
Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

Protocol Status: APPROVED

Date Submitted: 04/12/2018

Approval Period: 04/13/2018-11/20/2018

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
Brunworth, Joseph	MD	Assistant Professor

Email	Phone	Fax
brunworth@slu.edu	314-577-8884	

Department Name
Otolaryngology

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?*

As a fellowship trained Otorhinolaryngologist, Dr. Brunworth has been involved in clinical and basic science research for the last 11 years. He serves as the scientific reviewer for OTO's protocols and is OTO's Director of Clinical Research.

Research Team Member Duties Picklist

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

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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

UserID	CourseCompletionDate	Course
brunworth	2014-10-27	CITI Biomedical Research Basic Training

Administrative Contact

Name of Administrative Contact	Degree	Title
Patel, Kunjan	BA	Student
Webb, Deniece	BA	Research Coordinator
Gresham, Malia	MD	Otolaryngology Resident
Cass, Lauren	MD, MPH	Otolaryngology Resident

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**
Patel, Kunjan | BA | Student

Email | **Phone** | **Fax**
kpatel65@slu.edu | 6306393886

Department Name
Otolaryngology

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

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?

Kunjan has been involved in clinical and basic science research in genetics, otolaryngology, and telemedicine at SLU School of Medicine and Washington University School of Medicine for 6 years. He has completed multiple clinical projects working with Otolaryngology faculty at SLU School of Medicine.

Research Team Member Duties Picklist

1. Recruitment
2. X 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

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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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.	X	Subject Randomization or Registry	8.	X	Collection of Subject Data
9.	X	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	X	Data Analysis
11a.		Review Adverse Events	11b.		Treat and Classify Adverse Events
12.		Other (Please insert explanation below.)			

UserID	CourseCompletionDate	Course
kpatel65	2012-03-27	CITI Biomedical Research Basic Training

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

Name of Administrative Contact	Degree	Title
Webb, Deniece	BA	Research Coordinator
Email	**Phone**	**Fax**
deniecewebb@slu.edu	(314) 577-8884	

Department Name
Otolaryngology

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.)		

UserID	CourseCompletionDate	Course
deniecewebb	2016-02-23	Good Clinical Practice (GCP)
deniecewebb	2016-01-13	CITI Biomedical Research Basic Training

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

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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Name of Administrative Contact	Degree	Title
Gresham, Malia	MD	Otolaryngology Resident
Email	**Phone**	**Fax**
msgresham@slu.edu	314-577-8884	
Department Name		
Otolaryngology		
Is this individual also a member of the research team?		Y
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.**		Y

Research Experience ?HELP?

Dr. Gresham is an otolaryngology resident and is engaged in the study and treatment of sinonasal disorders. She has three years of experience in clinical research with projects on topics such as skull base tumors and craniofacial trauma.

Research Team Member Duties Picklist

1.	X	Recruitment	2.	X	Obtains consent
3.	X	Determine Subject Eligibility for Accrual	4a.	X	Subject Physical Examinations
4b.	X	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.	X	Subject Randomization or Registry	8.	X	Collection of Subject Data
9.	X	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	X	Data Analysis
11a.		Review Adverse Events	11b.		Treat and Classify Adverse Events
12.		Other (Please insert explanation below.)			

UserID	CourseCompletionDate	Course
msgresham	2017-10-30	CITI Biomedical Research Basic Training

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

Name of Administrative Contact	Degree	Title
Cass, Lauren	MD, MPH	Otolaryngology Resident
Email	**Phone**	**Fax**
lcass@slu.edu	314-577-8884	
Department Name		
Otolaryngology		
Is this individual also a member of the research team?		Y

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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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?

As an otolaryngology resident, Dr. Cass is actively involved with treating patients with medical and surgical sinonasal disease. She has been involved with medical and clinical research for eight years as a medical student and resident working on various hospital-based and large dataset-based projects. Additionally, she has earned her Masters in Public Health with training in biostatistics, epidemiology, and study design.

Research Team Member Duties Picklist

1.	X	Recruitment	2.	X	Obtains consent
3.	X	Determine Subject Eligibility for Accrual	4a.	X	Subject Physical Examinations
4b.	X	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.	X	Subject Randomization or Registry	8.	X	Collection of Subject Data
9.	X	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	X	Data Analysis
11a.		Review Adverse Events	11b.		Treat and Classify Adverse Events
12.		Other (Please insert explanation below.)			

UserID	CourseCompletionDate	Course
lcass	2011-01-01	CITI Biomedical Research Basic Training
lcass	2008-11-03	CITI Social/Behavioral Research Basic Training

Key Personnel (Research Team)

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Simpson, Matthew	MPA	Research Assistant, Sr.	Otolaryngology

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
Antisdel, Jastin	MD	Associate Professor
Email	**Phone**	**Fax**

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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antisdel@slu.edu (314) 577-8885

Department Name
Otolaryngology

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

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. Antsidel has 18 years experience in clinical research from med school through a rhinology fellowship and 8 years in academic medicine.

