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Protocol Title:	Analysis of hemostatic agents compared to physiologic hemostasis
Protocol Status:	APPROVED
Date Submitted:	01/31/2018
Approval Period:	03/04/2018-03/31/2019
Important Note:	This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

* * * Personnel Information * * *

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

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

Principal Investigator (PI) Mandatory

PI must be SLU affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD)	Title
Antisdel, Jastin	MD	Assistant Professor

Email	Phone	Fax
antisdel@slu.edu	(314) 577-8885	

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?*
Dr. Antisdel has many years of clinical trial experience

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

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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12. Other (Please insert explanation below.)

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

Administrative Contact

Name of Administrative Contact	Degree	Title
Webb, Deniece	BA	Administrative Assistant I
Gallogly, James	BS	Student

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
Webb, Deniece	BA	Administrative Assistant I
Email	**Phone**	**Fax**
deniecewebb@slu.edu	(314) 577-8885	
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.)		

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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UserID	CourseCompletionDate	Course
deniecewebb	02-23-2016	Good Clinical Practice (GCP)
deniecewebb	01-13-2016	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
Gallogly, James	BS	Student
Email	**Phone**	**Fax**
jgallogl@slu.edu	314-577-8884	

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?

1. Case report with Dr. Brunworth, Dept. of Otolaryngology (2016)--Mechanical Restriction of the Medial Rectus Due to Unknown Inflammatory Disease: A Case Report
2. Basic science research at Stowers Institute for Medical Research, undergraduate researcher, poster (2014)--Lysine-to-Methionine Mutation Alters Histone Protein Interaction
3. Basic science research at Stowers Institute for Medical Research, undergraduate researcher (2013)
4. SLU Emergency Medicine Research Associates Program, research associate and associate chief (2012-2014)--identified and enrolled eligible patients, collected data, oversaw 40 undergraduate researchers

Research Team Member Duties Picklist

1.	X	Recruitment	2.	X	Obtains consent
3.	X	Determine Subject Eligibility for Accrual	4a.		Subject Physical Examinations
4b.		Follow-up Visits including physical assessments	5.		Perform study procedures or Specimen Collection
6a.		Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.		Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	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
jgallogl	04-24-2012	CITI Biomedical Research Basic Training

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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Key Personnel (Research Team)

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Brunworth, Joseph	MD	Assistant Professor	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
Mikulec, Anthony

Degree
MD

Title
Professor

Email
mikuleca@slu.edu

Phone
(314) 577-8885

Fax

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
mikuleca	07-15-2005	CITI Biomedical Research Basic Training
mikuleca	03-01-2016	Good Clinical Practice (GCP)

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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Research Team Roles

Name(s), Degree	Department	Experience	Duties
Antisdel, Jastin, MD	Otolaryngology	Dr. Antisdel has many years of clinical trial experience	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
Gallogly, James, BS	Otolaryngology	1. Case report with Dr. Brunworth, Dept. of Otolaryngology (2016)--"Mechanical Restriction of the Medial Rectus Due to Unknown Inflammatory Disease: A Case Report" 2. Basic science research at Stowers Institute for Medical Research, undergraduate researcher, poster (2014)--"Lysine-to-Methionine Mutation Alters Histone Protein Interaction" 3. Basic science research at Stowers Institute for Medical Research, undergraduate researcher (2013) 4. SLU Emergency Medicine Research Associates Program, research associate and associate chief (2012-2014)--identified and enrolled eligible patients, collected data, oversaw 40 undergraduate researchers	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Brunworth, Joseph, MD	Otolaryngology	As a fellowship trained	Recruitment, Obtains

		Otorhinolaryngologist, Dr. Brunworth has been involved in clinical and basic science research for the last 11 years. He serves in the capacity of scientific reviewer for a number of OTO's IRBs.	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)

* * * Study Location * * *

Study Location(s) Checklist

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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

X 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

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

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

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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X University Indemnified Study (SLU is responsible for liability coverage) *?HELP?*
Other (clarify in text box to the right)

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

---

* * * Funding * * *

Funding Checklist

X NONE

Funding - Grants/Contracts

Funding - Industry Sponsor

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

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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 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.)

X 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.

