Personnel Information . . . 1

Subject Population . . . 4

Study Location . . . 5

General Checklist . . . 5

Funding . . . 6

Expedited Paragraphs . . . 7

Background, Purpose, Study Procedures . . . 9

Radioisotopes or Radiation Machines . . . 14

Devices . . . 15

Drugs, Reagents, Chemicals, or Biologic Products . . . 15

Other Levels Of Review . . . 16

Subject Population . . . 18

Subject Population . . . 19

Risks . . . 20

Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy . . . 24

Potential Conflict of Interest . . . 28

Informed Consent . . . 29

Assent . . . 30

HIPAA . . . 31

Attachments . . . 33

PI Obligations 34

Event History 35

Protocol Title:	SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty
Protocol Status:	APPROVED
Date Submitted:	04/16/2024
Approval Period:	05/07/2024-05/06/2025
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
Otto, Randall	MD	Faculty/Staff
Email	**Phone**	**Fax**
randy.otto@health.slu.edu	3149147987	

Department Name
Orthopaedic Surgery

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?***

15+ years of research as primary investigator and medical doctor with many publications, presentations, and abstracts

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.	X	Perform study procedures or Specimen Collection
6a.	X	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	X	Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	X	Subject Randomization or Registry	8.	X	Collection of Subject Data

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

UserID	CourseCompletionDate	Course
ottor	10-07-2018	Good Clinical Practice (GCP)
ottor	05-09-2006	CITI Biomedical Research Basic Training
ottor	03-24-2022	COI - Needs review

Administrative Contact

Name of Administrative Contact	Degree	Title
Peterson, Asa	MD	Housestaff Resident
Ellenberg, Elie	MD	Faculty/Staff
Kaar, Scott	MD	Associate Professor
Gruender, Allison	RN	Research Nurse
Bijanki, Vinieth	MS	Research Scientist

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
Place, Howard

Degree
MD

Title
Professor

Email
place@slu.edu

Phone
(314) 977-4014

Fax

Department Name
Orthopaedic Surgery

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

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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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
place	12-12-2003	CITI/University of Miami Training
place	07-13-2022	COI - No further review needed
place	04-24-2001	Protecting Study Volunteers in Research
place	02-13-2013	SLU Boot Camp Training

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Otto, Randall, MD	Orthopaedic Surgery	15+ years of research as primary investigator and medical doctor with many publications, presentations, and abstracts	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, 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
Peterson, Asa, MD	Graduate Medical Education	10 years of research in the biomedical field including several first authorships	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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			Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Ellenberg, Elie, MD	Graduate Medical Education	Years of research experience prior to and in medical school	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Kaar, Scott, MD	Orthopaedic Surgery	Attending surgeon with years of experience as a Primary Investigator	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, 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
Gruender, Allison, RN	Orthopaedic Surgery	Research experience includes analysis and evaluation of professional research through higher level education course (Research in Advanced Nursing Practice) completed for MSN degree. Work included literature reviews and critical appraisals of health-related research. All clinical research activities will be supervised.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices , Subject Randomization or Registry, Collection of Subject Data, Data Analysis, Review Adverse Events

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*** * * Subject Population * * ***

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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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)

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* * * Study Location * * *

Study Location(s) Checklist

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

Saint Louis University, Medical Center Campus
Saint Louis University, Frost Campus
Saint Louis University, Madrid Campus
Saint Louis University, SLUCare Practice Locations
X SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)
Cardinal Glennon Children's Medical Center
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 :

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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X Collection of Specimens
Data collection via e-mail or the Internet
Deception/Incomplete Disclosure
Dietary Supplements, Vitamins, and Other Food Agents
X FDA Approved Device
X FDA approved drugs, reagents, other chemicals administered to subjects (even if they are not being studied), or biologic products
Genetic Testing
HIV Testing
X 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
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
X University Indemnified Study (SLU is responsible for liability coverage) *?HELP?*
Other (clarify in text box to the right)

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

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* * * Funding * * *

Funding Checklist

NONE

Funding - Industry Sponsor

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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Sponsor Name	Sponsor's Protocol Version Date
Next Science	

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.