Research Team Member Duties Picklist

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

UserID	CourseCompletionDate	Course
antisdel	2017-03-08	Good Clinical Practice (GCP)
antisdel	2007-02-19	CITI Biomedical Research Basic Training

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Brunworth, Joseph, MD	Otolaryngology	As a fellowship trained Otorhinolaryngologist, Dr. Brunworth has been involved in clinical and basic science research for the last 11 years. He serves as the scientific reviewer for OTO's protocols and is OTO's Director of Clinical Research.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or

			Devices, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events, Treat and Classify Adverse Events
Patel, Kunjan , BA	Otolaryngology	Kunjan has been involved in clinical and basic science research in genetics, otolaryngology, and telemedicine at SLU School of Medicine and Washington University School of Medicine for 6 years. He has completed multiple clinical projects working with Otolaryngology faculty at SLU School of Medicine.	Obtains consent, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Gresham, Malia, MD	Otolaryngology	Dr. Gresham is an otolaryngology resident and is engaged in the study and treatment of sinonasal disorders. She has three years of experience in clinical research with projects on topics such as skull base tumors and craniofacial trauma.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Cass, Lauren, MD, MPH	Otolaryngology	As an otolaryngology resident, Dr. Cass is actively involved with treating patients with medical and surgical sinonasal disease. She has been involved with medical and clinical research for eight years as a medical student and resident working on various hospital-based and large dataset-based projects. Additionally, she has earned her Masters in Public Health with training in biostatistics, epidemiology, and study design.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Simpson, Matthew, MPA	Otolaryngology	Matthew has collaborated with PhD and medical students, faculty and physicians to produce a	Data Analysis, Other (Please insert explanation below.) Statistician

		number of abstracts and manuscripts for both publication and delivery at professional conferences.	
Antisdel, Jastin, MD	Otolaryngology	Dr. Antsidel has 18 years experience in clinical research from med school through a rhinology fellowship and 8 years in academic medicine.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events, Treat and Classify Adverse Events

* * * 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: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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* * * 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
- [X] Saint Louis University, SLUCare Practice Locations
- [ ] 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.

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* * * 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
- [X] FDA Approved Device
- [X] 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
- [ ] Photography, Video, or Voice-Recording Subjects
- [X] Questionnaires and/or tests

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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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)
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'.

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* * * 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).

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* * * 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.

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 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

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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.

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.)

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.

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

Title

Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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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?***

Endoscopic sinus surgery is commonly used to manage chronic inflammatory frontal sinus disease that is not adequately controlled with medical therapy alone. In recalcitrant cases, a more extensive procedure called the modified endoscopic Lothrop procedure or frontal drill-out (FDO) procedure is often performed [1, 2]. The frontal drill-out procedure is performed endoscopically and its goal is to create one large common cavity between the left and right frontal sinuses and nasal cavities to allow adequate drainage and communication for subsequent drug delivery through sinonasal irrigations if indicated.[3, 4] Failure of this procedure is most commonly the results of re-stenosis of the outflow tract due to scarring, adhesions, or progressive disease such as polyposis.[5, 6] One meta analysis assessing the long-term complications of frontal drillouts reported an overall failure rate to be 13.9%, defined as those individuals needing further surgery.[2] Another clinical trial reported a failure rate for a 200-person study to be 30%.[7]

Placing a steroid-eluding biodegradable stent into the sinonasal cavities after surgery is thought to reduce the occurrence of re-stenosis, both by physically stenting the opening and by treating resultant inflammation with corticosteroid.[8] Propel stents are made of synthetic dissolvable polymer that contains a corticosteroid (mometasone furoate) and has been FDA-approved to stent and reduce inflammation over 30 days. Similarly, Nasopore is an FDA-approved fragmentable nasal dressing that is used as a stent. Kenalog soaking the Nasopore is thought to act as the functional equivalent of the mometasone furoate found in the Propel stent, but this use is investigational. The effect of stenting and its consequences on the outcomes of FDO specifically has also not been well studied.[8] Recent randomized-controlled trial of Propel stent placement after frontal sinusotomy (a less extensive form of frontal sinus surgery compared to FDO procedure) showed improvement in outcomes compared to no stent placement and no major complications.[9] There are no known randomized-controlled trials to date of propel stent placement or Nasopore-soaked kenalog placement after FDO procedure. We wish, therefore, to perform a randomized trial to compare the efficacy and outcomes of Nasopore-soaked kenalog versus propel stenting.

1. Gross CW, Harrison SE. The modified Lothrop procedure: indications, results, and complications. Otolaryngol Clin North Am. 2001;34(1):133-137.

2. Anderson P, Sindwani R. Safety and efficacy of the endoscopic modified Lothrop procedure: a systematic review and meta-analysis. Laryngoscope. 2009;119(9):1828-1833.

3. Eloy P, Vlaminck S, Jorissen M, et al. Type III frontal sinusotomy: surgical technique, indications, outcomes, a multi-university retrospective study of 120 cases. B-ENT. 2011;7 Suppl 17:3-13.

