
Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Protocol Status: APPROVED

Date Submitted: 02/01/2018

Approval Period: 02/18/2018-02/17/2019

Important Note: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

* * * Personnel Information * * *

Study Personnel Roles:
-Principal Investigator: accepts responsibility for study, must sign obligations, can edit protocol and submit to IRB
-Administrative Contact: additional study contact, may or may not also be member of research team, can edit/prepare protocol and submit to IRB
-Key Personnel (Research Team): SLU member of research team, can view protocol (not edit)
-Non-SLU Collaborator: member of research team from another institution or organization outside of SLU, has no access to system, must be provided with PDF of protocol. NOTE: SLUH/SSM employees who collaborate regularly may obtain a guest SLU account if access to system is needed.
-Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

IMPORTANT NOTE: Human Subjects Protection Training is mandatory for all research team personnel.

Principal Investigator (PI) Mandatory

PI must be SLU affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD)	Title
Taylor, Jason	MD	Associate Professor

Email	Phone	Fax
jtaylo83@slu.edu	(314) 577-8764	

Department Name
IM-Gastroenterology

Human Subjects Training Completed? Y
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience *?HELP?*
Dr. Taylor is a board certified gastroenterologist and has been with SLU since 2011.

Research Team Member Duties Picklist

1.		Recruitment	2.		Obtains consent
3.	X	Determine Subject Eligibility for Accrual	4a.		Subject Physical Examinations
4b.		Follow-up Visits including physical assessments	5.		Perform study procedures or Specimen Collection
6a.		Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.		Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.		Subject Randomization or Registry	8.	X	Collection of Subject Data

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

9. Report Data (CRFs, e-CRFs, Spreadsheets)
10. X Data Analysis
11a. Review Adverse Events
11b. Treat and Classify Adverse Events
12. X Other (Please insert explanation below.)

Chart review and collect data from medical records. Manuscript development.

UserID	CourseCompletionDate	Course
jtaylo83	05-08-2012	CITI Biomedical Research Basic Training

Administrative Contact

Name of Administrative Contact	Degree	Title
Torretta, Susan	MS	Research Coordinator

Administrative Contact

Name an Administrative Contact if someone in addition to the PI should be contacted about the protocol.

Name of Administrative Contact	Degree	Title
Torretta, Susan	MS	Research Coordinator
Email	**Phone**	**Fax**
torretta@slu.edu	(314) 977-7829	
Department Name		
IM-Gastroenterology		

Is this individual also a member of the research team? N

Human Subjects Training Completed?
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience **?HELP?**

Research Team Member Duties Picklist

1.	Recruitment	2.	Obtains consent
3.	Determine Subject Eligibility for Accrual	4a.	Subject Physical Examinations
4b.	Follow-up Visits including physical assessments	5.	Perform study procedures or Specimen Collection
6a.	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	Subject Randomization or Registry	8.	Collection of Subject Data
9.	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	Data Analysis
11a.	Review Adverse Events	11b.	Treat and Classify Adverse Events
12.	Other (Please insert explanation below.)		

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

UserID	CourseCompletionDate	Course
torretta	11-05-2001	CITI/University of Miami Training
torretta	08-26-2010	Good Clinical Practice (GCP)
torretta	02-03-2017	Good Clinical Practice (GCP) Refresher

Key Personnel (Research Team)

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Reddy, Kavya	MD	Housestaff Resident	IM-Gastroenterology

SLU IRB

Department Chair Mandatory

The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.

Name of Department Chair	Degree	Title
Nayak, Ravi	MD	Professor
Email	**Phone**	**Fax**
nayakrp@slu.edu	(314) 577-8856	

Department Name
IM-Pulmonary

Is this individual also a member of the research team? N

Human Subjects Training Completed?
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience ***?HELP?***

Research Team Member Duties Picklist

1.	Recruitment	2.	Obtains consent
3.	Determine Subject Eligibility for Accrual	4a.	Subject Physical Examinations
4b.	Follow-up Visits including physical assessments	5.	Perform study procedures or Specimen Collection
6a.	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	Subject Randomization or Registry	8.	Collection of Subject Data
9.	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	Data Analysis

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

11a. Review Adverse Events **11b.** Treat and Classify Adverse Events

12. Other (Please insert explanation below.)

UserID	CourseCompletionDate	Course
nayakrp	11-12-2015	Good Clinical Practice (GCP)
nayakrp	09-06-2005	CITI Social/Behavioral Research Basic Training
nayakrp	08-22-2011	CITI Biomedical Research Basic Training

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Taylor, Jason, MD	IM-Gastroenterology	Dr. Taylor is a board certified gastroenterologist and has been with SLU since 2011.	Determine Subject Eligibility for Accrual, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Chart review and collect data from medical records. Manuscript development.
Reddy, Kavya, MD	IM-Gastroenterology	Gastroenterology research while an internal medicine resident.	Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Help with manuscript.

SLU eIRB

---

* * * Subject Population * * *

Subject Population(s) Checklist

Select All That Apply :

X Adults
Cognitively Impaired Subjects
Employees (specifically targeted)
Fetuses
Minors (under 18)
Neonates
Non English Speaking Subjects
Pregnant Women
Prisoners
Students (specifically targeted)
Terminally Ill Subjects
Wards of the State
Other (any population that is not specified above)

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

* * * Study Location * * *

Study Location(s) Checklist

Indicate where the study will be conducted. Select all that apply:

- [ ] Saint Louis University, Medical Center Campus
- [ ] Saint Louis University, Frost Campus
- [ ] Saint Louis University, Madrid Campus
- [ ] Saint Louis University, SLUCare Practice Locations
- [X] SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)
- [ ] Cardinal Glennon Children's Medical Center
- [X] Saint Louis University Hospital (SSM Health- SLU Hospital)
- [ ] SLU-SSM Cancer Center Research Alliance Sites
- [ ] Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study. You may provide such documentation as it becomes available, but you may not begin work at those sites until documentation of support is provided to the IRB.) Please refer to the Guidance for involving non-SLU institutions in human subject research.