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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.)

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

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

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

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

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

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

Title

SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

1. Background

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

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

Cutibacterium acnes (C. acnes) prosthetic joint infection is a devastating and somewhat unique complication to shoulder arthroplasty. It is a very slow-growing, aerotolerant anaerobic, non-spore forming, gram-positive rod-shaped bacteria that takes up to 2-3 weeks to grow in a lab setting. There have been several studies assessing various agents in the fight to prevent C. acnes prosthetic joint infection. These agents include standard peri-operative measures typically taken when performing shoulder replacement surgery - pre-operative prophylactic antibiotics, pre-operative skin cleanse/wash, topical adjuvants (povidone-iodine, chlorhexidine, etc.), and intra-operative antibiotic powders. The overall infection rate of shoulder arthroplasty has been cited to be between 0.9-2.9%, with C. acnes being the most common bacterium in shoulder arthroplasty periprosthetic infections. Morbidity and cost associated with shoulder prosthetic joint infection is extremely high, requiring multiple surgeries and months of treatment

to overcome the infection.

One of the main issues with C. acnes is its preferred location within the body, residing within the sebaceous glands of the hair follicles, deep to the epidermis where many preoperative topical preparations to cleanse the skin prior to surgery have little affect. These glands are commonly found around the shoulder and upper back, and lead to acne. C. acnes, along with other common prosthetic joint infection bacteria, quickly create a biofilm which is impenetrable to most antibiotic agents, further stressing the importance of prevention. Recently there have been studies analyzing the effects of Benzoyl Peroxide (BPO) on C. acnes as it relates to shoulder arthroplasty in an attempt to reduce this bacterial burden prior to surgery. There have been promising results with multi-day preparation skin cleansing with benzoyl peroxide. However, there are no studies looking at intra-operative skin incision preparations targeting the region of skin where the C. acnes bacteria resides. In vitro studies show SURGX antimicrobial gel (Next Science, Jasksonville, FL) results in a marked reduction of C. acnes in addition to other common bacteria affecting prosthetic joints. This gel uses citric acid to chelate the metallic bonds of biofilm. The bacteria are then destroyed by a combination of a high osmolarity environment coupled with a surfactant.

The first purpose of the study is to evaluate if a dermal layer preparation will reduce positive cultures of C. acnes after primary shoulder arthroplasty. There will be a control group consisting of no skin preparation. There will be two additional comparative groups. The second purpose of this study is to compare the use of standard povidone-iodine swab versus SURGX antimicrobial gel as an application into the dermal layer after the skin incision has been made with a skin knife to see if there is a reduction in bacterial burden in the superficial and deep tissues at the end of a primary shoulder arthroplasty. Superficial and deep cultures will be obtained at the conclusion of the shoulder replacement surgery. These cultures will be held in the lab for 2 weeks to identify if bacteria is present. Our hypothesis is that the SURGX antimicrobial gel will provide a greater reduction in bacterial burden compared to povidone-iodine within the deep tissues after primary shoulder arthroplasty.

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.

Comparing the growth of intra-operative tissue cultures of Cutibacterium Acnes after primary shoulder replacement when using a no-prep control group versus antimicrobial wound gel versus betadine applied to the skin layer after the skin incision has been made. Reducing the bacteria present in the deep tissues at the end of the surgery may prevent infections from developing in the future.

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).

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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Primary objective: skin incision preparation solution intraoperatively after the skin incision has been made will reduce the number of positive cultures after primary shoulder arthroplasty versus no intraoperative skin incision preparation. A control group with standard preoperative skin prep will be included. All patients will receive standard of care preoperative antibiotics and preoperative skin cleansing preparation prior to draping for surgery.

