Benzoyl Peroxide compared to Chlorhexidine skin treatment to reduce P. Acnes shoulder skin burden

IRB Protocol Date: March, 2015

Initial IRB Approval: 20July2015

IRB #: HP-00064296

NCT #: NCT02510144

University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@som.umaryland.edu

APPROVAL OF RESEARCH NOTIFICATION

Date: July 27, 2015

To: Mohit Gilotra
RE: HP-00064296
Type of Submission: Initial Review
Type of IRB Review: Full Board

Approval for this project is valid from 7/20/2015 to 7/19/2016

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced protocol entitled, "*Benzoyl Peroxide compared to Chlorhexidine skin treatment to reduce P. Acnes shoulder skin burden.*"

The IRB made the following determinations regarding this submission:
- Written informed consent is required. Only the valid IRB-approved informed consent form(s) in CICERO can be used.
- A waiver of HIPAA authorization for release of the PHI identified in the CICERO application has been reviewed and approved for recruitment purposes only.

Below is a list of the documents attached to your application that have been approved:
Eligibility Checklist for HP-00064296 v6-11-2015-1434035983255(0.01)
RESEARCH CONSENT FORM.docx
HIPAA Form.docx
University of Maryland Rehab and Ortho Institute IAA.pdf
Midtown Campus IAA.pdf
Chlorhex 4%.png
BO-drug 10% insert.png
Evaluation to Sign Consent.docx
Benzoyl Peroxide Instructions Final.docx
Chlorhexidine Instructions Final.docx

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year.** The regulations make **no provision for**

any grace period extending the conduct of the research beyond 7/19/2016. You will receive continuing review email reminder notices prior to this date; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond **7/19/2016**. Investigators should submit continuing review reports in the electronic system at least six weeks prior to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.

Date: Friday, October 4, 2019 9:55:08 AM Print Close

Introduction Page

1 * Abbreviated Title:
Skin Prep P. Acnes

2 * Full Title:
Benzoyl Peroxide compared to Chlorhexidine skin treatment to reduce P. Acnes shoulder skin burden

3

* Select Type of Submission:
IRB Application

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Mohit Gilotra

1.1 * Does the Principal Investigator have a financial interest related to this research?
○ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Logan Kolakowski

2.1 Does the Point of Contact have a financial interest related to this research?
○ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

Name	Edit Submission	cc on Email	Research Role	Has SFI?
Samir Kaveeshwar	yes	yes	Research Team Member	no
Ashley Klein	yes	yes	Research Team Member	no
Katrina Williams	yes	yes	Sub-Investigator	no
Grant Duvall	yes	yes	Research Team Member	no
Ralph Henn	yes	no	Sub-Investigator	no
Syed Hasan	yes	no	Sub-Investigator	no

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
The Principal Investigator, along with the Sub-Investigator's at our site, participate in the identification of eligible patient's on a daily basis with the Research Coordinator. When eligible patient's are identified, the Principal Investigator and/or Sub-Investigator will be present for the conversation with the potential participant about study

participation, to answer questions and ensure that the potential participant fully understand what will happen should they join the study.

The Principal Investigator also engages in regular review of all forms filled out in reference to enrolled participants, as well as regular meetings and reviews to monitor the status of the study and activities conducted for the study.
The Principal Investigator also participates in regular meetings with all members of the research team.

2 * Describe the facilities where research procedures are conducted:
Potential participants will receive information in private clinic rooms for privacy. During all patient interactions, study team will do their best to ensure that no study materials/information will be left in view of others not associated with the project. The healthy volunteer arm will occur in a private laboratory.

Study outcomes during anesthesia for surgery. Follow up visits will be conducted in a private room in the clinic.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
There are always research staff available to the patient should the patient have any questions or concerns, and the Principal Investigator and/or Sub-Investigator's are likewise available to the patient.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
All study staff are required to go through a training process for the study with the principle investigator, which includes knowledge assessments and regular meetings to ensure that all staff are fluent in all aspects of the study.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:
- (●) **Multi-Site**
- ( ) Single Site

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?
( ) Yes (●) **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?
(●) **Yes** ( ) No

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date
Midtown Campus IAA.pdf	6/18/2015 4:24 PM	6/18/2015 4:24 PM
University of Maryland Rehab and Ortho Institute IAA.pdf	6/18/2015 4:23 PM	6/18/2015 4:23 PM

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)
( ) Yes (●) **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)
( ) Yes ( ) No

6 * Institution(s) where the research activities will be performed:
University of Maryland Medical System (Select below)

* UMMS Sites:
UMMC Midtown Campus (formerly Maryland General Hospital)
University of Maryland Rehabilitation & Orthopaedic Institute (formerly Kernan Hospital)

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

Funding Information

1 * Indicate who is funding the study:
Department / Division / Internal

2 * What portion of the research is being funded? (Choose all that apply)
Drug
Other

3 Please discuss any additional information regarding funding below:
Funding will cover the different skin preps and the tools for obtaining culture.

