CHANGES TO THE RESEARCH TEAM

Over the course of one’s research, it is common for the members of a study’s research team to fluctuate for a variety of reasons. Maybe the individuals available at proposal time are no longer at the University in order to contribute to the design, conduct or reporting of the research. Or maybe there is a need within the team for additional resources or different talents, or some other sort of staffing change. Whatever the cause, it is important that eRS and eIRB remain an accurate and up-to-date reflection of the current research team.

Please remember to periodically review the Study Personnel Information section of both reporting systems for relevance, and update them when necessary. This allows for appropriate internal controls and communication within University systems and among different University offices, as well reflecting your commitment to accurate record-keeping. The Research Division has advised that whenever there are changes to the research team (whether an addition of a new member or the removal of one), the eRS record for the study should be updated. Additionally, the IRB protocol must be updated via the submission of an Amendment Form to reflect personnel changes and any new member may not perform research duties prior to IRB approval of that Amendment.

The research teams recorded in both programs will not always be identical. Within eRS, we are asked to use the NIH definition of “Senior/Key Personnel” which includes the Principal Investigator (PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. The IRB's definition of who to list on the research team is limited to those individuals who are considered to be engaged in the human subjects’ portion of the research. This definition can be found in the IRB Application, "Personnel Information" section, and differs by discipline. Therefore, the research team's statistician may be included as a Research Team/Key Personnel member within eRS but would not be listed as personnel on the IRB Protocol if they never interact with participants or have access to identifiable data.

Please direct any questions specific to the addition or removal of research team members to the Research Division. Questions for the IRB can be sent to irb@slu.edu or 314-977-7744 and questions related to eRS can be sent to your applicable department representative found at http://www.slu.edu/division-of-research-administration-home/office-of-research-services-(ors)/contact-ords.

Modifier 22 - Increased Procedural Services

When the work required to provide a service is substantially greater than typically required, it may be identified by adding modifier 22 to the usual procedure code. Documentation must support the substantial additional work and the reason for the additional work (i.e., increased intensity, time, technical difficulty of procedure, severity of patient’s condition, and physical and mental effort required).

Our J5 MAC provider WPS Medicare provides helpful information on the appropriate use of modifier 22:

WPS will consider claims submitted with a 22 modifier on a case by case basis. There is no set percentage of additional reimbursement. Any payment in addition to the fee schedule for the procedure will be dependent on the documentation describing the very unusual difficulty encountered. Therefore, additional reimbursement may or may not be allowed.

When the modifier 22 is used, two separate documents will be required to support the claim:

- An operative report and
- A separate statement indicating how the service differs from the usual (WPS Medicare provides an option to use their document titled “Modifier 22 Documentation Form” for this requirement).

For additional information on modifier 22 please visit:

Important Information about Billing and Documentation

Modifier 22 Fact Sheet
**Medical Record Documentation**

Accurate and complete documentation in the medical record is imperative in order for patients to receive the appropriate care that they need. Not only does the medical record facilitate the patient’s treatment but it is also one of the main sources of information used during continuity of care if the patient is to be transferred or receive care from another healthcare provider.

The goal of implementing the electronic health record system was to strengthen the relationship between patients and clinicians by improving the accuracy and clarity of medical records and making health information available. This would allow providers to make better decisions regarding their patient’s care and would allow patients to be more informed about their care (cms.gov). The responsibility of accurate and complete documentation in the medical record doesn’t fall solely upon the providers themselves. It is the responsibility of any clinical worker who is involved in the care of the patient to document events, communications, and other relevant information regarding the patient’s care.

To aid in making sure that our medical records meet state, federal, legal, regulatory and accrediting standards SLUCare has published requirements of the medical records content in their Medical Record Documentation Standards Policy. The following are a few important reminders regarding appropriate documentation procedures as outlined in SLUCare’s policy (in italics are additional comments not written into the policy):

- Each face to face credentialed clinician encounter must include the following documentation:
  - Chief complaint/purpose of visit;
  - *Avoid the use of a simple “patient is here for follow up” and elaborate on what the patient is following up on.*
  - Allergy/sensitivity and type of reaction; including documentation of no known allergies;
  - Research study participation, including documentation if none known;
  - Review of active medications;
  - Pertinent medical history and physical exam findings;
  - Differential and/or working diagnosis;
  - Diagnostic work up and plan of treatment; and
  - Follow up as indicated.

- The attending physician must review all face to face encounter notes in the medical record.
  *The appropriate Teaching Physician attestation statement should be made, when applicable, to the E/M, procedure, and/or diagnostic test, etc.*

- Telephone and electronic clinical contacts with or pertaining to patients are to be documented in the medical record.
  *Examples include but not limited to medication questions, treatment instruction questions and pre/post procedure inquiries.

- Copying and Pasting:
  - Copying and pasting previously documented notes or graphics into a new location is strongly discouraged and should be done with the utmost care, knowing that a physician pasting previous documentation is unequivocally stating that the given text or graphics are correct and appropriate. Accordingly, the physician who copies and pastes within the record assume complete authorship of the material so copied and pasted. Therefore this technique is appropriately used in the EHR only by the note's original author.
  - *As copying and pasting is not prohibited per this policy it is strongly recommended to limit the information carried forward to ensure that the documentation reflects the work performed and information reviewed by the provider during that specific patient encounter. Carrying forward of unnecessary or irrelevant information puts the provider at risk of inflating the medical record as well as increasing the potential for billing errors.*

- If erroneous documentation is charted, correct documentation in the patient chart.
  - If encounter is closed, create an addendum.

*The SLUCare Service Desk may be contacted for assistance*

References: [www.cms.gov](http://www.cms.gov)/SLUCare Physician Group Policy #1655926
What is the Hotline?

The Saint Louis University Compliance Hotline is available as a confidential, toll-free resource for anyone with a concern regarding business, billing, and/or ethical practices in his or her department. Anonymous or self-identified reports of any nature can be made to the Hotline at 1-877-525-KNOW (5669).

- The Hotline is available 24 hours a day, seven days a week.
- All calls are answered by a person who is not affiliated with Saint Louis University.
- No call tracing or recording devices are ever used during the phone call. Your call will be answered by a trained interview specialist who will submit a report to the SLU Compliance Department.
- You have the option to give your name or report anonymously.
- You will be given a password and call back date at the end of your call should you desire to follow up on the status of your report, or if you would like to provide additional information.
- All Saint Louis University employees, agents, and contractors are protected from discrimination and retaliation for filing a report to the Hotline.

Kerry Borawski
Interim Director
kborawsk@slu.edu
977-7720

Theresa Brewer
Compliance Coordinator
tbrewer3@slu.edu
977-5889

Hannah Halstead, MSW
Research Auditor
halstehf@slu.edu
977-5887

Ron Rawson
Privacy Officer
rawsonr@slu.edu
977-5884

Michael Reeves
Export Controls Officer
mreeves8@slu.edu
977-5880

Anne Schwartz, RHIA, CPC
Physician Billing Auditor
aschwai2@slu.edu
977-5885

Cynthia Stacy, CPC, CPMA,
CPC-I, CRC
Compliance Education Manger
stacyc@slu.edu
977-5888

The Compliance off will be
Closed
Friday, March 25, 2016
in observance of Good Friday.

Address:
Schwitalla Hall, M229
1402 S. Grand Blvd.
St. Louis, MO 63104

Fax Number:
977-5195