Hypothesis: the use of skin incision preparation solution will be more effective at reducing positive cultures compared to the control group and the SURGX antimicrobial wound gel will result in decreased C. acnes growth from intra-operative cultures when compared to the use of povidone-iodine.

Please save frequently

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

This is a prospective, sequential assignment study in which patients will be blinded to the intervention. Patients will be sequentially allocated based on enrollment ID number (alternating consecutive fashion) with every third patient in the control group (no skin incision preparation) beginning with patient #1. The treatment group #1 (betadine) will be every third patient beginning with patient #2. Treatment group #2 (SURGX anti-microbial wound gel) will be every third patient beginning with patient #3.

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).

All patients must be undergoing a primary anatomic or reverse shoulder arthroplasty. Patients will be screened for iodine allergies and excluded from participation if they have this allergy. Patients will be recruited and consented preoperatively in the office prior to surgery. There is no standard of care in regards to which topical incisional adjuvant is used, if any, in shoulder arthroplasty. Common agents that are frequently used for surgical preparation include chlorhexidine and betadine (povidone-iodine). No additional procedures will be required of the study subjects. All patients will receive standard pre-operative prophylactic antibiotics. They will all receive the same preoperative external skin preparation with Hibiclens (chlorhexadine) and ChloraPrep (2% chlorhexadine gluconate / 70% isopropyl alcohol solution) prior to draping. Intra-operative irrigation will be standardized with Irrisept (chlorhexidine gluconate 0.05% in sterile water). At the time of the surgery, after the skin incision has been made with a skin knife, the dermal layer will either be not prepped or be prepped with povidone-iodine (treatment group 1) or SURGX antimicrobial wound gel (treatment group 2). At the conclusion of the case, five total cultures will be obtained. Two will be superficial and three will be deep cultures, one of which will be an implant swab. These cultures will be held in the lab for 2 weeks to evaluate for Cutibacterium acnes. After 2 weeks, we will evaluate the data to determine if there is a difference in positive cultures between the two groups. Our goal is 20 patients in each group based on previous literature assessments of skin prep solutions prior to shoulder arthroplasty. This will likely take 2-3 months to collect the appropriate number of patients and have the complete 2 week results from the lab cultures. The conclusion of the study is when we have completed the number of patients (20) in each group and final 2 weeks lab results are final. We will also collect information from medical records, as outlined in the data collection sheet.

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.**

It has been reported in the literature that standard preoperative antibiotics and skin preparation prior to draping for the surgery does not eliminate the presence of bacteria in the wound after total shoulder arthroplasty. It is not known if this will lead to an increased risk of infections long term or if this is an incidental finding. No studies have looked at prepping the skin incision after the incision has been made to reduce this potential bacterial burden. Theoretically, if the bacterial burden is reduced at the time of surgery, this may reduce the risk of late term infection if it were to occur. The control group will receive standard pre-op skin cleansing. Since the study endpoint is presence/absence of C. acnes in the cultures, and we only plan to enroll 60 patients, we do not expect to cease enrollment early.

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.**

Statistics will be run through standard statistical programs, involving analyses that compare two groups of results - T-test, Chi-square etc. Our decision of sample size is based upon the literature with prior studies including comparative treatment groups of roughly 20 patients in each arm.

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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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 in regards to skin/dermis preparation for shoulder arthroplasty at SLU or in the field of shoulder replacement surgery. Common skin/dermis preparations include preoperative skin cleansers, betadine preparation, chlorhexidine skin preparation, and intra-operative irrigation with various solutions. All patients will receive standard pre-operative prophylactic antibiotics. They will all receive the same preoperative skin preparation with Hibiclens (chlorhexadine) and ChloraPrep (2% chlorhexadine gluconate / 70% isopropyl alcohol solution) prior to draping. Intra-operative irrigation will be standardized with Irrisept (chlorhexidine gluconate 0.05% in sterile water). During the study, the control group will not receive a skin incision prep after the incision is made while the other treatment groups will receive either povidone-iodine skin incision prep or SurgX gel prep. We are only looking for the presence of bacteria at the conclusion of the study. It is not known if this bacteria is clinically important but if present could potentially present as a late term infection. These infections may not present themselves for 2-10 years postoperatively. The assessment in this study is to see if this bacterial presence can be reduced after shoulder arthroplasty with the theoretical potential advantage of reducing late term infections. Patients will have standard of care follow up appointments with their physician which are typically at 2-weeks, 6-weeks, 3 months, 6 months, and yearly (no end date) following shoulder arthroplasty. These are not part of the research study.

