Preadmission Skin Wipe Use for Surgical Site Infection Prophylaxis in Adult Orthopaedic Surgery Patients

NCT03401749
Last updated 4/23/20

A prospective observational cohort study

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Human Subjects Protocol (HSP)

Form Version: July 29, 2019

• To avoid delay, respond to all items in order and include all required approvals and documents. For more tips, see the UAB IRB website. • To complete the form, click the underlined areas and type or paste in your text; click checkboxes to check/uncheck. • All responses should be Times New Roman, Bold, and Underlined.

• NOTES REGARDING VA RESEARCH: BVAMC research cannot be reviewed by an external IRB (only UAB IRB). Ensure you complete this form for any BVAMC research. BVAMC Research must be signed off by the BVAMC supervisor for scientific/scholarly review via PORF prior to submission of this form.

INDICATE THE TYPE OF REVIEW YOU ARE APPLYING FOR:

☒ Convened (Full) IRB

OR

☐ Expedited - See the Expedited Category Review Sheet, and indicate the category(ies) here: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

1. IRB Protocol Title: Efficacy of Preadmission Theraworx Wipe Use for Surgical Site Infection Prophylaxis in Adult Orthopedic Surgery Patients: A Randomized Controlled Trial

2. Investigator and Contact Person

a. Name of Principal Investigator: **Ashish Shah**
Degree(s)/Title: **MD** BlazerID: **ashpurvi**
Dept/Div: **Surgery/Orthopoedics** Mailing Address: **1313 13th St S** UAB ZIP: **35205** Phone: **(205) 930-6722** E-mail: **ashishshah@uabmc.edu**

b. Name of Contact Person: **Hina Amanullah** Title: **Regulatory Coordinator** Phone: **205-934-3796**
E-mail: **hkaman01@uab.edu**

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

• Certifying that I and all key personnel comply with reporting requirements of the UAB Conflict of Interest Review Board;

• Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;

• Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);

• Verifying that all key personnel listed on the submission have completed initial IRB training and will complete continuing IRB training as required;

• Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable; • Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;

• Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently; • Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: Date:

3. Protocol Personnel

a. Complete the **IRB PERSONNEL FORM to list all key personnel (each individual involved in the design and conduct of this protocol).**

b. Non-UAB Personnel Relying on UAB IRB - If you are requesting that the UAB IRB serve as the IRB of record for any non-UAB personnel, list these individuals below. Add additional rows as necessary.

Name and Degree	From Institution with or without own IRB?	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: Degree: Institution: Email:	☐Has own IRB but requests that UAB IRB serve as IRB of record?***-OR-*** ☐Does not have own IRB and needs to rely on UAB IRB.	☐No ☐Yes	

***** If the individual has a Financial Interest, ***include a copy of the report from his/her own institution's conflict of interest review with this submission to the UAB IRB.***

VA Personnel: The VA Financial Conflict of Interest (fCOI) form must be submitted to the VA fCOI Committee Chair. Include in 3.a above any financial conflict of interest as submitted on that VA fCOI form. If there is a conflict, submit a copy of the management plan with this submission.

c. Are any of the investigators listed on the IRB PERSONNEL FORM students using this research for their thesis or dissertation? ☐Yes ☒No **If No,** continue with Item 3d.

If Yes, provide the name of the student and the Thesis/Dissertation Title:

d. Is the principal investigator a student, fellow, or resident? ☐Yes ☒No **If Yes,** complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name:
Supervisor's Signature:_____

e. Is medical supervision required for this research? ☐Yes ☒No **If Yes,** who will provide the medical supervision?

☐ PI will provide ***-OR-***
☐ Other:
Name: Telephone:
If other than PI, obtain signature of person providing medical supervision:

Signature

f. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol: **He played a primary role in the development of this protocol in its entirety. Dr. Shah will make sure that patients in the three different groups receive the correct skin preparation and will perform the foot and ankle surgeries to patients in this study. He will devote a minimum of two hours per week to oversee the progress during different phases of the project: protocol troubleshooting, patient enrollment, procedures, and data collection/analysis. Many of these responsibilities fall within existing scope of clinical practice. Time is set aside each week on Tuesday afternoons and Fridays for all other research related activities, such as IRB paperwork, study design, data handling, and manuscript preparation**

g. Describe your process for ensuring all key personnel are adequately informed about the protocol and their research-related duties and functions:

Each person involved in this project is in complete understanding of the protocol and contributed to make the project safer for patients and more efficient. Each person will attend meetings scheduled by the PI to discuss their progress in their role. Each person has read these IRB forms throughout and authorized their understanding. Study personnel are briefed/instructed verbally on their research related duties prior to involvement in the study. Instructional documentation for study personnel will

also be provided to all individuals carrying out key study functions, and copies will be made available and stored in the Highlands clinic or OSI offices. Instructional documentation will include patient recruiting instructions/materials, inclusion/exclusion criteria; consent documentation, patient education materials, product storage, handing, and distribution instructions, preoperative nursing instructions, clinic follow-up instructions, and workflow diagrams.