4. Weber RK, Hosemann W. Comprehensive review on endonasal endoscopic sinus surgery. GMS Curr Top Otorhinolaryngol Head Neck Surg. 2015;14:Doc08.

5. Hunter B, Silva S, Youngs R, Saeed A, Varadarajan V. Long-term stenting for chronic frontal

5. Hunter B, Silva S, Youngs R, Saeed A, Varadarajan V. Long-term stenting for chronic frontal sinus disease: case series and literature review. J Laryngol Otol. 2010;124(11):1216-1222.

6. Hoyt WH, 3rd. Endoscopic stenting of nasofrontal communication in frontal sinus disease. Ear Nose Throat J. 1993;72(9):596-597.

7. Ting JY, Wu A, Metson R. Frontal sinus drillout (modified Lothrop procedure): long-term results in 204 patients. Laryngoscope. 2014;124(5):1066-1070.

8. Huang Z, Hwang P, Sun Y, Zhou B. Steroid-eluting sinus stents for improving symptoms in chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery. Cochrane Database Syst Rev. 2015(6):CD010436.

9. Smith TL, Singh A, Luong A, et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 2016;126(12):2659-2664.

Please save frequently

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.

Surgery on the frontal sinus is done for patients who have sinus problems that do not respond to medications. It involves making an opening within the right and left frontal sinus of the nose to help it drain. For severe frontal sinus disease the sinus is widely opened and the left and right sinuses become one large sinus. This is done with sharp instruments and rigid endoscopes placed through the nostrils. While the sinus heals after surgery, a stent or steroids or both may be used to try to help make sure that the opening does not close back up. Two current options for this are Propel stents and steroid-soaked Nasopore. Propel stents are FDA-approved. Nasopore and kenalog injection are both FDA-approved, but their use together is part of the study and not specifically FDA-approved. A previous study shows that Propel stents are useful to reduce scarring in other frontal sinus procedures. We would like to know whether this is true in larger frontal sinus surgery where one common cavity is made and whether both steroid-containing stents are the same.

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).

Aim 1: To compare the difference in mean post-operative SNOT-22 scores between the Propel stent and Nasopore groups.

Aim 2: To compare the incidence of other surgical postoperative complications (diagnosed post-operative CSF leak, epistaxis requiring treatment, adhesions) between Propel stent and Nasopore.

Aim 3: To ascertain the incidence of surgical complications based on the specific frontal sinus

pathology

Hypothesis: Patients in the Kenalog-soaked Nasopore group will have outcomes that are non-inferior compared to the Propel stent group when comparing the long term symptom control as measured by SNOT-22 scores at 24 months follow-up.

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.**

Single blind (Subject) randomized, active control study. Subjects will be randomized 1:1 using the rand function in Microsoft Excel program.

Timeline: There will be a 2 year recruitment period during which patients will be recruited and eligible to participate. Eligible patients are those with chronic inflammatory sinonasal disease for whom frontal drill out procedure is indicated after evaluation by otolaryngologist. Patients eligible for the study and consenting to participate will be randomly assigned to one of two treatment groups: 1) Nasopore group will receive frontal drill out procedure as indicated with Kenalog-soaked Nasopore stent applied to the post-operative outflow tract and 2) Propel stent group will receive frontal drill out procedure as indicated followed by Propel stent placement applied to the post-operative outflow tract.

After the surgery, we will ask patients to follow up 5 times: post-operatively once between week 1-2, once between week 6-8, month 6, month 12, and month 24. All visits are standard of care.

During those visits, patients will fill out a short research related questionnaire that will ask about whether or not their symptoms have improved after surgery. We will also assess sinus cavities with rigid nasal endoscopy. Surgical complications will be documented and SNOT-22 scores will be determined by patients filling out SNOT-22 questionnaire at each visit.

Preliminary analysis will be performed once 5 patients have been enrolled and then every 6 months thereafter until 2 years of follow up of the last subject. We expect enrollment to occur over a period of 2 years.

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:

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).

Patients who present with chronic inflammatory frontal sinus pathology with indication for frontal sinus surgery will be evaluated for frontal drill out candidacy per physician judgment and consented. Once consented, the patients will be randomized 1:1 using the "rand" function (random number generator) in Microsoft Excel program. Nasopore group will receive frontal drill out procedure as indicated with Kenalog-soaked Nasopore while the Propel stent group will receive the Propel Stent after frontal drillout. Lund-McKay CT staging system, a part of the standard of care, to determine overall and frontal sinus score will be used to help stage and evaluate patients pre-operatively. A preoperative SNOT-22 score, also done as standard of care, will be obtained to assess symptom burden. Those who undergo the procedure and have consented to participate in the study will be asked to present to the otolaryngology clinic for regularly scheduled follow-up as part of standard of care,where symptoms and complications will be assessed. Rigid nasal endoscopy and SNOT-22 score are standard of care for routine follow-up of patients with chronic inflammatory sinonasal disease and will be performed at each of the 5 visits: post-operatively 1-2 weeks, 6-8 weeks, month 6, month 12, and month 24. This data will be abstracted from the records for research purposes. The data collected from the medical record includes the patient's current ENT-related active medical problems.