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

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

We will be collecting 5 cultures per patient. These will included 2 superficial cultures and 3 deep cultures including one of the implant. We will hold these cultures for 2 weeks to determine the presence of Cutibacterium acnes. This bacteria is commonly present after shoulder replacement surgery (up to 73% of cases), although the clinical significance is not known. Presence of this bacteria does not mean that the patient will develop a clinical infection or indicate that antibiotics are needed. The purpose of the study is to see if this bacterial burden can be reduced for the potential reduction in the risk of late term infection if they were to occur.

There are no plans to contact the patients as the results of these cultures would not have an impact on their care. However, wound cultures obtained for the study will show up as lab results in the patients' medical records.

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

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

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* * * Radioisotopes or Radiation Machines * * *

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

4. Radioisotopes or Radiation Machines

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

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-233", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur after the IRB staff has drafted the informed consent radiation exposure risk statement, or verified the statement that was drafted by the research team (as noted below*). 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: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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*NOTE: Informed Consent Radiation Exposure Risk Statement- The appropriate Informed Consent Radiation Exposure Risk Statement template language must be inserted 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. Per IRB Guidelines, the language will either be drafted by the IRB staff or drafted by the research team and then verified by IRB staff prior to submission to the RSC for review. 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).
SURGX Wound Gel	NextScience	

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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).

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

FDA Approved Drugs, Reagents, Chemicals, Biologic Product

Drug Name	Manufacturer	Source (e.g., Pharmacy, Sponsor, etc.)	Dosage
Povidone Iodine	Medline	Stocked on shelf	swabstick

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

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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 <a href=https://www.slu.edu/research/faculty-resources/research-integrity-safety/documents/irb-protocols-requiring-rsc-review-instructions-for-coordinators.pdf target=_blank > instructions or contact the Radiation Safety Officer at 977-6895.

X **Not Applicable**

Yes, study involves radioactive materials

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@ssmhealth.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 SLUH South Campus and the infusion center at the DOB) and medical record access, requires Research Business Review (RBR) and approval 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 Clinical Trials Office (CTO) have approved the study. Please contact the Research Compliance Office at 577-8113 or sluh-research@ssmhealth.com or the CTO at 977-6335 or clinical-trials-office@health.slu.edu for more information.

X **Not Applicable**

Yes, study requires Saint Louis University Hospital review

5. SSMSL

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

Not Applicable

X **Yes, study requires RBR review**

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

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

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* * * Subject Population * * *

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

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

18 - 90 years of age

b) Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI). 60

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?* 60

d) If including vulnerable populations (minors, pregnant women and fetuses, neonates, non-English speaking, economically or educationally disadvantaged, prisoners, 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 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?*

shoulder arthroplasty does not occur in children

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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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 SLU Guidelines for additional considerations and strategies for mitigating risks.

g) Describe (labeled a-c): a) who you are recruiting for this study (e.g., your patients/students/colleagues, those in existing database or registry, the general public), and b) how you are recruiting (flyers, advertisements, direct call/mailing, membership networks, in-person recruitment in clinic, classroom, public locations, etc.). For secondary data analysis or specimen studies, state how you have access to materials. Importantly: do not contact participants prior to obtaining IRB approval for your study.

c) Also indicate whether or not you plan to obtain personal/private information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects prior to obtaining informed consent and how (obtained by communicating with prospective subjects or obtained by accessing records or stored biospecimens). Note: if you are accessing medical records other than those of your own patients or those in your immediate department, you will need to submit a <a href= https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/prep_to_research_form.doc target=_blank>HIPAA Preparatory to Research form and submit to the SLU Privacy Officer PRIOR to accessing records.