4. Funding

Is this protocol funded? ☐Yes ☒No

If No, specify that costs of the protocol will be covered by funds from the UAB department or other source named: **The costs of the products being compared (Theraworx bath wipes and Chlorhexidine bath wipes) will be covered by the UAB department of surgery, orthopedic surgery division. Patients will be responsible for the cost of their own bathing (soap and water). Participants will be financially responsible for their medical care, including clinic visits and surgeries, to the same extent as if they chose not to participate in the trial. Study participants will be responsible for the cost of any additional medical care related to serious adverse reactions to the products used in the study. Participants are made aware of their financial responsibilities in the consent form.**

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant, Contract, or Agreement:

b. UAB PI of Grant, Contract, or Agreement:

c. Office of Sponsored Programs (OSP) Assigned Number:
(If not yet available, enter "Pending" and provide upon receipt from OSP.)

d. Sponsor, Funding Route:
(Check and describe all that apply)
(If subaward, list both the funding source and the institution receiving the direct award)

☐ Gov't Agency or Agencies—Agency name(s):
- ☐ Department of Defense (DoD): Identify DoD component:
- ☐ Department of Energy (DOE)
- ☐ Department of Justice (DOJ)
- ☐ Department of Education

☐ NIH Cooperative Group Trial - Group name:
☐ Private Nonprofit (e.g., Foundation) - Name:
☐ Industry-sponsored, industry-initiated - Name:
NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.
☐ Industry-sponsored, investigator-initiated - Name:
Describe the funding arrangement:
NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.

☐ UAB Departmental/Division Funds—Specify:
☐ VA Funding —Specify:

5. Locations Involved

a. Indicate all performance sites that will provide space, services, or facilities for the conduct of this protocol.

☒ UAB Hospital
☒ UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital
☐ The Kirklin Clinic at Acton Road

☐ UAB Callahan Eye Hospital
☐ UAB Clinical Research Unit
☐ Children's of Alabama
☐ Birmingham Veterans Affairs Medical Center NOTE: *Research may only be conducted by investigators who have a BVAMC appointment*
☐ Jefferson County Department of Health
☒ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe: **UAB Orthopedic Specialties Institute (OSI)**
NOTE: Documentation of IRB approvals from sites receiving subawards must be received by the UAB OIRB before funding will be released for that subaward.

b. Describe the space, service, or facilities available for the conduct of the research in the performance sites listed in Item 5.a (For research on UAB campus, include building names): **UAB Hospital Highlands will serve as the primary site for the carrying out of research activities. Patients will be recruited, examined, and followed in the Highlands orthopedic clinics. In addition, patients will receive their pre-operative and surgical care primarily at this site. Patient recruitment, consent, and group allocation documentation will be stored primarily in the Highlands Clinics. Theraworx and CHE bathwipes and nursing and OR personnel instructions will also be stored and distributed at this site. The Orthopedic Specialties Institute (OSI) is located across the street from UAB Highlands and serves as the location of many key personnel offices, including the PI and administrative support staff. OSI will serve as additional office space for the storage of excess research documentation, and will function as the primary location for the sending and receiving of fax communication related to this research project. In addition, OSI serves as a primary site for research meetings among study personnel to discuss study progress, voice concerns, delineate responsibilities, and discuss reporting of results and manuscript preparation.**
UAB Hospital will serve as an additional study site. Orthopedic colleagues from this site may recruit patients for this study, and some procedures may be performed at the UAB main hospital. In addition, if any study patient requires care that can only be provided at UAB Hospital, care will be transferred to this location.

c. Does this protocol require clinical services at one of the sites listed in Item 5.a above? ☐Yes ☒No **If Yes,** will any of the services be billed to either participants/their insurance or to the study account through the Hospital Billing Office (PFS) or the HSF Billing Office (MSO)? ☐Yes ☒No