---

* * * General Checklist * * *

General Checklist

Select All That Apply :

- [ ] Collection of Specimens
- [ ] Data collection via e-mail or the Internet
- [ ] Deception/Incomplete Disclosure
- [ ] Dietary Supplements, Vitamins, and Other Food Agents
- [ ] FDA Approved Device
- [ ] FDA approved drugs, reagents, other chemicals administered to subjects (even if they are not being studied), or biologic products
- [ ] Genetic Testing
- [ ] HIV Testing
- [ ] Human blood, cells, tissues, or body fluids
- [ ] International Research or Research on International Populations
- [ ] Investigational drugs, reagents, chemicals, or biologic products
- [ ] Investigational Device
- [X] Investigator Initiated Study *?HELP?*
- [X] Medical Records

SLU IRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Photography, Video, or Voice-Recording Subjects
Questionnaires and/or tests
Radioisotopes/radiation-producing machines, even if standard of care
rDNA/Gene Transfer Therapy
Registry(ies)
Specimens to be stored for future research projects (must be in consent form)
X Study of existing data or specimens
X University Indemnified Study (SLU is responsible for liability coverage) *?HELP?*
Other (clarify in text box to the right)

Single Use. Provide a brief summary and justification for the Single Use Therapy. Note: This application will refer to research. For Single Use applications it is understood that 'research' will mean 'therapy'.

---

* * * Funding * * *

Funding Checklist

X NONE

Funding - Grants/Contracts

Funding - Industry Sponsor

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. You will be prompted for these in section #16 (Attachments).

---

* * * Expedited Paragraphs * * *

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b) Research on medical devices for which

(i) An investigational device exemption application (21 CFR Part 812) is not required; or

(ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited

SLU eIRB

review, including studies of cleared medical devices for new indications.)

EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

X 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Retrospective chart review of data that has already been obtained (2011-2014). We will evaluate SLU hospital's medical health record system for this data.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.

   a) Previously approved research where
      (i) The research is permanently closed to the enrollment of new subjects;
      (ii) All subjects have completed all research-related interventions; and
      (iii) The research remains active only for the long term follow-up of subjects.

   b) Previously approved research where no subjects have been enrolled and no additional risks have been identified.

   c) Previously approved research where the remaining research activities are limited to data analysis.

9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

* * * Background, Purpose, Study Procedures * * *

Title

Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Complete Sections 1 - 16. In sections that allow reference to sponsor protocol or grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate.

1. Background

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

a) **Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator Initiated studies must cite references in the response provided or attach a bibliography. *?HELP?***

Enteral nutrition is the recommended method of providing sufficient nutrition and calories to patients who are unable to tolerate oral feeding.1 Patients who suffered from an acute dysphagic stroke are unable to maintain sufficient oral caloric intake due to acute neurologic damage. There are a few methods to provide enteral feeding to these patients including nasogastric (NG) tubes, nasojejunal (NJ) tube, Percutaneous Endoscopic Gastrostomy (PEG) tubes, or Percutaneous Endoscopic Gastrostomy- Jejunostomy (PEG-J) tube. Nasoenteral tubes are recommended for short-term use in patients who are expected to resume oral nutrition within 30 days.1 According to the 2011 ASGE guidelines, if a patient is unable to resume oral feeding after 2-3 weeks with a nasoenteric tube then PEG tube placement is recommended.1 This recommendation to wait 2-3 weeks post stroke comes from 2 early studies published in the 1990s in which PEG tubes were not placed until at least 2 weeks post stroke. Furthermore, there were no studies that evaluated early PEG placement until 2005, where one study was done evaluating early PEG placement compared to NG tubes placement. The ASGE grades this recommendation as low quality, stating further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.1 There have not been any further guidelines or updates since the 2011 ASGE guidelines.

In reviewing the literature, the study by Park et al was a randomized 28-day trial of comparing PEG and NJ tube feedings in 40 patients with persisting neurologic dysphagia for at least 4 weeks. This study found that PEGs placed > 4 weeks post-neurologic dysphagia provided safe and effective nutrition compared to NG tubes.2 PEG patients received a greater portion of their prescribed feed and gained significantly more weight after 7 days of feeding.2

Norton et al included 30 patients who were evaluated with persisting dysphagia at 14 days post acute stroke. This study found mortality at 6 weeks was lower in the PEG group and the PEG group received significantly more of the prescribed feed compared to the NG group.3 According to several different criteria, including serum albumin, they concluded that the PEG fed patients showed greater improvement in nutritional state compared to the NG tube fed group.3 Neither of these studies address early (<4 weeks post stroke) PEG tube placement.

Another study evaluated outcomes in 321 patients who were randomized to early PEG tube placement versus NG tube feeding post acute stroke. No statistically significant difference in mortality was found between the two groups but there was borderline significance in poor outcome in the PEG group compared to the NG tube group (7.8% (0.0%- 15.5% CI, p=0.05).

4This study was not powered appropriately; there was insufficient statistical power to exclude more modest differences between groups.4

One retrospective study evaluated PEG complications after acute stroke in 74 patients.6 PEG tubes were placed between 5-27 days post stroke. There was no mention of evaluation of cardiovascular complications; nor did they evaluate complications of early placed PEG tubes versus late placed PEG tube post stroke. They did, however, evaluate in-hospital complications (aspiration, GI bleeding) and late complications (aspiration pneumonia, infection, accidental PEG removal) as well as death. They found a 30% incidence of late complications from PEG tube placement.6 Long term follow up was available in 48 patients. 12 out of 48 patients were dead at 3 months.6

A study published in Annals of Gastroenterology identified markers that predict early mortality in post PEG patients (female, low albumin, positive urine culture).8 This study also evaluated whether markers for early mortality after PEG insertion could be used to predict length of hospital stay post-PEG. They identified mechanical ventilation, low albumin levels and present of 2 or more co-morbidities as predictors of late discharge.8 This study also raises the issues of providing a waiting period to preclude unnecessary PEGs in patients likely to die in the immediate post- PEG placement period.8

Patients who suffer from a stroke require either intensive inpatient rehab post stroke or a skilled nursing facility. In order to be discharged from the hospital to one of these facilities, patients must either be able to resume oral nutrition or a PEG tube must be in place. Facilities do not accept patients with nasoenteral tubes, as these tubes have a high risk of displacement and treatment failure.2,3 Thus, the demand to initiate early PEG tube placement and feedings post stroke has risen.