Please refer to the <a href=https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_subject_recruitment.doc target=_blank>SLU IRB Recruitment Guidelines when designing recruitment strategies and upload recruitment materials to the Attachments page for IRB review. You are expected to obtain permission for individuals/organizations that assist with recruitment, and whenever possible, those assisting should share your materials with potential participants on your behalf rather than providing you with private contact information.

a) adult patients of Dr. Otto and Dr. Kaar pursuing primary anatomic or reverse shoulder arthroplasty
b) in-person recruiting in clinic
c) Exclusion of patients will include any surgery other than primary anatomic or reverse shoulder arthroplasty and patients with an iodine allergy

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* * * Subject Population * * *

8. Subject Population (continued)

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

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Age 18-90 years of age
Undergoing elective primary anatomic or reverse shoulder arthroplasty

Identify exclusion criteria.

revision shoulder replacement surgery
patients with an allergy to iodine, benzalkonium chloride, or polyethylene glycol

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.

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n/a

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

Next Science will cover the cost of the SURGX antimicrobial wound gel, betadine swabs, and laboratory cost for the tissue wound cultures (300 total cultures)

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.**

It will likely take 3-4 months to collect the appropriate number of patients per group. Each patient will have labs that will take 2 weeks for final results. Data analysis after the final patients labs have returned will take approximately 1 month. Total study time to submission for publication should be no longer than 6 months.

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* * * 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.**

Betadine (povidone-iodine): temporary skin irritation; potential for burning, itching, redness, blistering in patients with an serious iodine allergy. The frequency and severity are rare. Reversibility can be

accomplished with anti-allergy medication and local skin/wound care.

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.**

There are reported side effects for SURGX antimicrobial wound gel including skin irritation, localized burning and stinging.

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).**

The only potential risk would be an unknown risk of an allergy to iodine in the betadine group. No other risks will be incurred for the patient.

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?***

All patients will receive a standard and uniform preop skin prep and preop antibiotics. The control group will not receive a skin incision prep after the incision has been made. The treatment groups will receive either povidone-iodine or SurgX gel applied to the incision intraoperatively. There is no known risk between not receiving povidone-iodine versus SURGX wound gel incision skin prep. No standard treatment is being withheld from any subject.

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

n/a

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.**

All analysis will be performed in HIPAA compliant manners. The attending surgeon is prepared to treat any associated adverse effect. Anesthesiology will be on hand to help address any immediate allergic reaction.

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).

n/a

11. Data Safety Monitoring

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

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

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.

This is a single site study employing interventions that are not considered outside of the standard of care. The trial involves the use of FDA approved agents in a manner that is not off-label. The study is not employing high-risk interventions and can safely be monitored by the PI and research team members.

b. Is there a Data Safety Monitoring Plan (DSMP)? Y

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

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

a) Outcome and adverse event data will be collected by the research team and documented electronically. Any AEs/SAEs observed will be collected on the date of the patient's surgery by the research team and reported to the PI. This would include any reaction to the application of the product such as skin irritation, rash, or burning. This would be treated at the time of surgery with irrigation of the wound to flush the area and dilute the product. If a severe case were to happen then steroid medication would be administered. There are no follow up appointments or study procedures after the date of surgery included in the research study. AEs or SAEs will be recorded in a spreadsheet with severity and causality noted. The spreadsheet will be kept on a SLU-managed computer with encryption.

b) The data will be monitored by the PI and study team members. The PI, Dr. Otto, is an orthopaedic surgeon familiar with the use of the products in the study. He also has 15+ years of research experience. Other qualified team members include: Dr. Kaar, orthopaedic surgeon with years of research experience, Dr. Ellenberg, orthopaedic surgery resident, and Dr. Peterson, orthopaedic surgery resident.