If Yes, submit a Fiscal Approval Process (FAP)-designated unit submission and send to fap@uab.edu. For more on the UAB FAP requirements, go to FAP - SiteMinder Processes.

d. Is this a field study? ☐Yes ☒No **If Yes**, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors:

e. Has this protocol been rejected or disapproved by another review board (another IRB, similar review board, or

departmental review committee(s)) that authorizes the use of its patient populations? ☐Yes ☒No

If Yes, provide name(s) of the review board(s) and reason(s) not approved:
Attach copies of the disapprovals.
NOTE: If this protocol is subsequently rejected or disapproved by another review board, promptly notify UAB IRB.

f. Will the protocol be conducted at or recruit participants from the Birmingham Veterans Affairs Medical Center (BVAMC)? ☐Yes ☒No **If Yes,** describe the involvement of the BVAMC:

Attach the BVAMC consent form(s), if applicable. Attach any other applicable BVAMC forms (such as the Privacy and Information Security Checklist and The BVAMC FCOI forms).
NOTE: Investigators conducting research at BVAMC **must** have a BVAMC appointment.
NOTE: See the BVAMC section of the IRB Guidebook for more information.

g. Will the protocol be conducted at or recruit participants from the Jefferson County Department of Health (JCDH)? ☐Yes ☒No **If Yes,** describe the involvement of the JCDH and list the JCDH clinics being used:
Attach the JCDH Research Review Panel approval, if applicable.
NOTE: Human subjects research conducted at certain JCDH clinics requires review by the JCDH Research Review Panel. See the JCDH section of the IRB Guidebook for more information.

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☒Yes ☐No **A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial here.* **If Yes,** you will need to fulfill the following requirements (regardless of funding):

a. All key personnel must complete the Good Clinical Practices (GCP) training. For information on this requirement, visit the IRB website here.

b. This protocol must be registered on ClinicalTrials.gov. Provide the National Clinical Trial (NCT) identifier number: **NCT03401749**
If you have any questions regarding registering a study on ClinicalTrials.gov, email the UAB Center for Clinical and Translational Science at ccts@uab.edu.

7. Multi-Site Studies

a. Is this a multi-site study? ☐Yes ☒No **b.** Is the UAB Investigator the lead investigator? ☐Yes ☒No **c.** Is this a multi-site study with a coordinating site? ☐Yes ☒No **d.** Is this a multi-site study with UAB as a coordinating site? ☐Yes ☒No

If Yes to a, b, c, or d, describe the management of information obtained in multi-site research that might be relevant to the protection of participants:

Include, at a minimum, how the following items are managed: IRB approvals from other sites; Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?); Interim result; & Protocol modifications.

8. Drugs

Will any drugs or supplements be *used or studied* in this protocol? ☒Yes ☐No **If Yes,** attach the completed Drug Review Sheet.
If BVAMC, attached the completed BVAMC Drug Review Sheet .

9. Devices

a. Will any devices be *studied* in this protocol? ☐Yes ☒No

b. Will any *not FDA-approved* devices be *used or studied* in this protocol? ☐Yes ☒No **If Yes to a or b,** attach the completed Device Review Sheet.

10. Special Approvals

a. Does this protocol involve the use of radioisotopes? ☐Yes ☒No

If Yes, attach documentation of approval from the Radiation Safety Division.

b. Does this protocol include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☒No **If Yes,** attach documentation of approval from the Infection Control Committee of the appropriate facilities.

c. Does this protocol involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? ☐Yes ☒No **If Yes,** attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

d. Does this protocol require obtaining any remnant clinical laboratory biospecimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☒No **If Yes,** attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

e. Does this protocol use stored (existing) biospecimens from a repository? ☐Yes ☒No **If Yes,** attach documentation of approval for use of biospecimens, and describe how existing biospecimens are labeled:

11. Use of Biospecimens

Does this protocol involve the collection of biospecimens? ☐Yes ☒No **If Yes, complete 11.a-11.h.**
If No, skip to Item 12.

a. How will biospecimens be obtained, processed, distributed, and stored?

b. How will biospecimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)?

c. How will clinical data associated with the biospecimens be collected and stored?

d. What participant-identifying information will be collected and linked to the biospecimens?