ID: VIEW4DF85DF452400
Name: v2_Funding Information

Research Protocol

1 * Do you have a research protocol to upload?
No, I do not have a research protocol and will use the CICERO application to enter my study information

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:
Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):
Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).
Sample (Specimen) Collection and/or Analysis (including genetic analysis).
Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is 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.
● **Yes** ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.
This research is being done to help determine the best skin prep for shoulder surgery. Chlorhexidine is used in the operating room as a sterile prep. Chlorhexidine is the current standard operative and preoperative skin prep for all orthopaedic procedures and all parts of the body. The current data supporting it use is strictly based on hip and knee patients. The most common infection after shoulder surgery is from P. Acnes or the same bug that causes skin acne. It is prevalent in shoulder surgery because the shoulder is so close to the neck and back. Current skin preps, like chlorhexidine, in the operating room don't kill this bacteria. Even if we use the skin prep for a few days leading up to surgery, this skin bacteria may still linger. Our dermatology colleagues have a lot of experience with treating skin acne and they recommend trying benzoyl peroxide for a few days before surgery to help reduce shoulder infections. It is simple and safe to use for the past 40 years for the face, neck and back so I now we will try it for the shoulder. Surgical site infection in the orthopaedic surgery population is a big public health issue. Wound infections result in both longer length of hospital stay and total cost of care. Prevention is the key to decreasing this problem.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:
The purpose is to improve skin prep to decrease Propionobacterium Acnes and decrease the rate of shoulder surgical site infection.

Aim 1: To contrast P. Acnes burden after a 3 day prep of chlorhexidine with a 3 day prep of 5% topical benzoyl peroxide.
Aim 2: To estimate decrease in P. Acnes burden with preop skin preps compared to the contralateral side.

We hypothesize that three day preoperative application of 5% topical benzoyl peroxide will decrease patient's P. Acnes bacterial burden in comparison to chlorhexidine (positive control) and in comparison to the nonoperative shoulder (negative control).

2

* Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:
After surgical posting, patients will be randomized to chlorhexidine or benzoyl peroxide group. The solutions used will be 5% benzoyl peroxide emollient foam and 4% chlorhexidine gluconate skin cleanser. Participants will be instructed to conduct skin wash using the appropriate solution in the shower over the operative shoulder and axilla for three mornings prior to surgery (pre op day -2, pre op day -1, and morning of surgery). Specific instructions will include leaving the solution on the skin for three minutes and avoiding contact with eyes, ears, and mouth. Proper technique will be demonstrated at time of patient recruitment and given as a handout with the wash solution provided. A reminder phone call will occur two days before surgery to remind patients of proper procedure to improve compliance. On the day of surgery, patients be interviewed about pre-operative compliance.

On the day of surgery, two cultures will be taken in three separate sites on both shoulders (anterior, lateral, and posterior) using a detergent scrub technique, the current dermatologic standard for biopsy of the deep sebaceous glands. (3,11) This procedure is typically performed on the skin of awake patients and causes minimal pain and skin irritation. Cultures will be evaluated in our lab. We will also test for hemolysis as a possible indicator of a more virulent strain in the literature.

The research team may take photos of the shoulder skin being swabbed. Photos will not include the facial or defining characteristics. Photos may be taken either in the clinic at time of recruitment or in the operating room when samples are being taken.

Inclusion criteria: all patients undergoing open shoulder surgery or shoulder arthroscopy. Exclusion criteria: anyone with a history of allergic reaction to chlorhexidine or benzoyl peroxide. Anyone with a history of previous shoulder infection, current open skin lesions around the shoulder or the use of current anti-acne medications around the shoulder.