c) Aggregate data will be reviewed after the first 20 participants have completed the study to detect benefit, harm, or futility of the interventions in addition to any AE or SAE trends. Following this initial review, the data will be analyzed every three months if the study continues longer than the expected time frame of 3-4 months.

d) SAEs will be reviewed in real time by the PI (MD). The PI will ensure appropriate classification of the event.

e) Because the study interventions are not considered outside the standard treatment, we do not anticipate the need for stopping/halting rules that would differ from standard treatment of a patient undergoing surgery.

If no, please justify why not.

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

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

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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.

It is known that bacteria (Cutibacterium acnes) is present in up to 73% of cases after shoulder arthroplasty is performed. It is not known if this bacteria will increase the risk of infection late term. The goal of this study is to see if this bacterial presence can be reduced by prepping the skin incision after it has been made. The potential benefit is that if the bacterial presence is reduced or eliminated by prepping the skin incision (for those subjects in treatment groups), the potential development of late term infection may be reduced. An individual subject may or may not benefit from participation in the study. Society may benefit from the potential knowledge gained regarding skin incision preparation as a result of this study, improving practices for patients undergoing shoulder arthroplasty.

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.

There is no standard skin preparation, the alternative would be nonparticipation. Of note, povidone-iodine and SurgX gel are available for all patients and is stocked on the shelf at the hospital.

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 managed device (computer, tablet, etc.) with encryption	Not Applicable, I will not be sending/sharing electronic data outside of SLU	

b) Hardcopy (Paper) Data

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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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 Room/Office	Personnel Supervision	Intra-operative culture specimens will be stored by a SLU laboratory until final results are obtained, then will be discarded per lab protocol. Hardcopy consents will be stored in SLU locked cabinet/room/office under personnel supervision

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) The master list will be a separate Excel sheet stored in a SLU-managed encrypted device on a secure T drive. Only the research team will have access to the master list.
b) The list will be maintained until the study has ended and been published.
c) Participants will be coded 001, 002, 003, etc. and will be the only data sheet linked to patient identifiers. The coded data collection sheet will contain this number and no patient identifiers.

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.**

No data will be shared outside of the study team including with the drug/device manufacturer.

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 SLUCare Epic Research Charting Policy and Clinical Workflow: Documenting Research Encounters in Epic.

Wound cultures obtained for the study will show up as lab results in the patients' medical records.

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

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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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):

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* * * Potential Conflict of Interest * * *

12. Potential Conflict of Interest

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

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

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

Check all those that apply:

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

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

1. A Conflict of Interest Management Plan.
   has been approved for all investigators for this study
   is pending
   has not been initiated

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

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

Investigator(s) must have:

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

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

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

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* * * Informed Consent * * *

13. Informed Consent

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

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

State N/A if not applicable.

1) **How is consent being obtained? When and where will the discussion take place? If the study involves a Non-English Speaking participant/population, please include details about plans for translated consent materials and interpreters to be used (see SLU Guidelines for Involving Non-English**

Speaking Subjects for more details).

Participants will be consented in person during clinic pre-operative clinic visit or the on the day of surgery prior to surgery.

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 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 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_CR2024_consent_form_Version 2	Consent	09/12/2024

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* * * Assent * * *

14. Assent

Complete this section if your study includes minors. The Assent Form Templates (For children and For adolescents) provide guidelines for writing the assent document.

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 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.