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called “stripped” or “anonymized” biospecimens).

f. Is genetic testing planned as part of this protocol? ☐Yes ☐No **If Yes,** describe the planned genetic testing here.

i. Does this include whole genome sequencing? ☐Yes ☐No ii. Will participants be informed of the results of any DNA testing? ☐Yes ☐No

g. Will biospecimens be stored for future use? ☐Yes ☐No **If Yes,** indicate whether they will be used for the disease under study in this protocol or research on other diseases. In addition, indicate where the biospecimens will be banked

- If above is a BVAMC location, what IRB is responsible for overseeing the operations of the biospecimens bank (i.e., local IRB or other multi-site or central IRB?)

h. Will biospecimens be shared with other investigators in the future? ☐Yes ☐No i. What identifiers, clinical information and demographic information will be shared; or will the biospecimens be stripped of identifiers (i.e., anonymized)?

NOTE: *Coding data is not considered anonymous.*

ii. Outline your procedure for assuring IRB approval for release and use prior to release of biospecimens.

NOTE: *Investigators who receive and/or use these biospecimens must document approval from the appropriate IRB(s) before the biospecimens may be released.*

i. Will specimens be destroyed after the project-specific use is completed? ☐Yes ☐No **j.** Will specimens be used and/or shared for commercial profit? ☐Yes ☐No **k.** Will specimens be destroyed after the project-specific use is completed? ☐Yes ☐No

l. Will participants be informed of the results of the specimen testing? ☐Yes ☐No **m**. Are there any implications for family members based on specimen testing results? ☐Yes ☐No *(If yes, the family members may be participants.)*

12. Gene Therapy

Does this protocol involve gene therapy or administering recombinant materials to humans? ☐Yes ☒No **If Yes,** submit the Gene Therapy Project Review Panel Report ***-OR-*** the Protocol Oversight Review Form For Clinical Vaccine Trials, as applicable.

13. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? ☒Yes ☐No **If Yes, complete Items 13.a-**13.**f.**
If No, skip to 14.

a. Will the data/information be stored or managed electronically (on a computer)?

☒Yes ☐No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)? ☐Yes ☒No **If Yes,** attach copies of the privacy notices from each institution/entity, and provide the name of each institution/entity:

c. Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

☒ UAB Hospital or UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
☐ UAB Callahan Eye Hospital
☐ Children's of Alabama
☐ Jefferson County Department of Health
☐ School of Dentistry
☐ School of Health Professions
☐ School of Medicine

☐ School of Nursing
☐ School of Optometry
☐ University of Alabama Health Services Foundation
☐ UAB Health Centers

☐ Viva Health
☐ Ophthalmology Services Foundation
☐ Valley Foundation
☐ Medical West - UAB Health System Affiliate
☐ Birmingham Veterans Affairs Medical Center
☐ None - **If None, skip to Item 14.**

d. Indicate any information systems that will be the sources of information used for the protocol. ☒ A system maintained centrally by UAB Health System (these include the following: HealthQuest for registration, billing, and patient administration; PowerInsight (clinical data warehouse); Cerner IMPACT for PowerNotes for meds, Lab, Radiology, UED, Surgery

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

To request access to clinical systems for research purposes, visit https://www.oneuabmedicine.org/web/hsis/technical-support, click "Accounts Request" and complete the form indicating access for research purposed.

☐ Another system on a UAB or BVAMC server - Describe:

e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.

☒ Names
☐ Geographic subdivisions smaller than a state
☒ Elements of dates (except year) related to an individual
☐ Telephone numbers
☐ Fax numbers
☐ Email addresses
☐ Social security numbers
☒ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers
☐ Device identifiers and serial numbers
☐ Biometric identifiers
☐ Web universal resource locators (URLs)
☐ Internet protocol address numbers
☐ Full-face photographic images
☐ Any other unique identifying number - Describe:

NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual

☐ None - **If None, skip to Item 14.**

f. Choose one plan to describe your use of the personal health information:

☐ The data collected meet the specifications for a "limited data set" (LDS)

-If the LDS will leave the covered entity or will be received from another covered entity you will need a Data Use Agreement

☒ Research staff will obtain authorization from each participant to use the information

-Include the HIPAA Authorization form, complete except for participant name and IRB protocol number, as the final page of the consent form

☐ PI requests waiver of authorization to use the information

-Attach Waiver of Authorization and Informed Consent form

NOTE: For BVAMC research, the BVAMC HIPAA authorization form or UAB HIPAA waiver form must be completed and submitted with the HSP.

PROPOSED RESEARCH

• The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below. • Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.

14. Purpose - in nontechnical, lay language

a. Summarize the purpose and objectives of this protocol in one short paragraph.

