SAINT LOUIS UNIVERSITY

OFFICE OF UNIVERSITY COMPLIANCE

March 2017 Compliance Newsletter

IRB Self-Assessment Checklist

Principal Investigators (PIs) are ultimately responsible for all compliance matters on their project, yet they may not have first-hand knowledge of the day-to-day elements for which they are accountable. The Compliance Office recommends that PIs involved in human subject research launch their own review using the IRB's recently published Self-Assessment Checklist in order to independently identify compliance areas needing their attention.

The IRB encourages PIs, Research Directors or Study Teams interested in assessing their research operations to use this new tool, in whole or in part, to ensure that regulatory requirements are satisfied. The nine-page Checklist includes detailed questions in various categories to prompt the investigator to exam their procedures and documentation as a careful review against regulatory and institutional expectations.

The categories provided for self-review include the following:
- Research Team
- IRB Protocol Adherence, Amendments and Continuing Review
- Subject Recruitment Procedures
- Privacy, Data Storage and Confidentiality
- Subject Data Collection
- Informed Consent
- Data Safety and Monitoring
- External Site Monitoring
- Reporting
- Regulatory Documentation for Investigational Products
- Laboratory Documentation

Self-Assessment programs strengthen the research operations because they are effective in illustrating compliance areas that may require a PI's attention. It will offer investigators a broader perspective as to the compliance of their research efforts, and will reinforce to all research team members the PI's commitment to compliance. You are not obligated to report your findings to an outside office unless, of course, the finding qualifies as an IRB Protocol Violation which must always be reported to the IRB for the safety of our human subjects. Please use the IRB's Reporting Guidelines to determine if your finding constitutes mandated reporting.

The IRB offers their assistance to any researcher interested in customizing or implementing the Self-Assessment Checklist, at irb@slu.edu or (314) 977-7736. If you are interested in a Self-Assessment but do not have the available resources to commit to it, please contact us for support, Research Compliance Auditor Kerry Borawski, kborawsk@slu.edu or (314) 977-7720.

2017 Billers' Meeting Schedule
All meetings will be from 10:00-11:00am

April 11, 2017
May 9, 2017
June 13, 2017
July 11, 2017
August 8, 2017
September 12, 2017
October 10, 2017
November 14, 2017
December 12, 2017

COMPLIANCE REQUIREMENTS:

Please check your mySLU page, "Compliance Requirements" section to make sure you have completed all required training, such as Fair Warning Training, HIPAA Training, Annual Compliance Update, or New Employee Compliance Training.

Welcome New Employees!

All new employees of SLU are required to complete compliance training within 30 days of their start date. The module can be found on the "Compliance Requirements" section of your mySLU homepage.

The CODING CORNER

Causal Relationships

It is important to remember the way our documentation affects the reporting of diagnoses for a patient encounter. Typically, the coder would have to have specific documentation from a provider that would link two conditions as related. This in some cases would result in the use of a 'combination code.' An update to the ICD-10-CM Conventions & General Coding guidelines now state that "Use of the term 'with' presumes a causal relationship between the two conditions linked by this term. Code these conditions as related even in the absence of provider documentation explicitly linking them."

For Example:
- Code as Related: Diabetes Mellitus Type 2, uncontrolled with left heel ulcer (E11.621)
- Code as Unrelated: 1. Diabetes Mellitus Type 2, uncontrolled (E11.65) 2. Left Heel Ulcer (L97.429)

Effective Communication Is Paramount for Accurate Billing

Communication between a provider and the coder is one of the most important aspects of accurate billing. It is critical that both parties respect each other's skills and expertise. The coder must be comfortable approaching the provider for clarification of documentation. This communication can take place face to face, via email or text but, it is imperative that it take place.

It is the coder's responsibility to inform the provider when documentation issues arise, as well as when rules and regulation changes take place. It is the provider's responsibility to be open and accepting of the coder's advice. Providers often say "I've worked at SLU for __ years; I have never had any denials." "My coders never call me." "I have no issues with documentation."

At the same time the coders say "I am always telling the providers when there are documentation issues" "I communicate with my providers all the time." It appears that the coder believes he/she is communicating to the provider but, the provider does not seem to be 'hearing' the message. Effective communication is crucial.

Communication Tips:
- Communicate to be understood. Many people communicate to impress – not express. Use short words that communicate clearly and concretely; present one idea, at the most two ideas, in one sentence.
- Consider the sender/receiver's communications strengths and weaknesses, and communicate in the manner that is best accepted by the sender/receiver.
- Listen with purpose. Continue to listen even when the urge is to debate.
- Judge content not delivery. Look beyond the speaker's delivery and concentrate on what is being said.

It is up to both parties to reach out to the other. The Provider needs to ask "How is my billing?" "Do you see anything that I need to address?" The coder needs to reach out "I've noticed an increase in your denials. Can we meet to go over them?"
Proper documentation leads to increased reimbursement. Inadequate documentation will lead to increased denials, lower reimbursement as well as compliance issues.

Export Control Penalty

A Chinese technology firm, ZTE, recently agreed to pay a record $1.19 billion penalty for violation of Department of Commerce Export Control regulations. ZTE exported American made equipment to Iran in direct violation of U.S. embargoes. While this is a private corporation, it should serve as a reminder that Export Controls are a highly regulated and punishable area of federal regulations.

Any questions related to Export Controls should be directed to the Export Control Officer, Michael Reeves 977-5880; mreeves8@slu.edu.