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

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* * * HIPAA * * *

15. HIPAA

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

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

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

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

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

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

   - City/State/Zip codes
   - Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)
   - Age (if subjects are 90+ years)

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

   - X Names
   - Social Security numbers
   - Telephone numbers
   - Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)
   - All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
   - X All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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	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
	Physician/clinic records
X	Laboratory, pathology and/or radiology results
X	Biological samples
	Interviews or questionnaires/health histories
	Mental health records
	Data previously collected for research purposes
	Billing records
	Other

Please describe:

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

X	Not applicable (continue to question 5).
	Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.
	Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.
	With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

HIPAA Documents

HIPAA Documents	Title	Attached Date
HIPAA Authorization	Approved_HIPAA Authorization Version 2	01/27/2023

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* * * Attachments * * *

16. Attachments

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

Possible documents for this protocol could include:

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

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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etc.)

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

Document Type	Document Name	Attached Date	Submitted Date
Bibliography	Bibliography	10/18/2021	01/06/2022
Device Information/Documentation	AccessGUDID - DEVICE_ SurgX™ (00370858000041)	02/01/2022	02/04/2022
Package Insert	APLS31015S_Medline_Industries_Inc_05-10-22	05/11/2022	05/11/2022
Device Information/Documentation	NMS-40015-Rev.-B-SurgX-IFU	09/30/2022	10/28/2022
Device Information/Documentation	K163188	09/30/2022	10/28/2022
Package Insert	NMS-40015-Rev.-B-SurgX-IFU (1)	09/30/2022	10/28/2022
Package Insert	betadine insert	09/30/2022	10/28/2022
Data Collection Sheet	Approved_data collection sheet 2.0	01/27/2023	01/27/2023
Safety Information (DSM Information)	Safety Information (DSM Information)_2024	04/10/2024	04/16/2024

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* * * PI Obligations * * *

PI Obligations

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

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

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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

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

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

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

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

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

X **I accept this responsibility.**

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

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
09/12/2024	CONTINUING REVIEW 2 FORM APPROVED	Y	Y
05/17/2024	PROTOCOL EXPIRED		
04/29/2024	CONTINUING REVIEW 2 FORM REVIEWER(S) ASSIGNED		

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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04/22/2024	CONTINUING REVIEW 2 FORM PANEL MANAGER REVIEW		
04/22/2024	CONTINUING REVIEW 2 FORM PANEL REASSIGNED		
04/16/2024	CONTINUING REVIEW 2 FORM SUBMITTED	Y	
03/19/2024	CONTINUING REVIEW 2 FORM CREATED		
05/22/2023	CONTINUING REVIEW 1 FORM APPROVED	Y	Y
05/17/2023	PROTOCOL EXPIRED		
04/10/2023	CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED		
04/10/2023	CONTINUING REVIEW 1 FORM PANEL MANAGER REVIEW		
03/28/2023	CONTINUING REVIEW 1 FORM SUBMITTED	Y	
03/19/2023	CONTINUING REVIEW 1 FORM CREATED		
01/27/2023	NEW FORM APPROVED	Y	Y
01/25/2023	NEW FORM REVIEWER(S) ASSIGNED		
10/28/2022	NEW FORM SUBMITTED (CYCLE 1)	Y	
05/23/2022	NEW FORM CONTINGENT		
05/10/2022	NEW FORM REVIEWER(S) ASSIGNED		
05/09/2022	NEW FORM REVIEWER(S) ASSIGNED		
05/09/2022	NEW FORM PANEL MANAGER REVIEW		
05/09/2022	NEW FORM PANEL REASSIGNED		
05/03/2022	NEW FORM PANEL REASSIGNED		
02/07/2022	NEW FORM PANEL REASSIGNED		
02/04/2022	NEW FORM RESUBMITTED	Y	
01/28/2022	NEW FORM RETURNED		

Protocol Title: SURGX antimicrobial gel versus povidone-iodine skin incision prep for the prevention of bacterial seeding in total shoulder arthroplasty

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01/07/2022	NEW FORM PANEL ASSIGNED	
01/06/2022	NEW FORM SUBMITTED	Y
01/06/2022	NEW FORM PREREVIEWED	
12/19/2021	NEW FORM PREAPPROVAL	
10/18/2021	NEW FORM CREATED	