Note that to maintain uniformity in care, post-operative antibiotics (defined as up to day 60 post-op) will only be given to patients in any group if frank purulence is noted intra-operatively. In addition, in accordance with other trials involving drug eluting stents [1], oral and topic steroids will not be given to patients in any group until 60 days post-operatively. Because oral steroids and certain antibiotics have anti-inflammatory properties, this could confound the result of the study. For this reason, we wish to avoid using them in a random fashion.

1. Forwith KD, Chandra RK, Yun PT, Miller SK, Jampel HD. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. Laryngoscope. 2011;121(11):2473-2480.

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.

A difference in mean post-operative SNOT-22 score of 9 points will be considered a clinically significant difference. [1]

As such, preliminary analyses will be performed once 5 patients have been enrolled and then every 6 months thereafter until 2 years of follow up of the last subject. If clear statistically significant inferiority or superiority is demonstrated, the trial will be stopped.

[1] Chowdhury NI, Mace JC, Bodner TE, et al. Investigating the minimal clinically important

difference for SNOT-22 symptom domains in surgically managed chronic rhinosinusitis. Int Forum Allergy Rhinol. 2017;7(12):1149-1155.

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.

The SNOT-22 score assesses symptomatic improvement and burden for patients with rhinosinusitis and is a clinically validated measure with high internal validity, correlation to its impact on quality of life, and longitudinal stability after sinus surgery. The minimal clinically important difference (MCID) for SNOT-22 is 9 points. [1, 2, 3, 4,5] From historical SLU otolaryngology practice data, patients who present to the otolaryngology clinic undergoing sinonasal surgery have a mean SNOT-22 score of 42.0 ± 8.0.

For this randomized, active control study of two types of sinonasal stents with steroid, we are interested in determining whether the cheaper and more available alternative (Nasopore and Kenalog) is similar to an accepted treatment (Propel stent) in symptom control at 24 months as measured by post-operative SNOT-22 scores.

For our sample size determination, we explore the lower limit of a 95% confidence interval (CI) around the mean difference between post-operative SNOT-22 scores of the two groups. We'll define the lower limit of the CI, or the margin of inferiority, as -8, which does not include the predetermined MCID of -9.
We set power = 0.8 and alpha = 0.05.

Given: # subjects in each group = n = [(2(SD)^2) * (z1-(a/2)+z(1-B))^2] / [(u1 - u2)^2] [ref 6]
SD = 8.0, from SLU historical data
[(z(1-(a/2))+z(1-B))]^2 = 7.8, estimated from z-tables, a = 0.05 and B = 0.2

IF u1 - u2 = -8 then n = 16 subjects

To be conservative in our sample size calculation, we'll use u1 - u2 = -5, which yields a sample size of 40.
If we assume attrition rate of 10%, we estimate we'll need 45 subjects per group and a total of 90 subjects.

Difference in rates of complications will also be determined by chi-square testing for equality of proportions between groups. As these outcomes are expected to be few, our target sample size may not be adequate to determine statistical significance of differences. Reporting these complication rates nonetheless informs clinical practice.

The smallest group reported will be half of the sample target.

1) Hopkins C, Gillett S, Slack R, Lund VJ, Browne JP. Psychometric validity of the 22-item Sinonasal Outcome Test. Clin Otolaryngol. 2009;34(5):447-54.
2) Gray ST, Phillips KM, Hoehle LP, Caradonna DS, Sedaghat AR. The 22-item Sino-Nasal Outcome Test accurately reflects patient-reported control of chronic rhinosinusitis symptomatology. International Forum of Allergy & Rhinology. 2017;7(10):945-951.
3) Deconde AS, Mace JC, Alt JA, Rudmik L, Soler ZM, Smith TL. Longitudinal improvement and stability of the SNOT-22 survey in the evaluation of surgical management for chronic rhinosinusitis. International Forum of Allergy & Rhinology. 2015;5(3):233-239.
4) Hopkins C, Rudmik L, Lund VJ. The predictive value of the preoperative Sinonasal outcome test-22 score in patients undergoing endoscopic sinus surgery for chronic rhinosinusitis. The

Laryngoscope. 2015;125(8):1779-1784.
5) Chowdhury NI, Mace JC, Bodner TE, et al. Investigating the minimal clinically important difference for SNOT-22 symptom domains in surgically managed chronic rhinosinusitis. Int Forum Allergy Rhinol. 2017;7(12):1149-1155.
6) Brody T. Clinical Trials. Academic Press; 2016.