X 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

Analysis of hemostatic agents compared to physiologic hemostasis

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

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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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?***

In this study we wish to determine if the use of hemostatic agents after endoscopic sinus surgery is superior to no agent at all. We will treat patients with one of many different FDA approved hemostatic agents in one of their nostrils and compare it to a side in which no therapy is applied. We will then evaluate qualities of the patient's recovery (synechiae formation, granulation, edema, infection, and time spent debriding the sinuses) in response to intervention.

Functional endoscopic sinus surgery (ESS) is a safe, commonly performed procedure primarily in an outpatient setting. One of the most prevalent complications is post-operative epistaxis. To prevent this nasal packing is often employed. Traditionally non-absorbable packing was employed; yet, this has fallen out of favor with most otolaryngologists considering the great discomfort of the packing, especially upon removal (von Schoenberg). In addition to this, with removal of non-absorbable packing interruption of the wound bed is inevitable. This has led to a paradigm shift towards absorbable packing, which are biomaterials that provide substrate to stimulate clotting. Absorbable hemostatic agents tend to spare the mucosa and are less painful upon removal (Maccabee). However, absorbable packing comes with the possible drawback of increased rates of synechiae formation secondary to initiation of local inflammation (Valentine). Standard of care is no packing, one of these types of absorbable packing, or removing packing.
a). Sinufoam is a carboxymethylcellulose (CMC) derivative which provides a moist wound environment and with its viscosity and density, provides a scaffold for epithelialization and pressure lateralization against surfaces to which it is applied (Al-Reefy). On the other hand, Arista is composed of potato-starch derived mucopolysaccharide hemospheres (MPH) which are rapidly cleared from the human body with minimal interruption in wound healing (Antisdel). Nexfoam is made from plant pectin and is also rapidly cleared from the nasal cavity.
b). AristaTM is FDA approved for endonasal use and is currently available on the market. NexfoamTM is FDA approved for use as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post operative, donor sites, dermatological) and it has the number: K070211 under the name of TraumArrestTM. It also falls under Class I medical device that is exempt from the premarket notification procedures. SinufoamTM (Stamberger) is included under Rapid Rhino product line (RR 650) and it is a Class I medical device, FDA product registration is attached.
c). Nasopore nasal dressing is a fragment-able 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. It is FDA approved and filed under number K052099.
d). Nexfoam is a sterile, topical wound dressing comprised of plant based polysaccharides. The hemostatic particles dehydrate blood cells, resulting in hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding. It is FDA approved and filed under number K122886.
e). The Hemostasis PosiSep and PosiSep X Hemostat Dressings are sterile hemostats comprised
of modified Chitosan particles and polysaccharide binders. Chitosan has well known hemostasis
properties and, when combined with carboxymnethylcellulose and hydroxyethylcellulose binders,
forms a foam-type dressing that has an affinity to absorb and hold water. The PosiSep and PosiSep X Hemostat Dressings are used for topical wounds. The dressings quickly dehydrate blood cells, thereby
causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding and edema. It is FDA approved and filed under K120958.
f). Sinufoam, Arista, Nasopore, Nexfoam, Posisep and PosiSep X are all being used for purposes approved following sinus surgery by the FDA.

purposes approved following sinus surgery by the FDA.

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.**

Our study is a prospective comparison between absorbable hemostatic agents as a group and the body's natural hemostatic ability without aid of therapy in patients undergoing bilateral sinus surgery with or without septoplasty.

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).**

The purpose of this study is to evaluate the efficacy of absorbable hemostatic agents in comparison with physiologic hemostasis after endoscopic sinus surgery. We aim to determine the relative efficacy of hemostatic agents to halt epistaxis and compare this with the degree of epistaxis observed without therapy. Also will evaluate objective healing parameters.

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.**

Our study is a prospective comparison between absorbable hemostatic agents as a group and the body's natural hemostatic ability without aid of therapy in patients undergoing bilateral sinus surgery with or without septoplasty.