There are no studies comparing the outcomes of early PEG placement (<14 days post stroke) versus late PEG placement (> 14 days post stroke). It is important to evaluate the procedural and post-procedural complications of PEG tubes, mortality, predictors of mortality and overall patient outcomes. Addressing these questions will provide better evidence for timing of PEG tube placement in post stroke patients, which will aid the ultimate goal, better patient care.

Bibliography:
1.ASGE Guideline. Role of endoscopy in enteral feeding. ASGE 2011; 74: 7-12.
2.Park RH, Allison MC, Lang J, et al. Randomised comparison of percutaneous endoscopic gastrostomy and nasogastric tube feeding in patients with persisting neurological dysphagia. BMJ 1992; 304:1406-9.
3.Norton B, Homer-Ward M, Donnelly MT, et al. A randomized prospective comparison of percutaneous endoscopic gastrostomy and nasogastric tube feeding after acute dysphagic stroke. BMJ 1996; 312:13-6.
4.Dennis MS, Lewis SC, Warlow C. Effect of timing and method of enteral tube feeding for dysphagic stroke patients (FOOD): a multicentre randomised controlled trial. Lancet 2005; 365:764-72.
5.World Health Organization ICD. http://www.who.int/classifications/icd/en/
6.Eelco F.M. Wijdicksa Molly M. McMahon. Neurology Journal Cerebrovasc Dis 1999; 9:109–111
7.Ponsky JL, Gauderer MW. Percutaneous endoscopic gastrostomy: a nonoperative technique for feeding gastrostomy. Gastrointest Endosc 1981; 27:9-11.
8.V.V. Gumaste, K.R. Bhamidimarri, R. Bansal, L. Sidhu, J. Baum, A. Walfish. Factors predicting early discharge and mortality in post-percutaneous endoscopic gastrostomy patients. Annals of Gastroenterology (2014) 27, 42-47.

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

b) **Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.**

N/A

2. Purpose of the study

a) **Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.**

Our goal is to assess the safety of early PEG tube placement in post stroke patients by evaluating post PEG tube mortality, predictors of mortality and complications in patients who receive PEG tubes less than 7 days or greater than 7 days post acute dysphagic stroke.

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

b) **List your research objectives (specific aims & hypotheses of the study).**

Primary:
1.To compare mortality at 1 month and at 3 months in patients post acute dysphagic stroke who underwent PEG tube placement at less than or equal to 7 days post stroke versus greater than 7 days post stroke

Secondary:
2.To compare the periprocedural complications with PEG tube placement at less than or equal to 7 days or greater than 7 days post stroke. Periprocedural complications are defined as occurring during and immediately after PEG tube placement and within 24 hours of the procedure. Cardiovascular complications (stroke, MI), aspiration, bleeding, internal organ injury, perforation, and infection.
3.To compare the rate of post procedural complications with PEG tube placements at less than or equal to 7 days or > 7 days post stroke. Post procedural complications are defined as complications occurring > 1 day to 3 months post PEG. Complications include cardiovascular complications (new stroke, TIA, MI, coronary event).
4.To evaluate predictors of mortality. Factors that will be evaluated include: sex, age, comorbidities (dementia, diabetes, CAD), laboratory values including leukocytosis prior to procedure, blood/urine culture, albumin).

SLU eIRB

Please save frequently

c) **Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.**

This study is a retrospective chart review. We are unsure of the number of patients, but will estimate approximately 150 patients total, with 75 patients with PEG placed before 7 days since acute dysphagic stroke and 75 patients with PEG placed after 7 days for acute dysplagic stroke. Should our search criteria yield fewer or more patients than expected, then we will simply report the total number of patients that fit our inclusion and exclusion criteria. Patients will be enrolled from St. Louis University Hospital (SLU) along with other SSM hospitals. We will use data from our medical record system, Epic, and also the gastroenterology procedure

documentation program ProVation. We will include patients from 2011-2014 who underwent PEG tube placement post acute dysphagic stroke. Patients will be included in the study by evaluating International Classification of Diseases (ICD) codes associated with each patient's admission as well as ProVation biling diagnosis of PEG tube placement. ICD is a healthcare classification system, providing a system of diagnostic codes for classifying diseases.

PEG tubes were placed endoscopically using the standard "pull through" technique described by Ponsky and Gauderer.7 We will not be including PEG tubes placed surgically or radiologically. All patients were admitted to the hospital at the time of the PEG insertion and were post acute dysphagic stroke. A dose of antibiotics, most times, Ancef 1 gm IV 30 minutes prior to the procedure was given. However, other antibiotics with similar spectrum of coverage may have been used. The PEG site was examined for infection and bleeding 24 hours after insertion and tube feeds were subsequently recommended at that time.

d) **If subjects will be given placebo, please justify placebo use. *?HELP?***

N/A

3. Study Procedures

a) **N** Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites?

Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.

Will the SLU site be participating in all parts/procedures/arms of the study?

If No, explain what SLU will NOT participate in:

SLU IRB

Please save frequently

Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

b) **Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).**

This study is a retrospective chart review. We are unsure of the number of patients, but will estimate approximately 150 patients total, with 75 patients with PEG placed before 7 days since acute dysphagic stroke and 75 patients with PEG placed after 7 days for acute dysplagic stroke. Should our search criteria yield fewer or more patients than expected, then we will simply report the total number of patients that fit our inclusion and exclusion criteria. Patients will be enrolled from St. Louis University Hospital (SLU) along with other SSM hospitals. We will use data from our medical record system, Epic, and also the gastroenterology procedure documentation program ProVation. We will include patients from 2011-2014 who underwent PEG tube placement post acute dysphagic stroke. Patients will be included in the study by evaluating International Classification of Diseases (ICD) codes associated with each patient's admission as well as ProVation biling diagnosis of PEG tube placement. ICD is a healthcare classification system, providing a system of diagnostic codes for classifying diseases.

classification system, providing a system of diagnostic codes for classifying diseases.