Healthy volunteer portion: Healthy volunteers will respond to the study from fliers on campus. A cotton swab test on both shoulders will be performed prior to any treatment. If a threshold of P. Acnes is met (>1000 CFUs) then volunteers will be randomized to the same two groups and retested after three days of unilateral treatment. Finally, volunteers will undergo repeat cotton swab testing one week after 3 day wash was finalized.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:
We have no preliminary data at this institution. Current P. Acnes shoulder burden is estimated to be 36% based on recent literature with a periprosthetic infection rate is at least 1-2% with this number expected to increase as more shoulder surgery is expected with the aging population. Economic impact after a shoulder surgical infection is tremendous with additional estimated hospital costs of over $17,000 per infection not including the impact from wages lost (12).

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:
P.acnes is a gram-positive anaerobic bacillus that resides nonpathogenically in the sebaceous glands associated with hair follicles. P.acnes frequently becomes a pathogenic causing infection after arthroscopic and open shoulder procedures. Untreated infections of this nature present with shoulder pain, glenohumeral arthrosis, and arthroplasty failure months or years after a procedure(1). P.acnes forms a biofilm on implant surfaces; cultures taken at the time of surgical revision of failed shoulder arthroplasties are commonly positive for the bacteria(2).

The epidermal skin surface and dermal sebaceous glands are thought to be the source of P.acnes, harboring as many as 105 organisms per follicle(3). P.acnes from these sites are not completely eliminated by standard presurgical skin surface preparations, most likely because bacteria in the dermis cannot be reached by topical surgical preparations (2,3). Surgical incisions transect these area allowing P.acnes to enter the surgical wounds(3) Additionally, preoperative intravenous antimicrobial prophylaxis with traditional skin preparation has not been shown to successfully eliminate P.acnes from the surgical field(2). Thus, while there is evidence to explain the pathogenesis of P.acnes infections in this patient population, there are no effective ways to prevent related post-operative complications.

Conversely, P.acnes that cause facial and truncal inflammatory acne vulgaris have been successfully reduced using short contact benzoyl peroxide (BPO) solutions (4,5,6). BPO is an effective alternative to antibiotics against which P.acnes become more resistant(6). 5.3% BPO emollient foam significantly reduced P.acnes counts on the back by 1.9 log in one week and 2.1 log in two weeks with reduced baseline after discontinued use(7). 5% BPO solutions are maximally effective without negative side effects such as irritation and clothing bleaching observed with higher concentrations(4). Because BPO enhances follicular penetration, it is clinically effective at reducing counts in both the epidermis and dermis(5). Furthermore, BPO has been shown to have potentially beneficial effects on wound healing(8,9,10). 5% BPO washes used before shoulder arthroscopy or open shoulder procedures pose a potential method of reducing P.acnes and minimizing risk of delayed complications from periprosthetic infection.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***
1. Paul M. Sethi, James R. Sabetta, Samantha J. Stuek, Storm V. Horine, Katherine B. Vadasdi, R. Timothy Greene, James G. Cunningham, Seth R. Miller, Presence of Propionibacterium acnes in primary shoulder arthroscopy: results of aspiration and tissue cultures. Journal of Shoulder and Elbow Surgery. Available online 4 December 2014, ISSN 1058-2746, http://dx.doi.org/10.1016/j.jse.2014.09.042.

2. Frederick A. Matsen III, Stacy M. Russ, Alexander Bertelsen, Susan Butler-Wu, Paul S. Pottinger, Propionibacterium can be isolated from deep cultures obtained at primary arthroplasty despite intravenous antimicrobial prophylaxis. Journal of Shoulder and Elbow Surger. Available online 26 December 2014, ISSN 1058-2746, http://dx.doi.org/10.1016/j.jse.2014.10.016.

3. Matsen, F. A., Butler-Wu, S., Carofino, B. C., Jette, J. L., Bertelsen, A., & Bumgarner, R. (2013). Origin of propionibacterium in surgical wounds and evidence-based approach for culturing propionibacterium from surgical sites.The Journal of Bone & Joint Surgery, 95(23), e181.

4. Mills, O. H., Kligman, A. M., Pochi, P., & Comite, H. (1986). Comparing 2.5%, 5%, and 10% benzoyl peroxide on inflammatory acne vulgaris. International journal of dermatology, 25(10), 664-667.

5. Bikowski, J. (2010). A review of the safety and efficacy of benzoyl peroxide (5.3%) emollient foam in the management of truncal acne vulgaris. The Journal of clinical and aesthetic dermatology, 3(11), 26.

6. Brandstetter, A. J., & Maibach, H. I. (2011). Topical dose justification: benzoyl peroxide concentrations. Journal of Dermatological Treatment, 24(4), 275-277.