We calculated the sample size and power analysis in the following way:
Given the number of statistical tests, we calculated a Bonferonni correction to set the alpha for the analysis at 0.017 (alpha originally at .05 divided by the number of tests = .05/30 = 0.017).
Using G-Power statistical software, power analyses were completed using the Means: Wilcoxen-Mann-Whitney test (two groups). Given alpha at 0.017 and Power at 0.80, we determined that a total of 244 participants (122 in the control group, 122 in the hemostatics group) would be needed to detect a medium effect size (d=0.5). Since one nostril will be used as the control and the therapy applied to the other side, the number of participants needed drops to 122.
Based on previous studies, we conservatively expect a dropout rate of 15%. In order to maintain the same number of participants, we would need to enroll a total of 144 participants

Postoperatively, patients will rate subjective symptoms such as nasal obstruction, bleeding,

pain, and nasal discharge on a scale ranging from 1-10, of which 10 is the most severe. Similarly, the treating physicians on endoscopic examinations will rate objective measures such as mucosal edema, infection, time spent debriding, and synechiae formation. (Please see the attached patient and physician questionnaires) Patient questionnaires will be completed on postoperative days #1, 2, 7, and 14. Surgical healing outcomes will be noted during routine postoperative visits 1 and 2 weeks after surgery. Expected total duration of each subjects' participation is 6 weeks. Total subject accrual should take no longer than one year. Data analysis will take up to three months. Estimated time of completion is 03/2018.

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).

a.) Patients will have (standard of care) Endoscopic Sinus Surgery.
b.) Each patient will receive a hemostatic agent in one nostril and nothing in the other nostril.
c.) Products will be placed in patients' post-operative sinus cavities at the end of the procedure according to company recommended instructions. Essentially all products placed in the middle meatus are allowed to remain there until absorbed or removed at a post operative visit on weeks 1, 2, and 6. Post-operative irrigations (Standard of Care) will remove much of the material. Any residual material is removed in the office on normal, (Standard of Care) post-operative debridement on weeks 1, 2, and/or 6.
d.) Subjects will provide subjective pre- and post-operative data, such as rating their pain, bleeding, obstruction, and discharge on days 0, 1, 2, 7, and 14 (Standard of Care).
e.) Patients will be given a questionnaire packet pre-operatively (Research Related). Questionnaires will include post-operative data on days 0, 1, 2, 7, and 14. They are asked to bring completed questionnaires on standard post-operative visits.
f.) The physician will record objective and subjective data (synechiae, edema, infection, granulations, and time spent debriding) upon regular reexamination of the sinuses after surgery, at post-operative visits on weeks 1, 3, and 6. All procedures are standard clinical care.
g.) Follow up visits will conform to standard clinical care; patients will be seen in the physician's clinic.

clinic.

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.**

If side effects or discomforts do occur, Dr. Antisdel and/or Dr. Brunworth will try to minimize and treat these by irrigating the treated sinus with saline to remove the Arista, Nexfoam, Sinufoam, Nasopore, Posisep, or Posisep X.

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.**

Means and standard deviations will be obtained for data collected from patients and the physician. These outcomes will be used for comparative evaluation of hemostatic agents (n=144) against no therapy. Statistics will include descriptive statistics and a non-parametric ANOVA comparing the questionnaire patient data and the physician data followed by Post-hoc multiple comparisons.

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.

There is no standard of care for the use of hemostatic agents - half of surgeons use an absorbable hemostatic agent and half use no hemostatic agent.

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** N

looking for it).

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

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

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

* * * Radioisotopes or Radiation Machines * * *

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

4. Radioisotopes or Radiation Machines

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

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

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

a) If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)

b) Total estimated research radiation dose * :

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

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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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).
Arista	Medafor	exempt
Nexafoam	Hemostasis	exempt
Sinufoam	Arthrocore	exempt
Nasopore	Polyganics	exempt
Posisep Hemostat Dressing	Hemostasis	exempt
Posisep X Hemostat Dressing	Hemostasis	exempt

1. **Device Name** Arista
2. **Manufacturer** Medafor
3. **Describe the device to be used and attach the device manual in section #16.**
   hemostatic agent
4. **Provide the PMA approval or 510(k) clearance number or attach letters in section #16.**
5. **Does the research involve use of a commercially available device for an unapproved purpose?**
6. **This device research is:Note: Attach documentation/justification in section #16.** **Exempt from IDE regulations, (submit required attachments)**