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 received outside of the research context. *?HELP?*** Y

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

Pre-operative CT scan is standard of care for patients with chronic inflammatory frontal sinus pathology who are going to undergo surgery.
There is no specific standard of care for follow-up of chronic inflammatory sinonasal pathology and is left up to the discretion of the attending otolaryngologist. The standard of care for follow-up of chronic inflammatory sinunasal disease in SLU rhinology practice is what is proposed in this study (post-op week 1-2, week 6-8, month 6, month 12, month 24, and yearly thereafter).
SNOT-22 questionnaire is standard of care for every patient at every visit in SLU rhinology practice.
The standard of care for use of Propel stent and nasopore placement as well as topical nasal steroid at the discretion of the attending surgeon and based on patient's disease process, and these or a combination of these are routinely used in a large number of patients in a variety of procedures currently.
Rigid nasal endoscopy is standard of care at all follow-up visits for all patients with chronic inflammatory sinonasal disease.
As standard of care, patients may receive post-operative oral steroids or antibiotics based on intra-operative findings or the discretion of the attending surgeon. Strong evidence for or against use of antibiotics or oral steroids after sinus surgery is not found in the literature and it is considered an option based on current guidelines.[1]
The only non-standard of care portion of the protocol is placement of Kenalog within Nasopore.

[1] Orlandi RR, Kingdom TT, Hwang PH, et al. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis. Int Forum Allergy Rhinol. 2016;6 Suppl 1:S22-209.

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).** Y

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

It is possible that CT imaging pre-operatively or rigid nasal endoscopy may discover unexpected findings (which is true of patients in the study or not in the study since these exams are standard of care). If this occurs, findings will be communicated to the patient and the proper treatment/referrals will be recommended/performed.

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.

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* * * 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.

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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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.

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* * * 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.

FDA Approved Devices

Device Name	Manufacturer	Provide IDE #. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16).
Nasopore	Stryker	
PROPEL Mini Sinus Implant	Intersect ENT	

1. **Device Name** — Nasopore
2. **Manufacturer** — Stryker
3. **Describe the device to be used and attach the device manual in section #16.**
   From the FDA: Nasopore is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption. Nasopore is composed of a fragmentable polyurethane that fragments within several days after insertion in the nasal cavity, whereafter it is drained from the nasal cavity via the natural mucus flow.
4. **Provide the PMA approval or 510(k) clearance number or attach letters in section #16.** — K052099
5. **Does the research involve use of a commercially available device for an unapproved purpose?** — N
6. **This device research is:Note: Attach documentation/justification in section #16.** — **Exempt from IDE regulations, (submit required attachments)**

Non-Significant risk, (submit required attachments)

Significant risk, (submit required attachments)

The risk determination should be based on the proposed use of a device in an investigation and not on the device alone.

7. **Provide IDE #. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16). See Guidance.**
8. **Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor').**
9. **If a SLU Investigator is serving as sponsor-investigator of the IDE, click Yes to assure that the additional FDA requirements will be followed.** Yes, the additional FDA requirements will be followed.

1. **Device Name** PROPEL Mini Sinus Implant
2. **Manufacturer** Intersect ENT
3. **Describe the device to be used and attach the device manual in section #16.**

   From the FDA SSED: The PROPEL Mini sinus implant is intended for use in adult patients ≥ 18 years of age following ethmoid / frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening. The PROPEL Mini sinus implant separates/dilates surrounding mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces inflammation. The implant reduces the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids.

   From the FDA SSED: The PROPEL Mini sinus implant is a bioabsorbable implant designed to maintain patency of the sinus cavity. The PROPEL Mini implant is manufactured from a synthetic bioabsorbable copolymer, poly (L-lactide-co-glycolide) (PLG). The implant contains mometasone furoate (active ingredient), a synthetic corticosteroid with anti-inflammatory activity. Mometasone furoate is a white to off-white powder. The drug is embedded in a bioabsorbable polymer matrix containing poly-(DL-lactide-co-glycolide) and polyethylene glycol (inactive ingredients) which provides for gradual release of the drug.
4. **Provide the PMA approval or 510(k) clearance number or attach letters in section #16.** P100044/S018
5. **Does the research involve use of a commercially available device for an unapproved purpose?** N
6. **This device research is:Note: Attach documentation/justification in section #16.**

   Exempt from IDE regulations, (submit required attachments)

   Non-Significant risk, (submit required attachments)

   Significant risk, (submit required attachments)

The risk determination should be based on the proposed use of a device in an investigation and not on the device alone.

7. **Provide IDE #. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16). See Guidance.**
8. **Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor').**

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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9.	**If a SLU Investigator is serving as sponsor-investigator of the IDE, click Yes to assure that the additional FDA requirements will be followed.**	Yes, the additional FDA requirements will be followed.

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* * * 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	X 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).**

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).**

FDA Approved Drugs, Reagents, Chemicals, Biologic Product

Drug Name	Manufacturer	Source (e.g., Pharmacy, Sponsor, etc.)	Dosage
Kenalog (Triamcinolone Acetonide)	Bristol-Myers Squibb Company	SLU Hospital	40 mg/mL

1.	**Drug Name**	Kenalog (Triamcinolone Acetonide)
2.	**Manufacturer**	Bristol-Myers Squibb Company
3.	**Source (e.g., Pharmacy, Sponsor, etc.)**	SLU Hospital
4.	**Dosage**	40 mg/mL
5.	**Administration Route**	Topical (1-2 ml will be used to soak the packing material)
6.	**If not premixed, where will the material be mixed and by whom?**	N/A
7.	**Is the drug being used outside of its approved labeling?**	Y

Note: If you selected 'Yes' (to question 7) and an IND# is not provided below, either you must attach documentation from the FDA in the Attachments section (#16) indicating that one is not required or you must complete question 11 below, including providing an explanation for no responses.