7. Leyden, J. J. (2010). Efficacy of benzoyl peroxide (5.3%) emollient foam and benzoyl peroxide (8%) wash in reducing Propionibacterium acnes on the back.Journal of drugs in dermatology: JDD, 9(6), 622-625.

8. Alvarez, O. M., Mertz, P. M., & Eaglstein, W. H. (1983). Benzoyl peroxide and epidermal wound healing. Archives of dermatology, 119(3), 222-225.

9. Colman, G. J., & Roenigk, H. H. (1978). The healing of wounds in the skin of piglets treated with benzoyl peroxide. The Journal of dermatologic surgery and oncology, 4(9), 705-707.

10. Watcher, M. A., & Wheeland, R. G. (1989). The Role of Topical Agents in the Healing of Full-Thickness Wounds. The Journal of dermatologic surgery and oncology, 15(11), 1188-1195.

11. Wang, C. Y., & Maibach, H. I. (2011). Why minimally invasive skin sampling techniques? A bright scientific future. Cutaneous and ocular toxicology, 30(1), 1-6.

12. Padegimas EM, Maltenfort M, Ramsey ML, Williams GR, Parvizi J, Namdari S. Periprosthetic shoulder infection in the United States: incidence and economic burden. J Shoulder Elbow Surg. 2015 Jan 13.

2 If available, upload your applicable literature search:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:
Patients will be indicated for shoulder surgery based on the current standard of care. Once eligibility has been confirmed, the informed consent process will be completed by the Coordinator and the attending surgeon. Consent will be obtained in accordance with principles of GCP and ICH guidelines. Copies of the signed consent forms will be given to the patient, and will be placed in the patient's record.

Healthy volunteers will also be recruited via fliers with the same eligibility criteria other than indication for shoulder surgery. Consent will be obtained in accordance with principles of GCP and ICH guidelines. Copies of the signed consent forms will be given to the patient, and will be placed in the patient's record.

Following completion of informed consent, the patient will be randomized to either the chlorhexidine or benzoyl peroxide group. Patients and their families will be provided with a pamphlet describing the study and the consent form which describes the purpose of the study, the procedures to be followed, the risks and benefits of participation, and what will be expected of them if they choose to participate.

Assessing Capacity to Consent and Consenting a Proxy Respondent

The patient him or herself (as opposed to a proxy) should be consented. The research staff will endeavor to answer all questions posed by the patient and his/her family to ensure their understanding of the protocol. A limited number of questions will be asked of all patients after they are introduced to the study and have reviewed the consent form. These questions assess the person's understanding of the study and what it means to participate, their appreciation of the consequences of participation, and their ability to consider alternatives to participation. The Research Coordinator will ask the questions and determine the appropriateness of the responses. If the Research Coordinator is at all unsure about the patient's ability to consent s/he will consult with the study site PI. If a patient is unable to consent, then he/she will be excluded from the study.

Recognizing that consent is an ongoing process, the study team will encourage the participants to ask additional questions that may arise during the course of their participation in the study.

The only thing different than standard treatment/surgery is the additional skin prep three days prior to surgery. Chlorhexidine scrub is standard for hip and knee replacements but we believe have limited effect on P. Acnes. Benzoyl Peroxide may treat this better.
Anesthesia and antibiotic prophylaxis are standardized. Intraoperative skin prep is standardized as well. We will perform a standard dermatologic detergent scrub technique on both shoulders as a correlate of the P. Acnes burden in the sebaceous glands just prior to intraoperative skin prep. This technique is analagous to using a cotton skin swab.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
Patients will receive standard of care for all diagnostic or treatment purposes. They will be indicated for shoulder surgery a is the usual protocol. All procedures in the operating room with be under usual protocol including skin prep, sterile procedure as well as a usual post operative protocol and follow up. Patients will be followed to document infection, as would be standard of care as well. Monitoring will be at 2 weeks, 6 weeks, 3 and 6 months as well as 12 months which are standard visits after shoulder surgery and based on the standard protocol of asking the patient about their symptoms. No additional testing will be performed. Patient demographics will be reviewed from the chart.

3 * Describe the duration of an individual participant's participation in the study:
Patients will be monitored for the standard signs of infection for one year after shoulder surgery.

Healthy Volunteers will participate for about 12 days.

4 * Describe the amount of time it will take to complete the entire study:
24 months total. 6 month enrollment period. 12 month follow up. 6 month data analysis and manuscript preparation.