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		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.**	exempt
8.	**Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor').**	Medafor
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**	Nexafoam
2.	**Manufacturer**	Hemostasis
3.	**Describe the device to be used and attach the device manual in section #16.**	hemostatic agent
4.	**Provide the PMA approval or 510(k) clearance number or attach letters in section #16.**	
5.	**Does the research involve use of a commercially available device for an unapproved purpose?**	
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.**	exempt
8.	**Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor').**	Hemostasis
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**	Sinufoam
2.	**Manufacturer**	Arthrocore
3.	**Describe the device to be used and attach the device manual in section #16.**	hemostatic agent
4.	**Provide the PMA approval or 510(k) clearance number or attach letters in section #16.**	

5.	Does the research involve use of a commercially available device for an unapproved purpose?	
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.	exempt
8.	Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor').	Arthrocore
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	Nasopore
2.	Manufacturer	Polyganics
3.	Describe the device to be used and attach the device manual in section #16.	hemostasis
4.	Provide the PMA approval or 510(k) clearance number or attach letters in section #16.	
5.	Does the research involve use of a commercially available device for an unapproved purpose?	
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.	exempt
8.	Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor').	Polyganics
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	Posisep Hemostat Dressing
2.	Manufacturer	Hemostasis

3. Describe the device to be used and attach the device manual in section #16.
   Hemostatic agent
4. Provide the PMA approval or 510(k) clearance number or attach letters in section #16.
5. Does the research involve use of a commercially available device for an unapproved purpose?
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. — exempt
8. Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor'). — Hemostasis
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 — Posisep X Hemostat Dressing
2. Manufacturer — Hemostasis
3. Describe the device to be used and attach the device manual in section #16.
   Hemostatic agent
4. Provide the PMA approval or 510(k) clearance number or attach letters in section #16.
5. Does the research involve use of a commercially available device for an unapproved purpose?
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. — exempt
8. Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the 'sponsor'). — Hemostasis

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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).**

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

Please read the IND Statements.

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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)

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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

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.

* * * Subject Population * * *

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

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

≥18 yrs to 75 years

b) Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI). 144

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?* 144

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/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?*

Children are not included because the study is being done from an adult clinic.

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.

a.) The patients selected for this study will be recruited and treated by physicians, Dr. Jastin Antisdel and Dr. Joe Brunworth, at the Saint Louis University Hospital and Saint Louis University UMG Practice Locations (St. Louis, MO).
b.) Potential subjects will be recruited in person by the physician during regular appointments.
c.) Study information may be posted to a SLU approved website in a standard approved format.

* * * Subject Population * * *

8. Subject Population (continued)

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

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Inclusion criteria: ≥18 to <75 years of age with bilateral chronic or recurrent rhino sinusitis recalcitrant to medical therapy that requires ESS. Sinuses should have a similar degree of disease involvement bilaterally.

Identify exclusion criteria.

Exclusion criteria:
(1) massive sinonasal polyposis,
(2) history of underlying immunologic diseases, AIDS, cystic fibrosis, immunoglobulin deficiency, immotile cilia syndrome, and neutropenia,
(3) known hypersensitivity to the aforementioned agents,
(4) women who are pregnant or breastfeeding,
(5) anyone with a known allergy to any of the treatments (potato starch, iodine, shellfish)
(6) anyone with a known coagulopathy

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.**

No monetary compensation was offered to either the participants in this study or the investigators, physicians or other health care providers for identifying and enrolling subjects.

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. The study hemostatic agents are part of the total cost for the operation. There is no difference in the cost of a procedure that uses hemostatic agents and one that does not use hemostatic agents.

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.**

Each patient's participation is expected to be about six weeks. Study should be complete by 3/31/2018.

Patients will be recruited and added to the study as they are seen in clinic. Each subject's participation is expected to be six weeks total. Evaluation at six weeks post operation is standard of care for Endoscopic Sinus Surgery. Subject accrual should take no longer than one year to achieve the goal of 144 patients. Data analysis will take up to 3 months.