8.	**IND # (if available). Documentation required unless imprinted on sponsor protocol (attach in section #16).**	n/a

9.	Name of sponsor or investigator who holds the IND. (The sponsor could be a drug or device manufacturer or an individual investigator acting as the 'sponsor' for the application).	n/a
10.	If a SLU Investigator holds the IND, click yes to assure that the sponsor-investigator will follow the additional FDA requirements.	X Yes, the additional FDA requirements will be followed.
11.	Is the FDA approved drug, biologic or device being used in this study for a non-FDA approved use without an IND# or documentation of FDA approval?	Y
11.1.	Please note that answering 'YES' to any of the questions below means that submission for request of an IND is required.	
11.2.	Is the research being conducted with a commercially available drug to support a new indication or support a change in advertising or labeling of the product?	N
11.3.	Please explain why the response is "no", supported by documentation or information on the drug. Supporting documentation can be referenced and attached in the Attachments section (#16).	This is an investigator initiated study which is not being done to support a change in the manufacturer's label or support a new indication
11.4.	Does the research use a commercially available drug that is being administered via a new route or for use in a different part of the body that may significantly increase the risk associated with the use of the drug product?	N
11.5.	Please explain why the response is "no", supported by documentation or information on the drug. Supporting documentation can be referenced and attached in the Attachments section (#16).	Kenalog 40 is specifically approved for intramuscular or intra-articular use; however, there is data to support using Kenalog in other ways, mucosally included.
11.6.	Does the research use a commercially available drug that is being given at a dosage level that may significantly increase the risk associated with the use of the drug product?	N
11.7.	Please explain why the response is "no", supported by documentation or information on the drug. Supporting documentation can be referenced and attached in the Attachments section (#16).	The dose being used is 40-80mg topical (concentration is 40 mg/ml).
11.8.	Does the research use a commercially available drug that is going to be used in a new patient population that may significantly increase the risk associated with the use of the drug product?	N
11.9.	Please explain why the response is "no", supported by documentation or information on the drug. Supporting documentation can be referenced and attached in the Attachments section (#16).	No, in fact we are using the medication so that systemic effects are not expected. If anything, the risk is decreased because of this localized effect.

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

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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Please read the IND Statements.

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* * * 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 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

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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.

X Not Applicable
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) Y

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 information on NIH GCP Training requirements.

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* * * 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)

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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

Adults ≥18 and ≤90 years of age

b) **Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI).** 90

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.

c) **Number of evaluable subjects to be accrued study wide. *?HELP?*** 90

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

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?***

Propel stent is not FDA approved for patients under 18 years of age.

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.**

Patients who present with frontal sinus pathology and are candidates for frontal sinus surgery will be evaluated for Frontal Drill out candidacy per physician judgment and consented. Lund-McKay CT staging

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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system to determine overall and frontal sinus score will be used to help stage and evaluate patients.

Once patients are identified, they will be recruited in person and consented.The physician or a study team member will explain orally the benefits, risks, and nature of the intervention using the predetermined script. Patients will have the chance to ask questions directly. They will be asked whether they are interested participating in the study. The patient will have the ability to opt out of the trial at any time, with no impact on their care or treatment. In person, the patient will be able to consent via signature on the attached consenting document.

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* * * 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.

Adults ≥18 and ≤90 years of age
Patients able to speak and understand English.
Patients for whom frontal drill out procedure is medically indicated as judged by attending physician surgeon.

Identify exclusion criteria.

Patients who are cognitively impaired and unable to consent.
Patients who are not candidates for Frontal Drill out, whose frontal sinus pathology is responsive to medical therapy alone, or present with other comorbidities that makes them poor candidates for the procedure
Patients with contraindications to PROPEL Mini sinus implant or Kenalog soaked nasopore: Patients with a known hypersensitivity to mometasone furoate, Kenalog, lactide, glycolide or caprolactone copolymers.
Non-English speaking patients.

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.

There will be no compensation paid for participation in the study.

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

All procedures are standard of care; no additional research related costs will be incurred. Insurance will be billed for the standard of care procedure. Any administrative costs will be covered by the Otolaryngology department.

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.

The total length of study can be up to 4 years from enrollment to completion. Recruitment will take place over a two year time period. The total timeline of subject involvement will be 2 years (follow-up visit

schedule previously described). Preliminary analysis will occur once 5 patients have been enrolled and then every 6 months thereafter. Data analysis and publication of data after all follow-ups are completed will take approximately one year after completion of follow-up. Each subject, after consenting and undergoing the procedure, will be then followed for two years, which is when post-operative data will be collected. Pre-operative data will be obtained at the time of consent.

* * * 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".