5 * Describe any additional participant requirements:
N/A

ID: VIEW4E0280585B400
Name: v2_Study Procedures

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:
Power analysis. In primary shoulder surgeries, the overall incidence of P. Acnes is 36% in a recent series. We expect a 2/3 decrease in intraoperative incidence. Ninety eight patients are necessary, a 20% attrition rate is expected so a goal of 160 people to be recruited total and about 1/4 to be healthy volunteers.

See below from Stata/SE 13.0 for Mac (64-bit Intel), Revision 17 Jun 2013

power twoproportions 0.36 0.12, test(chi2)
Performing iteration …
Estimated sample sizes for a two-sample proportions test
Pearson's chi-squared test
Ho: p2 = p1 versus Ha: p2 != p1

Study parameters:

alpha = 0.0500
power = 0.8000
delta = -0.2400 (difference)
p1 = 0.3600
p2 = 0.1200

Estimated sample sizes: N = 98
N per group = 49

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:
Patient will be asked how many times they actually used the skin prep. We will utilize both intention-to-treat and as-treated analyses. We will employ a linear regression based on level of compliance (1 day, 2 day etc.). Paired t-test will be used as a comparison of mean CFUs to the contralateral side (negative control) and the primary outcome will be based on an aggregate chi-square comparison of proportions between chlorohexidine and benzoyl peroxide groups.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:
The results of specific tests and the overall study will not be shared with participants. The results will not affect the standard of care for each patient.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Research with Drugs or Biologics

You indicated on the "Type of Research" page that your study involves use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol AND/OR evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.

1 * List all drugs/biologics to be administered in this study. Be sure to list each drug/biologic with its generic name only.

	Drug Name	FDA Approved	IND Number	PI IND Holder
View	Benzoyl Peroxide	yes		no
View	Chlorhexidine	yes		no

2 * Attach the drug package insert or investigational drug brochure for the drugs being administered in this study:

5% BPO Label.jpg	8/26/2015 10:51 AM	8/26/2015 10:51 AM
Chlorhex 4%.png	3/30/2015 9:48 PM	6/17/2015 10:30 AM

3 If more than one drug is administered, discuss the risk implications of drug/therapy interactions:
Drugs will not be administered simultaneously

4 * Will you be using Investigational Drug Services?
○ Yes ● **No**

ID: VIEW4E0916E6E1400
Name: v2_Research with Drugs or Biologics

Drug or Biologic Storage and Handling

4.1 * Do you have a plan regarding access controls for essential and approproate research personnel?
○ Yes ● **No**

4.2 * Will you have procedures for verifying physical access to the drugs(s)?
○ Yes ● **No**

4.3 * Will you label the drug(s) so that it is (they are) used appropriately for the study?
● **Yes** ○ No

4.4

* Will there be an establishment of a drug transfer process both into and out of the research site?
○ Yes ● **No**

4.5 * Will the storage of the drug(s) be in a secure environment and include locks on doors and controlled access?
○ Yes ● **No**

4.6 * Do you have a plan for only allowing trained personnel to administer the drug(s)?
○ Yes ● **No**

4.7 If applicable, will the storage of the drug(s) be at the appropriate temperature, with a storage and temperature log?
○ Yes ○ No

ID: VIEW4E1D85CC57C00
Name: v2_Drug or Biologic Storage and Handling

Placebos

1 * Is this study placebo controlled?
○ Yes ● **No**

ID: VIEW4E0514EECCC00
Name: v2_Placebos

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:
Audio or video recording/photographing

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

Audio or Video Recording/Photographs

You indicated that this study involves audio or video recording/photographing.

1 * Indicate the type of recording (check all that apply):
Still Photo

1.1 If Other, specify:

2 * What is the purpose of the recording? (i.e., for therapeutic purposes, to establish treatment fidelity, or to establish reliability of assessments)
The purpose of the photos is to document and characterize the areas being evaluated by the research protocol. Additionally, they will help establish the reliability of assessments.

3 * Could the recording be likely to cause discomfort in participants or cause harm if their confidentiality were breached?
○ Yes ● **No**

4 * How will individuals' identities be protected?
Photos will only include skin area being study without any facial or identifiable characteristics.

ID: VIEW4E094C128C800
Name: v2_Audio or Video Recording / Photographs

Sample Collection/Analysis

You indicated on the "Type of Research" page that your study involves a sample (specimen) collection and/or analysis.