The purpose of this protocol is to assess the effect of the addition of 2 doses of 2% topical chlorhexidine gluconate wipes or topical TheraworxTM wipes to standard ChloroPrep skin preparation on patients undergoing orthopedic surgery procedures. Our objective is to test the hypothesis that administration of 2% topical chlorhexidine gluconate or topical TheraworxTM wipes (one dose the night before surgery and one on the day of surgery) will reduce the number of surgical site infections in patients undergoing orthopedic surgery procedures. Furthermore, we will explore whether the rate of surgical site infections from patients who utilized 2% topical chlorhexidine gluconate wipes significantly differs from those who utilized topical TheraworxTM wipes. We hope to reduce the rate of surgical site infections with this intervention.

b. Describe how outcomes will be measured for this protocol.

Primary Outcome:

1. Clinical evaluation for presence of SSI (and standard of care culture etiology, if SSI is present) at all follow-up visits.

Secondary Outcomes:

1. **Patient compliance survey: Patients will be assessed for compliance on the morning of surgery.** 2. **Patient satisfaction: Patient satisfaction will be measured by asking each subject a single subjective question at baseline and each subsequent follow-up visit. Subjects will be asked "How satisfied are you with your orthopedic care?" Response options include: "Very Satisfied, Satisfied, Dissatisfied, and Very Dissatisfied".**
3. **Patient Pain scores: Patients will be asked to rate their pain on a 1-10 scale at each visit.**
4. **Patient Reported Outcome Scores (PROMIS): PROMIS scores are clinical outcome questionnaire taken on iPad with emerging questions that change based on participant's response. http://www.healthmeasures.net/explore-measurement-systems/promis**
5. **Foot Function Index (FFI) questionnaire (attached)**
6. **Visual assessment of wound healing and scar formation will be performed at each post-operative**

visit

7. **Patients will be asked about any side effects regardless of intervention arm- the percentage of patients who report side effects, including rashes, irritation, or allergic reactions will be calculated for each intervention.**

15. Background - in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies).

There is currently no clear consensus in the surgical community regarding the best local surgical site treatment protocol for the prevention of surgical site infections. The most recent CDC guidelines on antiseptic prophylaxis from 2017 recommend the following:

> **"8A.1 Advise patients to shower or bathe (full body) with soap (antimicrobial or nonantimicrobial) or an antiseptic agent on at least the night before the operative day. (Category IB–strong recommendation; accepted practice.)**
> **8A.2 Randomized controlled trial evidence suggested uncertain trade-offs between the benefits and harms regarding the optimal timing of the preoperative shower or bath, the total number of soap or antiseptic agent applications, or the use of chlorhexidine gluconate washcloths for the prevention of SSI. (No recommendation/ unresolved issue.)" [1]**

Without a clear consensus on the best standard of care in this area and with uncertainty surrounding the efficacy and limitations of chlorhexidine gluconate (CHG), there is a need for more research in this area. This study hopes to compare a commercially available presurgical bath wipe, Theraworx™, to 2% chlorhexidine gluconate and simple bathing in adult patients undergoing orthopedic surgery.

Theraworx™ is a non-rinse skin formulation that combines multiple ingredients, including Aloe Concentrate, Allantoin, Tego Betaine F 50, Tego Betaine L-7, Lauryl Glucoside, Abil 8852, Vitamin E, Natural Fragrances, Methyl paraben, Propyl paraben, EDTA, Antimicrobial Preservative, Colloidal Silver, and Beta Glucan, in preoperative disposable bath wipes. The wipes are gamma irradiated for sterilization. The main proposed antimicrobial mechanism of action involves the local reduction in skin pH to around 4.6. In vitro studies have shown that Theraworx™ is effective in reducing carbapenem-resistant entero bacteriaceae and MRSA in skin analogue and plated collagen, respectively [2,3]. Another study comparing skin cultures from 30 health patients after full body scrub by either Theraworx™ or chlorhexidine, found that Theraworx™ had a statistically better log reduction in bacteria in 1 of 4 body areas at 2 and 6 hours, with a trend toward reduction in the other 3 areas [4]. In a multi-center study, the use of Theraworx™ wipes for urinary catheter insertion was found to reduce the rate of nosocomial CAUTI in ICU patients [5]. This study seeks to evaluate the in vivo efficacy of Theraworx™ for reducing surgical site infection rate in adult orthopedic surgery patients.