* * * 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.**

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.**

a.) The risks of this study are minimal and non-life threatening.
There are certain risks and discomforts that may be associated with this research. They include:
1) Allergic-type Adverse Reaction
There is a rare possibility of an allergic-type adverse reaction to AristaTM, NexfoamTM, SinufoamTM NasoporeTM, NexfoamTM and PosisepTM and PosisepX TM. Patients may experience itching, hives, hay fever symptoms, wheezing, difficulty breathing, and/or new swelling. These reactions may be serious or life threatening. These are the same risks they would have if they did not participate in the study.
2) Bleeding.
3) Obstruction/Blockage of sinus passage. Post operative irrigations will remove any excess material. Also, debridement during post operative visits will remove any material that irrigation can't.
4) Pain
5) Infection-- Dr. Antisdel and Dr. Brunworth will evaluate patients for signs of infection during post operative visits.
6) Delayed/ Asymmetric healing. One nostril will receive therapy while the other will not receive therapy. If therapy decreases wound healing time, asymmetric healing/healing may occur.
7) Embolization and Death. This risk has been identified with Arista AH. However, this risk exists only if Arista AH is directly injected into blood vessels. In this study we will only apply Arista topically to the interior of a patient's nostril. Nothing will be injected into or applied to an open vessel. Furthermore, any excess Arista will be removed with postoperative irrigation.

There are no other additional adverse reactions to these products associated with being in this study.

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

Unknown Side Effects
There is always the risk of developing previously unknown side effects.

Patients may encounter these risks regardless of participation in this research study.

If side effects or discomforts do occur, Dr. Antisdel will try to minimize and treat these by irrigating the

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treated sinus with saline to remove the Arista, Nexfoam, Sinufoam, Nasopore, Nexfoam, Posisep and Posisep X.

The investigator is wiling to discuss any questions the participant might 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?***

There is conflicting data in previous studies whether hemostatic agents are better than treatment with nothing or all. The goal is to answer that question definitively. Other options are to have both sides treated with a hemostatic, have neither side treated, or to place non-absorbable packing material that requires later removal.

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.**

If side effects or discomforts do occur, Dr. Antisdel and Dr. Brunworth will try to minimize and treat these by irrigating the treated sinus with saline to remove the Arista, Nexfoam, Sinufoam, and Nasopore. Also, removal of excess hemostatic agents during irrigation will lessen the risk of obstruction, embolization and death. The risk of embolization and death are only present if a hemostatic agent is directly injected or placed onto an open vessel. This will not be happening in this study. Hemostatic agents will only be topically applied to sinuses post operatively.

Use of questionnaires:
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.**

N/A

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

Some research medications or procedures can cause severe birth defects, mental retardation to an unborn baby, or loss of the unborn baby. If patients take part in a research study that includes a drug or medical procedure, they must be willing to have a pregnancy test done before beginning their participation. Patients must avoid becoming pregnant while they take part in 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)? N

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

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

If no, please justify why not.

All procedures are standard of care. Risks are minimal.

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.

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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 effects and side effects of available hemostatic agents, and help them make well educated decisions about which agents are 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 to absorbable packing is the use of non-absorbable packing (this is used as standard of care if the patient is experiencing excessive bleeding and requires a tamponade). Patients may also receive the absorbable packing off study with the same product in both nostrils. Other alternatives include to not use any packing or to not participate in the study.

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

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

   SLU ITS recognized document-level encryption

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

   Collection or Storage of data in SLU REDCap

   Collection or Storage of data in SLU Qualtrics

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

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

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

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

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

   Sponsor provided system or portal (Please specify):

   Other (Please specify):

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

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

   SLU Email account with an encrypted file attachment

   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.) For initial data collection identifier information (name, MRN, etc.) will be necessary. The master list containing the identifier information of the subjects will only be available to the PI, co-investigator and study coordinator. This list will consist of a Study ID number and the identifiable information will be kept according to this ID. The list will be kept in a locked cabinet in the Department of Otolaryngology-- Head and Neck Surgery. Any data taken from the medical record will be manually entered onto data collection sheets identified by study number only. Medical Records will be obtained from Saint Louis University Hospital. This includes the sex, ethnicity, age, surgical pathology, treatment type and duration. In addition, pre-treatment and post-treatment radiographic imaging (CT scans and MRIs) is to be acquired from the Kodak™ Directview Radiology Image Server used at Saint Louis University Hospital respectively.
Since this is a prospective study, it is important to emphasize that the data and materials were obtained with the primary intention to diagnose and treat rather than for research purposes only. Existing records and data will continue to be used for treatment of future related sequelae of this disease process.
b.) The PI, co-investigator, and study coordinator will be the only people with access to identifiers or coded information.
c) No samples or data will be provided from an outside source.
d) We will not be audio/video taping or photographing subjects.
e) No data will be collected via email or the internet.