PEG tubes were placed endoscopically using the standard "pull through" technique described by Ponsky and Gauderer.7 We will not be including PEG tubes placed surgically or radiologically. All patients were admitted to the hospital at the time of the PEG insertion and were post acute dysphagic stroke. A dose of antibiotics, most times, Ancef 1 gm IV 30 minutes prior to the procedure was given. However, other antibiotics with similar spectrum of coverage may have been used. The PEG site was examined for infection and bleeding 24 hours after insertion and tube feeds were subsequently recommended at that time.

c) **If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.**

N/A

d) **Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.**

Sample size calculation for this particular study is not feasible. This is a single center study and we are limited to the number of patients who have received PEG tubes at this institution and we cannot create a large sample size. Thus, no sample size calculation is needed. All patient's who fit the inclusion criteria will be included in this study.

Patient characteristics will be described using means and medians for continuous variables and frequencies (percents) for categorical level variables. Comparisons between PEG groups will be made using t-tests (continuous data) or chi-squared (categorical data). To address the main study objective, survival analysis will be conducted, using a log-rank test to compare overall survival between groups. Secondary objectives will be analyzed using chi-squared tests. Additional statistical analyses will be used when appropriate. Statistically significant differences are defined as alpha<0.05. All analyses will be performed using SPSS version 22.0.

Please save frequently

e) **State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#13) and the debriefing script/statement must be uploaded in the Attachments section (#16). See IRB Deception Guidelines.**

f) **Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be** N

---

the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. *?HELP?*

If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.

g) Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnoses, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). N

If yes, please describe and include whether there are plans to share findings with study participants.

h) Is this study subject to the NIH Genomic Data Sharing Policy? N

The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding mechanism. Click here for more specific examples.

---

* * * Radioisotopes or Radiation Machines * * *

You have not selected the Radioisotopes option in the General Checklist. If you would like to add Radioisotopes information, please select the option to enable this section.

4. Radioisotopes or Radiation Machines

In this section, investigators must enter all radiation usage associated with the protocol.

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-233", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur first, even before submission to IRB. For more information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

(1) It is the responsibility of the PI to assure the accuracy and completeness of the data submitted in this section, consistent with guidelines provided below. (2) For projects requiring radiation procedures, please refer to this guidance.

a) If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT,

---

radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)

b) Total estimated research radiation dose * :

* Calculate from the table above by adding the Effective Dose Subtotals for all procedures.

NOTE: Informed Consent Radiation Exposure Risk Statement- The applicant must insert the appropriate Informed Consent Radiation Exposure Risk Statement template language into the SLU IRB Informed Consent, inclusive of applying the total estimated research radiation dose specified in item b) from the table above, as instructed in the SLU IRB Informed Consent Template. Contact the IRB Office at 977-7744 or irb@slu.edu with any questions.

SLU eIRB

---

* * * Devices * * *

5. Devices

a) Please list in the space below all investigational devices to be used on subjects during this study.

b) Please list in the space below all FDA approved devices to be used on subjects during this study.

---

* * * Drugs, Reagents, Chemicals, or Biologic Products * * *

6. Drugs, Reagents, Chemicals, Biologic Products, or Dietary Supplements, Vitamins, and Other Food Agents

Pilot	Phase I	Phase II
Phase III	Phase IV	Not Phased

List placebo if it is considered a drug (contains more than inactive ingredients). For example, normal saline is considered a drug that should be listed, whereas placebo tablets are usually inert ingredients that do not need to be listed.

b) Please list in the space below all investigational drugs, reagents or chemicals to be administered to subjects during this study. Attach all applicable Investigator Brochures in section #16 (Attachments).

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

c) **Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to subjects during this study. Attach all applicable package inserts in section #16 (Attachments).**

d) **Please list in the space below all dietary supplements, vitamins, minerals, or foods to be administered to subjects during this study.**

Please read the IND Statements.

---

* * * Other Levels Of Review * * *

7. Other Levels Of Review

1. University Radiation Safety

Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). For information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

X **Not Applicable**

Yes, study involves radioactive materials (per instructions, submit to RSC before IRB)

2. Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g., Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the SLU Biological Safety Officer. Most of these protocols also require review and approval by the SLU Institutional Biosafety Committee (IBC). Please contact the SLU Biological Safety Officer at 977-6888 for more information.

X **Not Applicable**

Yes, study requires Institutional Biosafety review

3. Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee

Saint Louis University Hospital requires that all research involving the administration of medications

SLU IRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital's Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmsluh.com for more information.

X **Not Applicable**

Yes, study requires PTNT review

4. Saint Louis University Hospital

All research involving Saint Louis University Hospital, including the Emergency Department, inpatient or outpatient services (including outpatient surgery at ABI and the infusion center at DOB) and medical record access, requires approval from the Saint Louis University Hospital Research Review Committee prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. Documents should be submitted as soon as possible, or at the latest, concurrently with IRB submission. Please contact the Research Compliance Office at 577-8113 or sluh-research@ssmhealth.com of the SLU Clinical Trials Office (CTO) at 977-6335 or clinical-trials-office@health.slu.edu for more information.

Not Applicable

X **Yes, study requires Saint Louis University Hospital review**

5. SSMSL

All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy.Young@ssmhealth.com for more information.

Not Applicable

X **Yes, study requires RBR review**

6. Does this project require registration on ClinicalTrials.gov, and/or is this project subject to the NIH GCP Training Requirement? (Select "Yes" if either apply) **N**

Registration may be required if any of the following apply: 1) The project meets the FDAAA definition of an "Applicable Clinical Trial", which requires registration on ClinicalTrials.gov. 2) As of January 1, 2017, a new NIH policy mandated biomedical and behavioral "Clinical Trials" to be registered on ClinicalTrials.gov. In addition, NIH policies require personnel on NIH "Clinical Trials" to take GCP training every three years. 3) Registering may be required for Journal Publication (ICMJE). Please review relevant definitions here. Contact the CTO at clinical-trials-office@slu.edu with questions about registering on ClinicalTrials.gov and refer to the training page of the IRB website for

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

information on NIH GCP Training requirements.