[1] Berrios-Torres, et al. "Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017" *JAMA Surg.* 2017
[2] Huckfeldt, R. "Duration of Action of Theraworx® Against Methicillin Resistant Staphylococcus Aureus Utilizing an Inoculated Collagen Model" St John's Medical Research Institute, 2009.
[3] "Efficacy of a novel skin antiseptic against carbapenem-resistant Enterobacteriaceae" *American Journal Of Infection Control,* 2015
[4] Huckfeldt, R. "Theraworx® v. Chlorhexidine Gluconate Bathing and Peri-operative Skin Cleansing Study" St John's Medical Research Institute, 2009
[5] "Theraworx® skin care formulation reduces nosocomial associated CAUTI rates when used for urinary

catheter insertion and maintenance" *Journal of Clinical and Medical Investigations* 2015 [6] "Patient preoperative skin preparation evaluation of one test product, Theraworx®, and one comparator product, Hibiclens® 4% chlorhexidine solution (CHG)" Bioscience laboratories, Inc 2017 [7] "Forearm controlled application test for evaluating the relative mildness and skin moisturization effectiveness of two products" Theraworx® and Hibiclens® 4% chlorhexidine solution (CHG), Bioscience laboratories, INC 2017
[8] "An In-vitro evaluation of one test product, Theraworx® and one comparator product Dyna-Hex2® 2% chlorhexidine solution (CHG) for mucosal irritation using the MTT ET-50 reduction method", Bioscience laboratories, INC 2017

[9] "An In-vitro evaluation of one test product Theraworx® and one reference product Dyna-Hex 2® 2% chlorhexidine solution (CHG) for its antimicrobial properties using the time-kill method", Bioscience laboratories, INC 2017

16. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB (if other sites relying on UAB IRB, list the number for each site)? **500 patients**

If multi-site study, total number at all sites/institutions:

b. Describe the characteristics of anticipated or planned participants (if multiple groups, repeat list for each group).

Sex: **Male or Female**
Race/Ethnicity: **All**
Age: **18 or older**
Health status: **Deemed healthy enough for orthopedic surgery and without clinical signs of infection**

c. From what population(s) will the participants be derived? **Majority of patient participants will likely be older adults from Birmingham, Alabama and the surrounding area. These will be patients who will undergo surgical procedures by board certified orthopedic surgeons in UAB Division of Orthopaedics.**

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants: **The participants are patients of Dr. Shah and Dr. Naranje and employees who work with researchers. Orthopedic research fellows will recruit participants for this study through directly talking to the patients in clinic.**

d. Describe the inclusion/exclusion criteria:
Inclusion Criteria: deemed healthy enough for orthopedic surgery, age 18 and older, willing to comply with study protocol, and without clinical signs of skin infection
Exclusion Criteria: previous allergic reaction or absolute contraindication to topical chlorhexidine gluconate or any other study product ingredient, dermatologic disorders around the surgical site, signs of other infections, age under 18, pregnancy

e. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group.

Control group – 160 patients who will receive only standard skin preparation prior to surgery. Intervention group 1 – 160 patients who will be administered 2% Chlorhexidine Gluconate wipes once on the night prior to surgery and once on the day of surgery in addition to standard skin preparation. Intervention group 2 – 180 patents who will be administered Theraworx™ wipes once on the night prior to surgery and once on the day of surgery in addition to standard skin preparation.

f. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

☐ Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

☐ Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

☐ Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates

☐ Prisoners: Attach SPRF—Prisoners

☐ Minors (<18 years old): Attach SPRF—Minors **NOTE**: For BVAMC Research <19 years old

☒ Employees or students at institution where research conducted

☐ Persons who are temporarily decisionally impaired

☐ Persons who are permanently decisionally impaired

☐ Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion: **There's no reason to exclude participants who are employees or students at UAB. We will explain that the decision to participate or not in this study will not affect the participant's relationship with UAB and the investigators.** **g.** List any persons other than those directly involved in the protocol who will be at risk. If none, enter "None": **None**

h. Describe the recruitment process (e.g., medical record review, referrals, letter of invitation, existing patients) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening. **Dr. Shah and Dr. Naranje will screen their pre-surgical clinic patients for potential participants though their clinic encounters and ask patients if they are interested in participating. Orthopaedic research fellows, will provide explanations to patients and consent patients for the study in Highlands hospital following a guideline set by Dr. Shah. Additionally, Drs. Shah and Naranje may enroll their own patients if clinical time permits. Other orthopedic surgeons at UAB Highlands hospital may be invited to participate in recruiting patients for this study in the future if needed to achieve an adequate number of participants. They will be fully instructed on all recruitment guidelines and procedures.**

i. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., IRB Protocol Number for approved databases) from which you will recruit participants. **Participants will be recruited from Dr. Shah's and Dr. Naranje's clinic**

j. Describe the screening process/procedures for potential participants. **Dr. Shah and Dr. Naranje will screen their pre-surgical clinic patients for potential participants though their clinic encounters by asking if patients are interested in participation and meet inclusion/exclusion criteria. If patient is interested and eligible, a research fellow, research nurse, or Dr. Naranje will proceed to consent the patients.**