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.

not applicable

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

Use of drapes or other privacy measures

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

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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):

*** * * 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

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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).**

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a.) Informed consent will be sought from the patient at the time of their out-patient visit.
b.) An Institutional Review Board approved Investigator will initially discuss the study with the potential subject, including the risks, benefits, and alternatives. The study coordinator may be involved to discuss procedures and arrange testing, should consent be obtained. The reconfirmation of consent at subsequent visits will be the responsibility of both the study coordinator and the PI. The subject will be provided with information about the study and their role in it. They will be informed that they may terminate their participation at any time for any reason. The informed consent process will be documented using a standard Research Enrollment Note, which will include information regarding what version of the Informed Consent document (ICD) was used, who discussed the study with the subject, that questions/answers occurred, that no study-related activity was performed until after execution of the ICD, and the time of actual consent.
c.) The discussion will occur at the time of the surgery consultation as part of the decision to undergo ESS, since the use of the agents being evaluated is standard of care. The patients will have no limit on time to consent.
d.) The discussion will occur in the physician's clinic in a private, quiet environment.
e.) If the subject could not write, they would be allowed to make their mark on the appropriate signature line of the ICD, and the process will be witnessed. These issues would be documented in the Research Enrollment Note.

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	03/10/2017

Title Approved_Consent version 4
Consent Type Consent
Upload Consent Form/Document X Attachment Approved_24331 consent v4

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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.

*** * * 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.

*** * * HIPAA * * ***

15. HIPAA

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

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

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

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

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

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

   City/State/Zip codes

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

   Age (if subjects are 90+ years)

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

   X Names

   Social Security numbers

   Telephone numbers

   X 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)

   X 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
- Laboratory, pathology and/or radiology results
- Biological samples
- X 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

Protocol Title: Analysis of hemostatic agents compared to physiologic hemostasis

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HIPAA Documents	Title	Attached Date
HIPAA Authorization	hippa authorization form 24331	03/20/2014
HIPAA Authorization	24331 marked HIPAA	04/09/2014
HIPAA Authorization	HIppA authorization form 24331 Version 2	04/16/2014
HIPAA Authorization	Approved_HIppA authorization form 24331 Version 2	05/13/2014

Title hippa authorization form 24331
HIPAA Documents HIPAA Authorization
HIPAA Form HIPAA_Authorization_Form 2014 24331 new title
HIPAA Authorization Template

Title 24331 ed HIPAA
HIPAA Documents HIPAA Authorization
HIPAA Form 24331 ed HIPAA
HIPAA Authorization Template

Title HIppA authorization form 24331 Version 2
HIPAA Documents HIPAA Authorization
HIPAA Form 24331 ed HIPAA Version 2
HIPAA Authorization Template

Title Approved_HIppA authorization form 24331 Version 2
HIPAA Documents HIPAA Authorization
HIPAA Form Approved_24331 ed HIPAA Version 2
HIPAA Authorization Template

SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	Analysis of hemostatic agents compared to physiologic hemostasis

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

SAINT LOUIS UNIVERSITY

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

Participant				**IRB Number**	24331
Principal Investigator (PI)	**Antisdel**	**Jastin**	**MD**	**PI's Phone Number**	**314-577-8885**
	Last	**First**	**Credentials**		
Title of Project:	Analysis of hemostatic agents compared to physiologic hemostasis				

"You" refers to the person who takes part in the research study.

You are being asked to participate in a research study conducted by Dr. Jastin Antisdel and colleagues because you have a longstanding sinus infection requiring surgery.

This consent document may contain words that you do not understand. Please ask Dr. Antisdel or his colleagues to explain any words or information that you do not clearly understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research is to compare the effects of six different agents (Arista™, Nexfoam™, and Sinufoam™, Nasopore®, Posisep®, and Posisep®X) when used to stop bleeding after sinus surgery. Each agent is FDA approved for this use and has been used extensively. This study will compare how well these agents work as a group from the patient and physician perspective versus no therapy. This will provide knowledge for their future use in patients requiring sinus surgery. Up to 144 people will be enrolled at Saint Louis University.