1 * What type of samples will be involved in this study? (Check all that apply)
Prospective (will be collected)

2 * Will genetic analysis/testing be done on any of the samples?
○ Yes ● **No**

3 * Will this study involve banking of samples (storing for future research use)?
○ Yes ● **No**

4 * What is the purpose of the sample collection and/or analysis?
To identify P. Acnes burden

5 * Is there the possibility that cell lines will be developed with any of the samples?
○ Yes ● **No**

6 * Will the samples be released to anyone not listed as an investigator on the protocol?
○ Yes ● **No**

6.1 If Yes, give name(s) and affiliation(s):

7 * Will the sample material be sold or given to any third parties?
○ Yes ● **No**

7.1 If Yes, give name(s) and address(es):

ID: VIEW4E0E1A4B80000
Name: v2_Sample Collection/Analysis

Prospective Samples

You indicated that the study involves collection of prospective samples (specimens).

1 * What type of sample will be collected? (Check all that apply)
Other

1.1 If Other, specify:
Skin follicles sampling from a skin swab

2 For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subject's entire participation time:

3 * What type of samples will be collected? (Check all that apply)
Samples obtained specifically for research purposes-obtained via a separate collection procedure done solely for the purposes of the study

3.1 If Other, specify:

4 * How are these samples labeled? For example, do they contain name, initials, dates, Social Security number, medical record number, or other unique code?
Labeled with unique patient identifier established at time of enrollment

5 * Will sample(s) be made available to the research subject (or his/her medical doctor) for other testing?
○ Yes ● **No**

6 * If a participant withdraws from the study, will that participant have the option to get the remaining portion of their sample(s) back?
○ Yes ● **No**

7 * If the participant withdraws, explain how their sample(s) will be handled (For example, will sample(s) be destroyed, anonymized, etc.):
Samples will be destroyed.

8 * Will the samples be destroyed after the study is over?
● **Yes** ○ No

8.1 If No, describe how the samples will be stored, where they will be stored, and for how long.

ID: VIEW4E0E257D60C00
Name: v2_Prospective Samples

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)
Prospective (data is not yet in existence and/or collected)

2

* Will this study involve adding data to a registry or database for future use?
○ Yes ● **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?
○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)
Medical records

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.
Name
Date of Birth
Gender
Race/Ethnicity

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0E25B643800
Name: v2_Prospective Data

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?
○ Yes ● **No**

2 * Has this trial been registered?
● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
● **Yes** ○ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
○ Yes ○ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:
To prevent future publishing issues

3 * Registration Number
NCT02510144

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
200

2

* How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
160

Worldwide - the number being enrolled total at all sites (including local enrollment):
160

3 * Gender:
Male
Female

4 * Age(s):
18 years and older (Adult)

5 * Race/Ethnicity:
All Races Included

6 * Language(s):
English

6.1 Specify Other:

7 * Are you excluding a specific population, sub-group, or class?
○ Yes ● **No**

7.1 If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)
Employees or Lab Personnel
Students

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

Vulnerable Populations - Employees or Lab Personnel

You indicated that employees or lab personnel are included in this study.

1 * Describe how you will ensure participtionin this research will not affect employment and prevent undue influence:
Employees may voluntarily elect to participate in the research based on response to the flier. Employees will not be coerced into participating. There is no risk or benefit for an employee to voluntarily participate in the study.

ID: VIEW4E0E5192BA800
Name: v2_Vulnerable Populations - Employees or Lab Personnel

Vulnerable Populations - Students

You indicated that students are included in this study.

1 * Describe the types of students that are included in this study:
Any student on campus may volunteer for the study.

2 * Describe how you will prevent undue influence.
There is no pressure for any student to be recruited for the study.

ID: VIEW4E0E519F32000
Name: v2_Vulnerable Populations - Students

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?
○ Yes ● **No**

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
There are no items to display		

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Age >18
View	2	Patient is indicated for shoulder surgery OR
View	3	Healthy Volunteer

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Patient has history of previous shoulder infection
View	2	Patient has history of allergy to chlorhexidine or benzoyl peroxide
View	3	Patient is currently using other anti-acne medication around the shoulder
View	4	Patient is pregnant, concerned about pregnancy, or lactating (this is part of the usual preoperative blood work)
View	5	Participants will be asked directly about previous topical skin cleanser usage, and asked if there is a history of allergies to either chlorhexidine or benzyl peroxide. If the participant is not a healthy volunteer, their medical records will be screened specifically for allergies to these medications. This procedure is in accordance with current dermatology allergy screening guidelines for both chlorhexidine and benzoyl peroxide.