---

* * * Subject Population * * *

8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) **Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).**

≥18 years old

b) **Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI).**

150 patients, 75 patients with PEG placed less than 7 days post stroke and 75 patients with PEG placed greater than or equal to 7 days post stroke

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

SLU eIRB

c) **Number of evaluable subjects to be accrued study wide. *?HELP?***

150 patients,75 patients with PEG placed less than 7 days post stroke and 75 patients with PEG placed greater than or equal to 7 days post stroke

d) **If including vulnerable populations (<a href=https://www.slu.edu/Documents/research/IRB/Minors_in_Research.doc target=_blank>minors, <a href=https://www.slu.edu/Documents/research/IRB/Pregnant_Women_Fetuses.docx target=_blank>pregnant women and fetuses, <a href=https://www.slu.edu/Documents/research/IRB/Neonates.docx target=_blank>neonates, <a href=https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc target=_blank>non-English speaking, economically or educationally disadvantaged, <a href=https://www.slu.edu/Documents/research/IRB/Prisoner_Research.doc target=_blank>prisoners, <a href=https://www.slu.edu/Documents/research/IRB/Adults_Unable_to_Provide_Consent.docx target=_blank>adults temporarily or permanently unable to consent for themselves): 1) provide the rationale for the importance of including this population in the research, and 2) specify the measures being taken to minimize risks to potentially vulnerable subjects. Click on hyperlinks to access <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-(irb)/general-guidelines target=_blank>SLU Guidelines containing additional considerations and strategies for mitigating risks.**

N/A

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

e) **If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. *?HELP?***

Minors are not included in the study as acute dysphagic stroke is rarely seen in minors.

f) **If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects. See <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-(irb)/general-guidelines target=_blank>SLU Guidelines for additional considerations and strategies for mitigating risks.**

g) **Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? Upload recruitment materials in the Attachment Section (#16). Important to remember: potential subjects cannot be contacted before IRB approval. NOTE: The use of SLU owned websites in an approved SLU format (e.g., Cancer Center website, etc.) are always approved methods of recruitment.**

Data will be collected by means of ICD-9 codes from Epic and diagnosis codes from ProVation. Data will be collected by myself and another member of the research team. The data will be extrapolated and de-identified.
Data will be collected from 2011-2014. Data includes, indication for PEG placement (stroke), date/time procedure was done, date patient was discharged from the hospital, new diagnosis codes post procedure prior to discharge from the hospital, date of death, reason for death, hospital length of stay (date of admission to date of discharge), complications noted in the procedure note or chart documentation by diagnosis code.
Records will be kept on confidential, on a password protected device.

---

* * * Subject Population * * *

8. Subject Population (continued)

Page numbers from a sponsor's protocol/grant may be referenced in 8h.

h) **Inclusion and Exclusion Criteria.**

Identify inclusion criteria.

Inclusion criteria: patients who suffered an acute dysphagic stroke, ≥18 years old. Patients who had a PEG tube placed endoscopically through the "pull through" method (not surgically or radiologically placed).

Identify exclusion criteria.

Exclusion criteria include: Other underlying neurologic disorder causing dysphagia NOT stroke, age < 18 years old.

i) **Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.**

---

in the study. Include provisions for prorating payment.

N/A

j) Describe who will cover study related costs. Explain any costs that will be charged to the subject.

N/A

k) Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected. If the study is Investigator-initiated, a timeline for individual subject recruitment, follow-up, total time for subject accrual, and data analysis for the study is required.

After IRB approval:
Stage 1: Review medical records, 3-4 months
Stage 2: Data collection, 2-3 months
Stage 3: Data analysis, 1 month
Stage 4: Manuscript development for publication, 1 month

---

* * * Risks * * *

9. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

SLU eIRB

Page numbers from a sponsor's protocol/grant may be referenced in 9.1, 9.2, 9.3, and 9.4.

1. Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.

2. Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.

3. Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

4. **Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.**

5. **Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).**

Potential risk of loss of confidentiality

6. **Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).**

7. **Describe why this investigational compound/drug/device/procedure's risks/benefits are potentially better than standard of care or other common alternatives. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form. *?HELP?***

N/A

8. **Describe any psychological, social, or legal risks the subject may experience. *?HELP?***

Potential risk of loss of confidentiality

Page numbers from a sponsor's protocol/grant may be referenced in 9.9 and 9.10.

9. **Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.**

N/A

10. **Reproductive Risks.**

a. **Please list the pregnancy category of any drugs or N/A.**

SLU eIRB

N/A

b. Please describe any reproductive risk associated with any part of the research study. Include any data from other studies (animal or human).

N/A

11. Data Safety Monitoring

Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring board. Please refer to SLU Guidelines for Data and Safety Monitoring as you complete the questions below.

a. Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N/A

If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor and research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time (MD or DO), and g) stopping/halting rules (if any exist).
A DSM charter can be referenced for all items except for "f) who is reviewing SAEs in real time."

If no, please justify why not.

b. Is there a Data Safety Monitoring Plan (DSMP)? N/A

Note, if all relevant plan information is included in DSMB question above, select 'Yes' and state "see above" in the answer box.

If yes, provide details (labeled a-e) including: a) what types of data or events are captured and how are they documented, b) who is monitoring data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, d) who is reviewing SAEs in real time (MD or DO), and e) stopping/halting rules (if any exist).

If no, please justify why not.

12. In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects. Include whether research is sensitive given cultural norms.

a. State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.

b. Will there be language barriers and if so, how will they be addressed?

Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.

NOTE: Export control laws include the transfer of technical information and data, as well as information and technology to foreign nationals. If this study has international components, contact the SLU Export Control Officer for direction on whether export control policies apply.

SLU eIRB

* * * Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy * * *

10. Benefits/Alternatives

a) Benefits. Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.

There is no direct benefit to the patients studied in this research project. However, results will benefit future post stroke PEG tube patients as we will determine which patients are at lowest risk for morbidity and mortality post PEG placement.

b) Alternatives. Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.