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.**

From the FDA-warning regarding Kenalog: The following adverse reactions may be associated with corticosteroid therapy:

Allergic reactions: Anaphylactoid reaction, anaphylaxis including anaphylactic reactions and anaphylactic shock, angioedema. "In clinical trials, common adverse effects for triamcinolone acetonide include sneezing, dry, mucosa, nasal irritation, sinus discomfort, throat discomfort, epistaxis and headache." [1] These are imminently preventable as corticosteroids are used commonly, so patients generally have a history of reaction to them.
Additional risk of complications for the Nasopore group include forming adhesions, scarring caused by surfaces of the nose healing together to cause a scar, in the nose.
•Possible allergic reactions: severe allergic reaction with shortness of breath • throat or mouth swelling
•Formation of bands of scar tissue (synechiae) is a risk of sinus surgery and covered in your surgery consent. In one study, 4% of patients had scar band present 3 months after surgery. The use of the Nasopore is to try to decrease scar formation. However, there is still a small risk of scarring with the Nasopore material used in the sinuses. The impact of scarring may not be significant and not need

treatment; however, it may require having the scarring cut in clinic during rigid nasal endoscopy, or if very extensive, could rarely result in return to the operating room
•Common adverse effects for triamcinolone acetonide include sneezing • dry mucosa, nasal irritation • sinus discomfort • throat discomfort • nose bleeds • headache • burning, itching, irritation, dryness, blistering or peeling not present prior to therapy • perioral dermatitis • allergic contact dermatitis • maceration of the oral mucosa • secondary infection and thinning of the oral mucosa.
These are imminently preventable as corticosteroids are used commonly, so patients generally have a history of reaction to them.

Additional risk of complications for the Propel stent group include developing headaches, ear infections and nausea after surgery. These complications are not severe and are medically treatable in most cases.
Potential adverse effects associated with the PROPEL sinus implant are anticipated to be similar to those associated with other sinus stents, gels or packing. Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.
•Potential adverse effects associated with the PROPEL Mini sinus implant include, but may not be limited to: • premature displacement of implant or small implant fragments out the nares • swallowing implant or implant fragments • adherence of crusting to implant, resulting in, or contributing to sensations of pain/pressure/headache • aspiration of small implant fragments (not observed in clinical trials) • foreign body response, including formation of granulation tissue.
•Potential risks or side effects associated with intranasal mometasone furoate include: • nasal irritation • hypersensitivity reaction • intranasal bleeding • localized infection (bacterial, fungal or viral) in the nose or pharynx • nasal burning • nasal dryness • susceptibility to secondary infections due to bacteria, fungi or viruses • glaucoma/elevation of intraocular pressure • cataracts/change in lens opacities • headache • pharyngitis.
•Potential risks or general side effects associated with steroids: • hypersensitivity reactions • headache • nose bleeds • coughing • vomiting • fungal infection• glaucoma/elevation in eye pressure • cataracts/changes in lens opacities • joint and muscle pain.

Note that a lot of these AEs are extremely rare (<1%) - see attached document. Corticosteroids are pervasively used in Otolaryngology as well as the field of medicine, and the doses used here are unlikely to result in significant AE's, especially as corticosteroids are commonly used after surgery in order to prevent complications.

[1] Gawchik SM1, Saccar CL. A risk-benefit assessment of intranasal triamcinolone acetonide in allergic rhinitis. Drug Saf. 2000 Oct;23(4):309-22.

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.**

Based on clinical trials and FDA's SSED, the adverse event rate for Propel stent is as follows (see attached document): Acute sinusitis (15.0%), Chronic sinusitis (11.3%), Headache (11.3%), Upper respiratory tract infection (6.3%), Presyncope (5.0%), Epistaxis (5.0%), Otitis media acute (3.8%), Asthma (3.8%), Nasal congestion (3.8%), Eyelid edema (2.5%), Nausea (2.5%), Influenza (2.5%), Nasopharyngitis (2.5%), Nasal polyps (2.5%). All of these events are not severe and treatable.

The AEs associated with Nasopore include formation (see attached document) of adhesions (10.5%), inflammation of nasal mucosa (<5%), post-operative bleeding (2%), and sinus infection (4%). All of these events are not severe and treatable.

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).

There are no aspects of this study that involve risk of harm or discomfort greater than ordinarily encountered in the standard course of the participants' medical treatment in patients for whom frontal drill out is indicated regardless of study participation. Frontal drillout complications may include epistaxis, orbital/periorbital ecchymoses and emphysema, dental pain, adhesions, hyposmia, and stenosis, meningitis and brain abscess and intraoperative trauma. Intraoperative trauma may cause CSF leaks, intraorbital hemorrhage, diplopia, blindness, epiphora, intracranial injury, stroke, tension pneumocephalus, significant epistaxis, and anosmia. There is always the risk of developing previously unknown side effects. Patients may encounter these risks regardless of participation in this research study. The investigator is willing to discuss any questions the participant may have about these risks and discomforts.

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?***

No standard treatment is being withheld. We are attempting to determine which device used in the standard of care is more beneficial than the alternative.

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

Breach of Confidentiality
Information will be kept under lock and key with password protection on the computer. Coding will be used with no patient identifiers attached to confidential information. Even with these precautions, breach of confidentiality is a risk.