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00064296_4 v1-29-2017-1485704393178(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
Patients will be approached for recruitment only after indicated for shoulder surgery in the office.

Volunteers will respond to fliers on campus.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):
Potential participants will be approached by both their treating physician and the research coordinator so that any potential clinical care questions can be answered by their treating surgeon. Patients will be reminded that study participation is voluntary, and that the decision to participate or not will not alter the care they receive in any way.

Healthy members of the population will enroll strictly on a volunteer basis.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)
PI
Study Staff

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

Advertising

1 * Will you be using advertisements to recruit potential participants?
● **Yes** ○ No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):
Print

1.1.1 If Other, specify:

1.2 * Provide exact text of all proposed advertisement(s):
Shoulder infection and bacteria study.

OVERVIEW:
The shoulder infection and bacteria study is volunteer study where participants are asked to undergo a skin swab to review the level of P Acnes bacteria on skin around the shoulder. If a threshold of P Acnes is met, then participants will be randomized to try one of two antibacterial wash to assess reduction in this common bacteria. Participation is for less than two weeks and will require up to three 5-minute swab tests.

KEY ELIGIBILITY CRITERIA:
• Over 18 years of age, any gender or race

FREQUENTLY ASKED QUESTIONS:
• What is the cost of study participation to me?
Answer: None.

• Are there any risks?
Answer: There is a small risk of allergy to chlorhexidine or benzyol peroxide

• Do I receive any compensation?
Answer: None

• Who is providing grant funding for the study?
Answer: The Orthopaedic department at the University of Maryland School of Medicine.

PARTICIPATE IN THE STUDY:
If you would like to participate in the shoulder infection and bacteria study, please contact us and leave a message at 410-706-2464. A research team member will contact you via phone with more information.
KEY STUDY TEAM MEMBERS:
Principal Investigator: Dr. Mohit Gilotra, University of Maryland Orthopaedics Associates
Co-Investigator: Dr. S. Ashfaq Hasan, University of Maryland Orthopaedics Associates
Co-Investigator: Dr. R. Frank Henn III, University of Maryland Orthopaedics Associates
Project Coordinators: Logan Kolakowski BS, University of Maryland School of Medicine and Grant Duvall BS, University of Maryland School of Medicine

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Shoulder infection and bacteria study advertisement.docx	1/5/2017 1:40 PM	1/5/2017 1:40 PM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:
There is a risk of skin reaction with any skin prep that is used in the operating room or preoperatively. Patients are screened for any allergic reaction prior to eligibility. If any skin reaction is to occur, although the risk is low, a participant should call the research team immediately to provide appropriate dermatologic care. Avoid prolonged exposure of treated areas to sun, sunlamps, or tanning booths as skin may be more sensitive after use of benzoyl peroxide or chlorhexidine.

Any time information is collected for a study there is a small risk of breach of confidentiality. However, this risk is not greater than the risk that already exists in clinical settings when handling medical data.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
The benefit for patients would be the potential for a decrease in surgical site infection. Volunteers will have no potential benefit.

2 * Describe the importance of the knowledge expected to result from the study:
The knowledge from results of this study may change the standard of care in how we prepare patients for shoulder surgery.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
The risks of using OTC safe topical skin preps are low to the individual patient. Risks of a breach of confidentiality are also low. The overall benefit of reducing surgical site infection would be in the reduction of healthcare costs and a quicker recovery for patients. The potential benefits exceed the risks.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of

treatment available to subjects.
Participation is voluntary and the alternative is to not participate.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
A participant may be withdrawn from the study without consent if the PI decides to end the study. Other reasons for removing a participant without consent may include but are not limited to non-adherence with the protocol and/or therapy, and inappropriate behavior towards study personnel.

2 * Describe procedures for orderly termination:
N/A

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
Should a participant terminate the study prematurely, if at all possible, all evaluation at 12 month visit will be finalized at his/her final visit.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
It is the investigator's responsibility to conduct the protocol under the current version of Declaration of Helsinki, ICH Guidelines, Good Clinical Practice, and rules of local IRBs. The investigator must ensure that the patient's anonymity be maintained in their data submission to the Data Coordinating Center.

Patients will be identified only by an identification code but not by their name, SSN, or hospital medical record number. Study Site Investigators will maintain a separate confidential enrollment log which matches identifying codes with the patients' names and addresses available only to local clinic staff.