2. WHAT AM I BEING ASKED TO DO?

Your participation will involve:
(1) Having sinus surgery in the standard fashion. The surgery itself and the post-operative care will be no different than if you do not participate **(Standard of Care).** The one difference is that at the end of your surgery, one sinus will be treated with one product **(Research Related).** Your surgeon will choose the product that is applied to your sinus. An envelope will be selected out of the stack just before the surgery and there will be a note inside that states which sinus the material will be applied to.

One of these products (specific product will be chosen by your surgeon) will be placed in one of your sinus cavities at the end of surgery and allowed to remain there until it is absorbed or removed at a post-operative visit on weeks 1, 2, and 6. This will be done with post-operative irrigations (rinsing the sinus cavity) which will remove much of the products **(Standard of Care)**. If any of this packing still remains in your sinus cavity, it will be removed by debridement (removing dead tissue) in the office by Dr. Antisdel at a regularly scheduled office visit on weeks 1, 2, and/or 6. This procedure is **standard of care** and would be done whether or not you participate in this study.

(2) You will provide information about how you are feeling after surgery such as your pain, bleeding, blockages, and drainage. This will be done on post-operative days 1, 2, 7, and 14 **(Standard of Care).**

(3) You will be given a packet of questionnaires before your surgery. You will be asked to fill out the questionnaires (on days 0, 1, 2, 7, and 14) regarding your experience. These can be returned before your surgery and at your regularly scheduled office visits on weeks 1, 2 and 6. This would not be done if you were not in the study **(Research Related).**

(4) On your normal post-operative visits (weeks 1, 2 and 6) your physician will record information from your normal exam. We will evaluate the differences between the two sides of your sinus cavity for scar tissue, swelling, infection, how you are healing, and time needed to remove dead tissue out of your sinus cavity **(Standard of Care).**

Questionnaires
Your participation will involve filling out provided questionnaires. The questionnaires will take approximately five minutes each. The questionnaires do not require your name. They will be stored in Dr. Antisdel's office until all of the surveys have been returned. The data will then be entered into a database with your identifying information removed.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?
Your participation in this study is expected to last six weeks. This is the normal time period for office visits after sinus surgery and requires no greater time commitment.

4. WHAT ARE THE RISKS?
Your participation in this study will involve both standard of care and research procedures. The risks associated with the standard of care procedure will be discussed with you or, when appropriate, addressed in a separate clinical consent document.

There are certain risks and discomforts that may be associated with this research. They include*:*

1) Allergic-type Adverse Reaction
There is a rare possibility of an allergic-type adverse reaction to Arista™, Nexfoam™, Sinufoam™ Nasopore®, Posisep®, or Posisep®X. You may experience itching, hives, hay fever symptoms, wheezing, difficulty breathing, and/or new swelling. These reactions may be serious or life threatening. These are the same risks you would have if you did not participate in the study.

There are no other additional adverse reactions to these products associated with being in this study.

2) 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.

3) Use of Questionnaire
Some questions in the questionnaires may make you feel uncomfortable. You may choose to not answer any question that makes you feel uncomfortable.

4) As with any surgery the risk of bleeding is present, but all precautions will be taken to ensure that blood loss is minimal. Also, since material is being placed into your nose there is a risk that this material can block your ability to breath through your nose by completing blocking this passage. As discussed earlier any excess material will be removed with postoperative (after the surgery) nasal irrigation. Chance of infection will be minimized by postoperative evaluation for signs of infection by Dr. Antisdel. This study is designed to evaluate the utility of materials that are used to lessen bleeding and scar tissue formation. For this reason one side of your nose may heal faster than the other.

5) **Pain.** The risk of pain exists, as it does for almost any procedure. Dr. Antisdel will take all precaution to ensure that pain (during and after the operation) is minimized.

6) Unknown Side Effects
There is always the risk of developing previously unknown side effects

Pregnancy/Childbearing Potential

If you are a woman of childbearing potential, please read and sign below.
Some research medications or procedures can cause severe birth defects, mental retardation to an unborn baby, or loss of the unborn baby. If you take part in a research study that includes a drug or medical procedure, you must be willing to have a pregnancy test done before beginning your participation. You must avoid becoming pregnant while you take part in the research study. If you are pregnant, or become pregnant, you cannot take part in this research study. It is important that you let the research study doctor know if you are breast-feeding. If you are pregnant or think you are pregnant, it is important for you to let the investigator know immediately. If you are sexually active during your participation in the research, you will use effective measures (chosen in consultation with your health care provider) to avoid becoming pregnant. Your signature below indicates you agree to these requirements. Signature Date

You may encounter these risks regardless of participation in this research study.