N/A

11. Procedures to Maintain Confidentiality and Privacy

Federal regulations require that research materials be kept for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Confidentiality

To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).

For the questions below, please use the following definitions:

     Anonymous/De-identified: data contain no identifiers, including code numbers that investigators can link to   individual identities;

     Coded: data in which (1) identifying information, such as name or social security number, has been replaced   with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists   enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept   separately from coded data; AND/OR

     Identifiable: data that includes personal identifiers (e.g., name, social security number), such that   information could be readily connected to respective individuals.

a) Electronic (Computer) Data

Click "Add" to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Electronic Data

SLU eRE

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Type of Data	Storage Location	Data Transmission Outside of SLU	Supplemental information related to above items can be entered here or leave blank:
Coded	SLU ITS managed device (computer, tablet, etc.) with encryption; SLU ITS network storage (T: drive (shared drive), U: drive (personal drive)); SLU ITS recognized document-level encryption	Not Applicable, I will not be sending/sharing electronic data outside of SLU	

1. What type of electronic (computer) data does your study involve? Note: only one data type can be selected. Click on Add from the main page to enter information for additional data types once you've saved this information.

   Anonymous/De-identified

   X Coded

   Identifiable

2. Where are the data being kept/collected? (Check all that apply)
   NOTE: THE ITEMS LISTED BELOW IN ITALICS CANNOT BE USED FOR DATA WHICH ARE (1) SENSITIVE AND CODED OR (2) IDENTIFIABLE unless an exception has been granted by the SLU Info Security Team (InfoSecurityTeam@slu.edu). Please attach proof of exception in section #16.

   X SLU ITS managed device (computer, tablet, etc.) with encryption

   SLU ITS managed device (computer, tablet, etc.) without encryption

   X SLU ITS network storage (T: drive (shared drive), U: drive (personal drive))

   X SLU ITS recognized document-level encryption

   SLU Google Drive/Documents (can only be shared with slu.edu addresses)

   Collection or Storage of data in SLU REDCap

   Collection or Storage of data in SLU Qualtrics

   Removable storage devices (flash drive, USB hard drive) with encryption

   Removable storage devices (flash drive, USB hard drive) without encryption

   Personally owned/non-SLU managed device (computers, tablets) with encryption

   Personally owned/non-SLU managed device (computers, tablets) without encryption

   Third party services such as Dropbox, Box, Evernote, SurveyMonkey, etc. (Please specify):

   Sponsor provided system or portal (Please specify):

   Other (Please specify):

3. If the data will be sent/shared outside of SLU, how are they being sent/shared? (Check all that apply)

   X Not Applicable, I will not be sending/sharing electronic data outside of SLU

   SLU Email account with an encrypted file attachment

SLU eIRB

Posting of data directly to an external web portal using secure connection (i.e., HTTPS)
Sending of data to a secure FTP site (e.g., SFTP, FTPS)
Use of Virtual Private Network connection (VPN)
Use of SLU REDCap account
Use of an external Secure Web Mail account
Physical delivery of encrypted files via CD/DVD or other medium (e.g., USPS, FedEx, Courier)
Other (Please specify):

4. Supplemental information related to above items can be entered here or leave blank:

b) Hardcopy (Paper) Data

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data
Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Hardcopy Data

Type of Data	Storage Location	Transported Data Security	Supplemental information related to above items can be entered here or leave blank:
Coded	SLU Locked Room/Office; SLU Locked Suite; SLU Long Term Storage Facility	Personnel Supervision; SLU Email account with an encrypted file attachment	

1. What type of hardcopy (paper) data does your study involve? Note: only one data type can be selected. Click on Add from the main page to enter information for additional data types once you've saved this information.
   Anonymous/De-identified
   X Coded
   Identifiable
2. Where are hardcopy materials being kept? (Check all that apply)
   SLU Locked Cabinet
   X SLU Locked Room/Office

SLU eIRB

X SLU Locked Suite
X SLU Long Term Storage Facility
Non-SLU Location (Please specify):
Other (Please specify):

3. If hardcopy materials are transported at any time in the study (e.g., from data collection site to storage site, shared with co-investigators), how are they secured?
Locked container
X Personnel Supervision
Physical delivery (e.g., USPS, FedEx, Courier)
Fax Machine
X SLU Email account with an encrypted file attachment
Non- SLU Email account with an encrypted file attachment
Other (Please specify):
4. Supplemental information related to above items can be entered here or leave blank:

SLU IRB

c) If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.

Information (Patient name/DOB, MRN) will be replaced by a number i.e. code. A key to decipher the code exists enabling linkage of the identifying information to the private data that are collected as part of the research. This decipher code will be kept secure on one password protected device (computer) until the manuscript has been accepted.

d) If data or specimens are being shared outside of the research team, indicate who will receive the material, specifically what they will receive (data or specimens), and if an agreement has been signed to cover the transfer. Note: unless covered under a Clinical Trial or other agreement, the transfer of data or specimens to an external entity will require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) is used; for the transfer of data, a Data Use or Data Transfer Agreement is used. Please contact the Research Innovation Group at 314-925-3027 for assistance.

N/A

e) If samples or data will be provided to SLU from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected. Note: unless covered under another agreement (e.g., Clinical Trial Agreement or subcontract), the transfer of data or specimens from an external entity to SLU may require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) may be required; for the transfer of data, a Data Use or Data Transfer Agreement may be required. Please contact the Research Innovation Group at 314-925-3027 for assistance.

N/A

f) If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be

---

Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).

g) If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).

h) Describe any study-specific (non standard of care) information or documentation that will be put in the participants' medical records for this research (e.g., study visit notes, lab results, etc.). If none, state "not applicable". NOTE: documentation of research in Epic should be done in accordance with the <a href=https://www.slu.edu/Documents/research/IRB/Epic_Research_Charting_Policy.pdf target=_blank>SLUCare Epic Research Charting Policy and <a href=https://www.slu.edu/Documents/research/IRB/Reasearch_Documentation_Epic.pdf target=_blank>Clinical Workflow: Documenting Research Encounters in Epic.