17. Protocol Procedures, Methods, and Duration - in nontechnical, lay language

a. Describe the procedures for all aspects of your protocol. Tell us what you are doing.

This study is a randomized study that will include three groups: a control group, intervention group 1 that will be administered topical 2% chlorhexidine gluconate (CHG) wipes once the night before

surgery and once on the day of surgery, and intervention group 2 that will be administered topical Theraworx™ wipes once the night before surgery and once on the day of surgery. After IRB is approved, 500 participants (160-180 per group) will be collected for the prospective study. Patients will be randomized into groups using a random number list generated in excel, which will be consulted by a research nurse or research fellow, who will instruct the patient in the use of the product related to their group assignment. Dr. Shah or Dr. Naranje will perform orthopedic surgery on the participants without knowledge of their group assignment. Patients will be assessed for regimen compliance by survey. At clinic visits, patients will be assessed for the presence of surgical site infection, wound healing and scar formation, pain scores, and will be asked to complete a self-administered patient satisfaction questionnaire.

b. What is the probable length of time required for the entire protocol (i.e., recruitment through data analysis to study closure)? **2 years**

c. What is the total amount of time each participant will be involved? **1 year**

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "None." **None**

e. List the procedures, the length of time the procedure takes, the total # of times the procedure is performed, and indicate whether each is performed solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population.

-Insert additional table rows as needed.

-If procedure is sometimes research and sometimes routine care, include on separate lines with number of times as each.

Procedure	Length of Time Required of Participants	Total # of Times the Procedure is Performed	Research (Res) –OR- Routine Care
Orthopedic surgery	**1 day**	**1**	☐Res ☒Routine
Skin product application	**5 min**	**2**	☒Res ☐Routine
Patient Survey	**5 min**	**1**	☒Res ☐Routine

f. Will an interview script or questionnaire be used? ☒Yes ☐No **If Yes,** attach a copy.

g. Will participants incur any costs as a result of their participation? ☐Yes ☒No **If Yes,** describe the reason for and amount of each foreseeable cost.

h. Will participants be compensated? ☐Yes ☒No **If Yes, complete i-v.**

i. Type: (e.g., cash, check, gift card, merchandise):

ii. Amount or Value:

iii. Method (e.g., mail, at visit):

iv. Timing of Payments: (e.g., every visit, each month):

v. Maximum Amount of Compensation per Participant:

18. Benefits

Describe the potential benefits of the research. **The research has the potential to benefit the U.S. health care system, surgeons, and patients. In recent years, surgical site infections occur in about 2% of all patients undergoing orthopedic procedures. Surgical site infections often necessitate longer hospital stays, increased use of antibiotics, and even revision surgery and puts economic burden on patients, physicians, and hospitals. This research aims to highlight the effectiveness of Theraworx™ wipes to reduce the rate of surgical site infections and to introduce the wipes as a part of the standard skin preparation for various orthopedic procedures.**

19. Risks - in nontechnical, lay language

a. List the known risks for participants as a result of participation in the research. This should not include the minimal risk of loss of confidentiality. However, it should include any physical, psychological, social, economic, and/or legal risks. If there is a greater than minimal risk of loss of confidentiality describe why this is so. Do not list risks associated with the standard-of-care procedures.