If side effects or discomforts do occur, Dr. Antisdel will try to minimize and treat these by irrigating the treated sinus with salt water to remove the Arista™, Nexfoam™, Sinufoam™ Nasopore®, Posisep®, and/or Posisep®X.

The investigator is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?
You will not benefit from this research study. Your condition may get better, stay the same or worsen. Even though you may not receive any benefit, other people who have sinus surgery may benefit in the future because of what the researchers learn from this research study.

6. WHAT OTHER OPTIONS ARE THERE?
You may choose not to participate in this research study. If you choose not to participate in the research, then you will have the standard surgical procedure. The packing used at the end of the surgery will be at the surgeon's discretion.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published but your name or identity will not be revealed and your record will remain confidential. In order to maintain confidentiality, Dr. Antisdel or his assistant will enter the information from the questionnaires, data sheets, and medical record into a number coded spreadsheet. The database will then be kept on a password-protected computer in a locked office. A master list linking the code number and your identity will be kept separate from the research data. The master list will be kept in a locked file and only the principal investigator and designated members of the research team will have access to the master list.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of research participants recruited to participate in research) and other University officials may review your study records. The Food and Drug Administration (FDA) may also review your research study records, including your medical record. State laws or court orders may also require that information from your research records be released.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

8. WHAT ARE THE COSTS AND PAYMENTS?

Standard of Care to be billed to Insurance

Because this research provides standard treatment and follow-up tests for the disease or condition being studied, insurance carriers ordinarily cover the costs. You may check with your insurance company to verify that they will provide coverage for the care before you agree to participate. No additional costs will be incurred by you or your insurance company by participating in this study. The study packing materials that will be used are part of the total charges for the operation and you will not incur any additional charges because a hemostatic material is being used. You will be responsible for any costs not covered by your health insurance company.

You will receive no payment for your participation in this research study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the study, please contact the Principal Investigator and/or the Chairperson of the Institutional Review Board as stated in section 10.

The University will provide medical treatment in the event that an injury results because of your participation in this research; however, the University reserves the right to make decisions concerning payment for medical treatment for injuries solely and directly relating to the research. The University makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns regarding this study, or if any problems arise, you may call the Principal Investigator Dr. Antisdel at 314-577-8885. For questions after hours, you may call 314-577-8000 and ask for the ENT resident on call.

If you have any questions about your rights as a research participant or in the event you believe you have suffered an injury as a result of participation in the research project, you may contact the Chairperson of the Saint Louis University Biomedical Institutional Review Board (314-977-7744), who will discuss your questions with you or will be able to refer you to the individual who will review the matter with you, identify other resources that may be available to you, and provide further information as how to proceed.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary and refusal to participate will involve no penalty to you or loss of any benefits to which you are otherwise entitled. You may withdraw from the research study at any time without penalty or loss of benefits to which you are otherwise entitled. You will be informed of any significant new findings developed during the course of participation in this research that may have a bearing on your willingness to continue in the study. The investigator may withdraw you from this research if circumstances arise which makes this necessary.

The investigator may terminate your participation even without your consent when, in the investigator's judgment, it is in your interest to do so, or under certain circumstances*:*

- Conditions worsen or do not improve and an alternative treatment is medically indicated,
- A side effect or medical condition occurs that may place you at risk of further complications if study participation is continued,
- Inability to take the medication /participate as instructed,
- Inability to keep scheduled appointments,
- Cancellation by the regulatory agency

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator(s). I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. I believe I understand the purpose of the study as well as the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to be a participant in this study. I will be given a signed copy of this consent document for my records.

_____ _____

Consent Signature of Research Participant (18 and over) Date

_____

Print Name of Participant

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #: 24331
Approved: 03-07-17
Expires: 03-31-18
Board #: 1
Saint Louis University

I certify that I have explained to the above individual(s) the nature and purpose of the study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the subject/patient has received a copy of this signed consent document.

_____ _____

Signature of Principal Investigator or Research Team Member **Date**

_____

Print Name of Principal Investigator or Research Team Member

NOTE: The Principal Investigator or Research Team Member that signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.