N/A

i) Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc. N

If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.

Privacy

Privacy refers to persons having control over the sharing of oneself with others.

j) Please indicate how participant privacy will be protected in this study (select all that apply):

Discussion of health related and/or personal information in a private room/area

Research interactions/interventions are conducted in a private room/area

Use of drapes or other privacy measures

X Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

X Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

---

* * * Potential Conflict of Interest * * *

12. Potential Conflict of Interest

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

SLU eIRB

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

1) X No equity interest and/or Financial Interest less than or equal to $5K
2) Any equity interest and/or Financial Interest exceeding $5K but not exceeding $25K in the past year or expected in the current year
3) Financial Interest exceeding $25K in the past year or expected in the current year

Check all those that apply:

Consulting
Speaking Fees or Honoraria
Gifts
Licensing agreement or royalty income
Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors
Other fees/compensation

If you have marked #2 or #3, please contact coi@slu.edu to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan.
   has been approved for all investigators for this study

---

is pending

has not been initiated

2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:

Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

1. Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.

   . This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.

2. You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact coi@slu.edu.

SLU eIRB

* * * Informed Consent * * *

13. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) **How is consent being obtained? When and where will the discussion take place? If the study involves a Non-English Speaking participant/population, please include details about plans for translated consent materials and interpreters to be used (see <a href=https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc target=_blank>SLU Guidelines for Involving Non-English Speaking Subjects for more details).**

A waiver of consent is being sought.

2) **If the study involves adults unable to consent for themselves (whether diminished capacity to consent**

---

is temporary, permanent, progressive or fluctuating), please address the following: a) how is capacity to provide consent being assessed (initially and throughout study, if applicable); b) if unable to provide consent, how is LAR being determined (See <a href=https://www.slu.edu/Documents/research/IRB/LAR_Guidelines.docx target=_blank>SLU LAR Guidelines); c) if unable to provide consent, will assent be obtained and if not, why not?; d) if unable to provide assent, will dissent be honored and if not, why not? Note: participants initially unable to provide consent for themselves are expected to be given an opportunity to provide consent once capacity is gained. See <a href=https://www.slu.edu/Documents/research/IRB/Adults_Unable_to_Provide_Consent.docx target=_blank>SLU Guidelines for Adults Unable to Provide Consent for additional detail.

N/A

Note: Any assent documents which will be used per the Adults Unable to Provide Consent guidance, should be appropriately named and uploaded using the Add button and the Consent drop down menu selection.

Informed Consent

Title	Consent Type	Attached Date
Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes	Waiver of Consent	

Title	Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes
Consent Type	Waiver of Consent

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

Upload your additional recruitment statement. Use the Model Recruitment Statement/Cover Letter to create your recruitment statement. If more than one statement will be used (e.g., adult, parental, etc.), label the documents with these headings to help distinguish them from one another.

NOTE: Investigators seeking a waiver of consent must provide justification to all items. Simply restating the criteria in the response box is not acceptable; responses must include a justification as to how/why the study meets each criterion. ?HELP?

Address the following four points. A Yes/No response is not adequate.

1. **The research involves no more than minimal risk to the subjects.**

   Correct, there is no direct contact with study subjects during this study. This is a retrospective chart review. There is no more than minimal risk to subjects. There is a potential risk of loss of confidentiality.

2. **The waiver will not adversely affect the rights and welfare of the subjects.**

   This study will not adversely affect the rights or welfare of the subjects as this is a retrospective chart review and information obtained from patient charts will be coded. Subjects were already treated, thus, their care will not be affected.

3. **The research could not practicably be carried out without the alteration.**

   Once the PEG tube is placed, patients are not seen or evaluated by gastroenterology after this admission. I do not have regular contact with this patient population. Due to the fact that post dysphagic stroke PEG tubes are a very specific criteria for inclusion, we will need all patients who fit this criteria included in this study. Previous studies have had small sample sizes and we hope have include as many patients that fit our criteria as possible to improve the power of our study.

4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**

   No additional information will be obtained or provided to the subjects.

SLU 2006

---

* * * Assent * * *

14. Assent

Complete this section if your study includes minors. The Assent Form Template provides guidelines for writing assent documents.

1. **Will minors be asked to give assent, then consent once they reach adulthood? If not, please justify. If not capable to provide assent initially, please address whether assent will be obtained as the minor gains capacity. Note: children who reach the age of adulthood during participation should be given the opportunity to provide consent as parent/guardian consent no longer applies. If obtaining consent would be impracticable (e.g., this is a registry with data/specimen obtained long ago), a waiver of consent should be added for IRB review. See <a href=https://www.slu.edu/Documents/research/IRB/Minors_in_Research.doc target=_blank>SLU Guidelines for Research Involving Minors for additional detail.**

2. **If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.**

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

3. **How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition). If capacity is fluctuating, please explain how capacity will be assessed throughout the study.**

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

---

* * * HIPAA * * *

15. HIPAA

Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information visit the IRB HIPAA page or refer to the SLU IRB HIPAA Guidance.

1. **Will health information be accessed, received or collected?**

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

2. **Which personal identifiers will be received or collected/recorded?**

   No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. (Skip remainder of page).

   Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

   City/State/Zip codes

   Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

   Age (if subjects are 90+ years)

   At least one direct identifier will be received or collected/recorded.

   X Names

   Social Security numbers

   Telephone numbers

   Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

   All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such

SLU eIRB

---

geographic units containing 20,000 or fewer people is changed to 000

X All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Fax numbers

Electronic mail addresses

X Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locations (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.

3. Sources of Protected Health Information:

X Hospital/medical records for in or out patients

X Physician/clinic records

X Laboratory, pathology and/or radiology results

Biological samples

Interviews or questionnaires/health histories

Mental health records

X Data previously collected for research purposes

X Billing records

X Other

Please describe:

Procedure records

4. If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.

X Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited

SLU eIRB

Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.

With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5. HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.

