a New Employee?

New employees of SLUCare, SOM, CADE, and DCHS are required to complete Compliance Training. Please go to myslu.edu and check the Home Page for any requirements.

Why is Ethics in Our Title?

Compliance is generally understood to be following the laws, regulations, and University policies. However, our office has "ethics" in the title to ensure that, as we seek to fulfill our corporate purposes of teaching, research, healthcare, and service, we maintain a culture of integrity. Guided by the mission of Saint Louis University and our Jesuit tradition, our office is committed to excellence in corporate integrity and responsibility. Our office promotes the highest standards of ethical, moral, and lawful practices to maintain SLU's values.

For additional information please visit our [website](#).

Policy Updates

- The [Workplace Violence Prevention Policy](#) is currently accepting [feedback](#) during the 30-day comment period. Feedback will be accepted until January 3, 2020
- The *Non-Retaliation Policy* and the *Reporting Concerns of Misconduct Policy* were both approved in November 2019 by the University Leadership Council, after Dr. Pestello approves the policies, they will be available in [PolicyStat](#).
- Additional information on the University Policy Program can be found on the [Compliance and Ethics web-site](#) or by contacting Michael Reeves, Ph.D. 977-5880, Michael.reeves@health.slu.edu

University Policy vs. Unit/Department Policy

University Policy	Unit/Departmental Policy
Applies across the University	Applies only to unit/department
Notifies people outside unit of rights and responsibilities	May not conflict with University Policy
Defines rules and regulations between units of the University	

From the Export Control Desk

As Santa travels to make all of his deliveries on Christmas Eve, he will be exporting many controlled items (i.e. laptops, tablets, UAV's), luckily similar to anyone traveling over the holidays, Santa is covered by the Gift (15 CFR 740.12) or BAG (personal technology, 15 CFR 740.14) exceptions, these exceptions allow the transport of gifts or personal technology without a license. However, if Santa, or a SLU employee are taking their work computer on a personal trip, a TMP would still be required and they should contact the Export Control Officer.

For additional questions or comments on Export Controls, please contact Michael A. Reeves, Ph.D. at 977-5880 or michael.reeves@health.slu.edu

In the University, we understand that our faculty have many responsibilities and demands on their time. One of those responsibilities is following federally-mandated guidelines for reporting relationships and financial interests outside of SLU. We in the Compliance Office have collaborated with the Research Integrity and Safety Group and the School of Medicine to create a combined electronic disclosure form to streamline the process of completing this required annual Outside Interest Disclosure. The disclosure period wrapped up in early December and we are working with the individuals who have not yet submitted. The three conflict of interest committees will now review the data and recommend management plans when appropriate to mitigate any significant risk. Kerry Borawski welcomes questions about the process or when and what to disclose at 314-977-7720.

Reporting to ClinicalTrials.gov

One of the requirements of the Food and Drug Administration Amendments Act of 2007 (FDAAA) is an expanded database of clinical trials information through a national clinical trials registry. The National Institutes of Health (NIH) established an easily accessible website, ClinicalTrials.gov. The purpose of the legislation was to ensure the timely availability of clinical research outcomes for applicable trials to increase patient enrollment, track subsequent progress of applicable trials, and increase transparency.

The principal investigator (PI) of an investigator-initiated clinical trial is required to report descriptive information on the study, updates to the recruitment status, and annual updates. For those studies deemed to be an Applicable Clinical Trial ("ACT"), the study results are to be reported within one year of the trial's completion.

Research trials subject to ClinicalTrials.gov reporting requirements are those that are funded, even partially, by a grant from any agency of the Department of Health and Human Services. ACTs must be interventional in design, have at least one site in the US, and be conducted under an Investigational New Drug application (IND) or Device Exemption (IDE).

The Quality Control guidelines of the ClinicalTrials.gov site require that PIs correct identified registration issues within 15 days and result-related issues within 25 days. Noncompliance consequences are intense, including the potential for criminal proceedings, civil penalties up to \$12,100/day, and the possible withholding of future federal grant funding.

HHS frequently asked questions <https://clinicaltrials.gov/ct2/manage-recs/faq> and the staff of the Clinical Trials Office clinical-trials-office@health.slu.edu are available to assist you.

Did you Know (Physician Billing)?

The appropriate code for poisoning is T36-T50 first, followed by the manifestation(s) of the poisoning. If the intent of the poisoning is unknown or unspecified, code the intent as accidental intent.

Office of University Compliance & Ethics

North Campus—DuBourg Hall, Room 33:

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