



COMPLIANCE E-NEWS

The Office of General Counsel Has Moved!

The OGC is now located:
3556 Caroline Mall
Caroline Building C307
St. Louis, MO 63104
Telephone: 314-977-5767
Facsimile: 314-977-5192

Ways to Report Adverse Incidents & Risk Management Concerns:

1. Call the Office of the General Counsel at 314-977-5767
2. Call the URPT Line at 314-977-URPT (8778). This is a dedicated line where a message can be left reporting an incident.
3. Go to <http://slucareincident.slu.edu> to make an online report of an incident. Username: incident; Password: slucare. This report will be sent to the OGC for handling.



Upcoming Education Sessions:

HIPAA
Thursday, Feb. 10, 2011
3:30 p.m. – 4:30 p.m.
LRC Room #
110

If you have any comments or questions regarding the Compliance E-News please contact Lynn Monahan at monahanl@slu.edu

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Managing a Conflict of Interest in Research

Kerry Borawski, Senior Research Compliance Auditor

The Office of University Compliance formed the Research Compliance Team in 2009 to coordinate and document the University's efforts to comply with increasingly complex regulations related to research. Should anyone ever ask for proof that we have a first-rate secure research compliance environment; our goal is to answer YES & immediately show them evidence to support it.

One of the areas the Research Compliance Team first addressed is Conflicts of Interest in Research, which is defined by the University's COI Policy as "A situation in which a significant financial interest of an investigator could directly and significantly affect the design, conduct, or reporting of the investigator's sponsored or educational activities". COIs arise when someone has two relationships with a single outside sponsor, such as serving as a compensated advisor to an outside company and also conducting research on a product made by that same external company. Conflicts indicate that the University's research is both marketable and practical. They are inevitable in the current model of research and medicine because the private sector, with their commercial interests, will naturally seek out and compensate the leading thinkers of their industry. The University encourages such collaboration with industry while simultaneously encouraging a full and transparent disclosure of the conflicted relationship.

The COI disclosure is the responsibility of the investigator and is coordinated by the Office of Responsible Conduct in Research under the leadership of Dr. Raymond Tait. Disclosures are made annually and will be electronically captured within the University's research platform, eRS, in the first quarter of 2011. Every person on campus who touches research, "through the design, conduct or reporting of research", should complete a COI Disclosure Statement. This group includes Principal Investigators as well as lab technicians, graduate students, nurse managers, etc.

The Manager of Responsible Conduct in Research, Johnny Kidd, reviews all of the disclosure statements and identifies positive disclosures of financial conflicts. He works with the researcher and the Committee on Conflict of Interest in Research (comprised exclusively of faculty members) to develop an effective and verifiable COI Management Plan.

Managing conflicts is essential to our research. Management Plans protect researchers from suspicion of misuse of consulting monies by creating an environment of transparency. The COI Disclosure and Management Plan Process protect the integrity of our research ... the integrity of our researchers ... and the integrity of our University

Governmental Requests for Information

Visits by government investigators have become a more frequent occurrence for companies in recent years. Government investigators may arrive unannounced at the work places or the homes of present or former Saint Louis University employees. Although the University has no reason to believe that such an investigation is imminent, it is important employees be familiar with the recommended course of action.

Frequently, individuals contact the Compliance Department requesting advice and information regarding the following potential scenarios:

- Unannounced visits by investigators
- Requests for information – verbal, written, electronic
- Serving of search warrants and subpoenas

When any of the above instances occur in the workplace or at home, the following course of action should be taken:

- Notify your immediate supervisor and the Office of the General Counsel, Medical Center Campus at 977-5767.
- Ask to see and make a copy of the investigator's agency identification card. Verify the name, agency affiliation, and business telephone number.
- Escort the investigator to a sequestered conference room to await the arrival of your supervisor.
- Verify the reason for the investigator's visit.
- Do not answer any questions of substantive nature. You may politely decline to answer these questions.
- If there is a subpoena or warrant to be served, respectfully inform the investigator that our procedure for responding is to immediately involve supervisory personnel and General Counsel.
- In all instances, be polite and courteous. Do not attempt to impede the investigator.

The employee's supervisor and University General Counsel will assist in securing the necessary information after the legitimacy of the request is verified and evaluated.