HIPAA Documents

HIPAA Documents	Title	Attached Date
Waiver of Authorization	Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes	01/24/2018

Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes

HIPAA Documents: Waiver of Authorization

NOTE: Investigators seeking a waiver of authorization must provide justification to all items. Simply restating the criteria in the response box is not acceptable; responses must include a justification as to how/why the study meets each criterion.

a) **Please provide a brief description of the protected health information for which use or access has been determined to be necessary.**

The research team will compile data from SLU Hospital's medical record systems EPIC and Provations. The data will include either patient's name or MRN number, dates, medical history, labs, procedure details. There will be no direct patient contact, this is a retrospective chart review. Patient identifying information will be coded. One master key will be stored on a password protected computer until the manuscript is accepted.

b) **To obtain approval for a waiver or alteration of HIPAA authorization for the use and/or disclosure of PHI resulting from participation in a research study, the project has to meet the criteria listed below. Please explain how your study meets these criteria.**

SLU eIRB

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

1) **The use or disclosure of PHI involves no more than minimal risks to the privacy of individuals.**

   The only risk is loss of confidentiality. The data will be coded and stored on a password protected computer.

2) **PHI information will not be reused or disclosed to any other person or entity, except as required by law for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.**

   Correct. The PHI will not be shared with anyone outside of the research team. It will only be shared by IRB and if required by law.

3) **The research could not practicably be conducted without the waiver.**

   Once the PEG tube is placed, patients are not seen or evaluated by gastroenterology after this admission. I do not have regular contact with this patient population. Due to the fact that post dysphagic stroke PEG tubes are a very specific criteria for inclusion, we will need all patients who fit this criteria included in this study. Previous studies have had small sample sizes and we hope have include as many patients that fit our criteria as possible to improve the power of our study.

4) **The research could not practicably be conducted without access to and use of PHI.**

   Correct. It is necessary to use PHI to open patient's chart and evaluate data as well as initially organize data.

c) **Please describe an adequate plan to protect any identifiers from improper use and disclosure.**

The PHI will be kept on a password protected computer, patient information will be coded with only one master key. This information will only be accessed only by the research team.

d) **Please describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**

The code will be destroyed after the manuscript has been submitted. After the code is destroyed, there is no more PHI is present.

---

* * * Attachments * * *

16. Attachments

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.

Possible documents for this protocol could include:

- **Bibliography**

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

- **Cooperating Institution's IRB Approval**
- **Data Collection Sheet**
- **Debriefing Script**
- **Device Information/Documentation**
- **Grant Proposal/Sub-Contract**
- **Human Subjects Training Certificate/Proof of Training**
- **Information Sheet/Brochure**
- **Interview/Focus Group Questions**
- **Investigator's Brochure**
- **Letter of Agreement/Cooperation**
- **IND Application Letter**
- **Package Insert**
- **Patient Diary Form**
- **Questionnaire/Survey**
- **Recruitment Material (e.g., flyers, ads, e-mail text)**
- **Safety Information (DSM Information)**
- **Scientific/PPC Review or Department Chair Review**
- **Sponsor's Protocol**
- **Sponsor's Protocol Amendment**
- **Study Design Chart/Table**
- **Other files associated with the protocol (most standard formats accepted: pdf, jpg, tiff, mp3, wmv, etc.)**

SLU eIRB

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Scientific/PPC Review or Department Chair Review	29062 Scientific Review Form	01/30/2018	02/01/2018
Data Collection Sheet	Approved_PEG Data Collection Sheet	02/19/2018	02/19/2018

Document Type Scientific/PPC Review or Department Chair Review
Attachment 29062 Scientific Review Form
Document Name 29062 Scientific Review Form

Document Type Data Collection Sheet
Attachment Approved_PEG Data Collection Sheet
Document Name Approved_PEG Data Collection Sheet

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

---

* * * PI Obligations * * *

PI Obligations

By clicking the box below you indicate that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, and the Ethical Principles of the American Psychological Association (if applicable) for the research described. It also indicates that you have the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol.

Clicking the box also affirms that the activities involving human subjects will not begin without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and Saint Louis University's assurance with the Department of Health and Human Services. The PI assures that if members of the SLU research team access protected health information (PHI) from a covered entity in order to seek consent/authorization for research or to conduct research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without IRB authorization or approved waiver. PI further assures that the SLU research team will comply with the terms of a Data Use Agreement to PHI (if any).

1) Have you completed the annual Conflict of Interest in Research Disclosure Form? Y

You can only select N/A if you are not currently listed on any externally funded research projects nor listed on any proposals for externally funded research support.

NOTE: An annual disclosure must be completed by all faculty, staff and students involved in the design, conduct or reporting of externally funded research applications and awards.

2) Have your financial interests changed significantly since you completed the annual disclosure form? N

The PRINCIPAL INVESTIGATOR certifies that he/she has read the University's Conflict of Interest Research Policy and has checked the appropriate box in the 'Potential Conflict of Interest' section of the application. In addition, the PRINCIPAL INVESTIGATOR certifies that, to the best of his/her knowledge, no person working on this project at SLU has a conflict of interest or if a conflict of interest does exist, that an appropriate management plan is in place.

According to the Saint Louis University Conflict of Interest in Research Policy, as PI, it is your responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of externally sponsored research of their requirement to complete a Conflict of Interest in Research Disclosure Form.

Protocol Title: Percutaneous Endoscopic Gastrostomy (PEG) tube placed less than or greater than 7 days post stroke: Mortality, Predictors of Mortality, Complications, and Outcomes.

X **I accept this responsibility.**

X **The Principal Investigator has read and agrees to the above certifications and will abide by the above obligations.**

---

* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
02/19/2018	NEW FORM APPROVED	Y	Y
02/19/2018	NEW FORM REVIEWER(S) ASSIGNED		
02/19/2018	NEW FORM SUBMITTED (CYCLE 1)	Y	
02/18/2018	NEW FORM REVIEWER(S) ASSIGNED		
02/02/2018	NEW FORM PANEL ASSIGNED		
02/01/2018	NEW FORM SUBMITTED	Y	
02/01/2018	NEW FORM PREREVIEWED		
01/30/2018	NEW FORM PREAPPROVAL		
01/24/2018	NEW FORM PROTOCOL CLONED (26190)		

SLU eIRB