NOTE: Risks included here should be included in the consent form or information sheet, as applicable. **The major risk of this study is possible allergic or serious skin reaction to the 2% topical Chlorhexidine Gluconate or Theraworx™ wipes. Up to 10% may experience dryness, itching, or rash on the application site. Very rarely (less than 1% of patients), patients may experience a serious allergic reaction within minutes after the application of the wipe.**

b. Estimate the frequency, severity, and reversibility of each risk listed. **N/A**

c. Is this a therapeutic study or intervention? ☐Yes ☒No **If Yes, complete i.-iii.**

i. Describe the standard of care in the setting where the research will be conducted:

ii. Describe any other alternative treatments or interventions:

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using:

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☒No **If Yes,** describe the provisions that have been made to make these resources available.

e. Do the benefits or knowledge to be gained outweigh the risks to participants? ☒Yes ☐No **If No,** provide justification for performing the research:

20. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks. **There are minimal risks and risk of randomization involved with this study. Even so, patients will be in the clinic under the care of the nursing staff and the operating team. Patients will be closely monitored for any adverse reaction due to the topical products before their surgery begins. Patients will also be informed about the possibility of adverse reactions and instructed to discontinue use and seek immediate medical attention if they experience any signs or symptoms of serious adverse effects or severe allergic reactions. Patients with contraindications to any of the interventions will be excluded from the study.**

If the protocol involves drugs or devices skip Items 20.b. and 20.c. and go to Item 21. Instead, include this information in the Drug Review Sheet or Device Review Sheet, as applicable.

b. If hazards occur to an individual participant, describe (i) the criteria that will be used to decide whether that participant should be removed from the protocol; (ii) the procedure for removing such participants when

necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants.

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire protocol and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants. **N/A**

21. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☒Yes ☐No **If Yes,** complete the items below.
If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.
*For research being conducted at the BVAMC, the UAB Consent waiver form must be completed and submitted with the HSP.

b. Do you plan to document informed consent (obtain signatures) for this protocol? ☒Yes ☐No **If Yes,** complete the items below.
If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained? **Interview,**

d. Who will conduct the consent interview? **Dr. Naranje, Dr. Shah**

e. Who are the persons who will provide consent, permission, and/or assent? **Patients**

f. What steps will be taken to minimize the possibility of coercion or undue influence? **Patients will not be financially compensated, and each patient will be asked if they are interested in participating. If they decline, no attempts will be made to convince them to participate.**

g. What language will the prospective participant and the legally authorized representative understand? **English**

h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "None." **None**

j. If any protocol-specific instruments will be used in the consenting process, such as supplemental handouts, videos, or websites, describe these here and provide a copy of each. If not, enter "None." **No supplemental handouts or instruments will be prepared by the research staff or provided to the patients by the research staff. Patients will be verbally instructed in the use of the products by research personnel. Additionally, patients may at their own discretion consult any instructional materials that are included inside or on the product packaging or made publically available by the manufacturers**

k. How long will participants have between the time they are told about the protocol and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. **>24 hours**

22. Procedures to Protect Privacy

Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed.

Individuals will not be publicly identified and all conversations pertaining to study participants will be held in private rooms.

23. Procedures to Maintain Confidentiality

a. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the department and all computer systems used to store protocol related data.
Data will be stored in the UAB hospital server. It will be accessed from hospital computers at Highlands. The file will only be accessible by directly involved investigators.

b. Will any data from this protocol be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☒Yes ☐No **If Yes, complete i-iii.**
i. Who will receive the data? **Data will be used for publication but it will be de-identified** **ii.** What data will be shared? **Study data**
iii. How will the data be identified, coded, etc.? **De-identified, coded with unique identifier number**

24. Genomic Data Sharing (GDS)

Researchers who collect genomic data as part of a NIH grant funded after January 25, 2008 may be required to submit those data to a NIH database for broad scientific sharing. See Genomic Data Sharing in the IRB Guidebook for more information.

a. Does this protocol involve the proposed submission of genetic data into genomic repositories created to share genetic information for research purposes? ☐Yes ☒No

b. Will UAB be uploading the final genomic data to the central repository (e.g., dbGaP)? ☐Yes ☐No **If Yes to both a and b,** submit a Detailed Data Sharing Plan to the IRB for review. This plan should include any known data use limitations and indicate whether aggregate-level data are appropriate for general research use. For guidance see the NIH Genomic Data Sharing Policy.

c. Submit a copy of the NIH Institutional Certification Form.
To determine which certification form to include, answer i-ii.
i. Was this protocol funded prior to January 25, 2015? ☐Yes ☐No • **If yes,** and consent will be obtained, submit the Extramural Institutional Certification - Before January 25 - With Consent.
• **If yes,** and consent will not be obtained, submit the Extramural Institutional Certification - Before January 25 - Without Consent.
ii. Was this protocol funded after January 25, 2015? ☐Yes ☐No • **If yes,** submit the Extramural Institutional Certification - After January 25.

25. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None." **None**