Use of Questionnaires:
Some questions in the questionnaires may make subjects feel uncomfortable. Subjects may choose not to answer any question with which he/she feels uncomfortable.

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.**

Patients may opt out at any time without penalty. Regular postoperative follow-up to assess any complications from the procedure will minimize potential risk. In case of adverse event or complication from the procedure discussed above, clinician judgment and follow-up will ensure necessary medical intervention.

Use of questionnaire: Subjects may choose not to answer any question with which he/she feels uncomfortable

10. Reproductive Risks.

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

Kenalog Pregnancy Category: C

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

The frontal drill out procedure and steroids used are topical, so they do not have systemic effects. Thus, reproductive risk is not associated with any part of the research study.

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)? Y

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).

a) The types of data and events are that are captured are included in the data collection sheet. In short, they include responses to questionnaires, procedural data (sinus patent or not) from the rigid endoscopy, CT scan evaluation, and a patient's past medical history (ENT related). The data will be found in the electronic medical record (EPIC) and the data collection sheet. With the exception of the data collection sheet and the consent form, no PHI will be documented anywhere besides EPIC. Protocols are in place to ensure that they are safe (see section 11 of the protocol).
b) The data will be monitored by Dr. Brunworth (MD, Assistant Professor of SLU Department of Otolaryngology), who is the PI of the study.
c) The aggregate data will be formally reviewed once every 10 patients have completed follow up.
d) Dr. Brunworth will be reviewing SAEs in real time as he is the only faculty (at SLU or otherwise) who will be involved in the study. We don't expect the AE frequency, type and severity to be significantly different between the Kenalog and Nasopore groups as the treatment options are quite similar. This is because the surgical technique (i.e. the frontal drill-out) is identical - the only difference is the type of stent (both of which have steroids), and the AE profile of both interventions is similar and treatable (see section 9, subpoint 4). Regardless, we are planning to record and review the AE number and type (major, minor) every after the first 5 patients have enrolled and then every then every 6 months thereafter until 2 years of follow up of the last subject.
e) n/a

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.

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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* * * 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.**

a.) Subjects will not benefit from the research.
b.) Society may benefit from research findings because they will provide physicians with evidence of the effectiveness of the two devices and help them make well educated decisions about which device is best in practice

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.**

The alternative is non-participation in the study. The patient will still undergo your sinus surgery as planned and receive one of the two stents described in this study, Propel or Nasopore, as determined by Dr. Brunworth.

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.

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

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 Google Drive/Documents	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.

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

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

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

   SLU ITS recognized document-level encryption

   X 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
   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:
Identifiable	SLU Locked Cabinet; SLU Locked Suite	Personnel Supervision	

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
Coded
X Identifiable

2. Where are hardcopy materials being kept? (Check all that apply)
   - X SLU Locked Cabinet
   - SLU Locked Room/Office
   - X SLU Locked Suite
   - 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
   - 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:

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.

A master list linking each patient with code will be kept on a separate spreadsheet. The data will be stored on a SLU ITS managed device.until the end of the study and completion of the manuscript, approximately November 2021, when it will be disposed of by electronic deletion. It will be password protected by SLU's secure network domain. In addition, the computers will be username and password protected by SLU's domain. No data will be downloaded or stored on local or private hard drives or flash drives. Only study team members will have access to the data.

The code will be numeric (1, 2, 3, 4....).

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 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):

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

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

X 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)

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

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* * * 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.

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.

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* * * 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).

Patients who present in clinic with chronic inflammatory frontal sinus pathology with indication for frontal sinus surgery will be evaluated for frontal drill out candidacy per physician judgment and consented. Informed consent will be sought from the patient at this out-patient visit prior to their procedure. The patients will have no limit on time to consent. The PI or study team member will initially discuss the study with the potential subject, including the risks, benefits, and alternatives. The subject will be provided with information about the study and their role. They will be informed that they may terminate their participation at any time for any reason. If they agree to participate, consent will be signed at that time.

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
Approved_Consent version 4	Consent	04/05/2018

Title Approved_Consent version 4
Consent Type Consent
Upload Consent Form/Document X Attachment Approved_Consent version 4

Upload your informed consent document. Use the SLU Informed Consent Template to create your consent document. If more than one consent will be used (e.g., adult consent, parental consent, etc.), label the consent documents with these headings to help distinguish them from one another.

Upload any assent documents which will be used for adults who are unable to provide consent here and not in the assent section.

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

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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* * * 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.

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.

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* * * 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)

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

X Names

Social Security numbers

X 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 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

Protocol Title: Randomized trial of Propel stent vs Kenalog-soaked Nasopore after Frontal Drill-out

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Biological samples
Interviews or questionnaires/health histories
Mental health records
Data previously collected for research purposes
Billing records
Other
Please describe:

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 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
HIPAA Authorization	Approved_HIPAA version 2	04/05/2018

Title — Approved_HIPAA version 2
HIPAA Documents — HIPAA Authorization
HIPAA Form — Approved_HIPAA version 2
HIPAA Authorization Template