All study forms, reports, and other records that are part of the study data collection materials will be identified by coded number to maintain patient confidentiality. All paper records will be kept in locked file cabinets. All electronic records of study data will be identified by coded number. Clinical information will not be released without written permission of the patient, except as necessary for monitoring by the IRB. Consent procedures and forms, and the communication, transmission and storage of patient data will comply with individual site IRB for compliance with The Health Insurance Portability and Accountability Act (HIPAA).

Regarding privacy, patients will not be contacted for further information or asked to revisit the medical center for any repeat visits. No further information will be further relayed other than the time of consent. Confidentiality and protection of patient information as stated above is an extension of the patient's privacy.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
Potential participants will receive information in private clinic rooms or private clinical/hospital areas with a curtain drawn for additional privacy.

3 * Describe potential environmental stressors that may be associated with the research:
There are no environmental stressors associated with the research.

4 * Will this study have a site based in the European Union?
○ Yes ○ No

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?
○ Yes ○ No

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?
Yes

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)
All study records will be identified by coded number to maintain patient confidentiality. All electronic records will be identified by coded participant numbers, and will be password protected. Clinical information will not be released without written permission from the patient, except as needed for monitoring by the IRB. Data will be in stored in a locked office in the Allied Health Building at the University of Maryland Medical Center. Only the study team will have access to this information.

3 * How will such data be secured?
All data will be password protected and/or locked in an office to which there is limited access. Data will be in stored in a locked office in the Allied Health Building at the University of Maryland Medical Center. Only the study team will have access to this information.

4 * Who will have access to research data?
Identifiable data will be accessible to the investigator and study team at the site.

5 * Will study data or test results be recorded in the participant's medical records?
○ Yes ● **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research and VA research cannot be deleted)***
● **Yes** ○ No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?
Study records will be maintained in accordance with current ICH guidelines. Data will be maintained for five years following the end of research-related activities. At the end of this period, each site will provide the Coordinating Center a signed verification that these data have been destroyed.

7 Do you plan to obtain a Certificate of Confidentiality?
○ Yes ● **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:
N/A

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:
Data Safety Monitoring by an Individual

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

Monitoring Plan - Individual

You indicated that the monitoring will be done by an Individual.

1 * Identify the individual who will be performing the safety monitoring:
Eugene Koh MD

2 * Describe this individual's role in relation to the protocol:
Dr. Koh has no role in relation to the protocol. He will review data every 30 patients to ensure safety profile and compliance.

3 * What data will be reviewed?
Adverse Events
Raw Data
Outcomes (Primary, Secondary)

3.1 If Other, specify:

4 * What will be the frequency of the review?
Other

4.1 If Other, specify:
Every 30 patients

5 * Safety monitoring results will be reported to:
IRB

5.1 If Other, specify:

ID: VIEW4E1B026A2A400
Name: v2_Monitoring Plan - Individual

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?
Yes

1.1 If Yes, check all that apply:
Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)
Investigational or Study Drug

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?
There will be no uncovered research-related costs

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?
○ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?
○ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?
○ Yes ● **No**

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HIPAA (Health Insurance Portability and Accountability Act)

1 * HIPAA applies to the University of Maryland School of Medicine, the University of Maryland School of Dentistry and the VA. Are you affiliated with, or will be accessing data from, any of these places? ● **Yes** ○ No

2 If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA? ● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)
Name
Dates
Telephone numbers

2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
Once consented into the study, baseline data regarding age, gender, ethnicity and previous allergies will be collected as necessary background data for the study.

3 * What is the source(s) of the PHI?
Medical Records

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
This PHI collected for this study will not be reused on any other studies.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)
Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")*
Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
All data will be kept private, and any information that could identify a particular individual will be removed from all study forms. All study forms will be labeled with a unique study number. The link between each name and study number will be kept confidential to the greatest extent provided by law. The information collected for the study will be stored in a password protected, HIPAA verified computer database that only authorized members of our research team can use. All study records will be considered confidential, and names will not be used in reports or publications.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
All study information and materials will be stored in password protected, HIPAA verified databases that only reseach team members can access. All paper documents will be kept in a secure, locked location.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
Any PHI that is no longer needed will be shredded.

4 * Why could the research not practicably be done without access to and use of this PHI?
The only way to determine eligibility is to view patient allergies.

5 * Why could the research not practicably be done without the waiver or alteration?
We need to be able to determine which patients are eligible before approaching them for consent and enrollment in the study. The only way to determine eligibility is to view their allergies. It would not be practical to conduct this study without first determining their eligibility.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
○ Yes ● **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)
Written Consent Form

2 * Describe the Informed Consent process in detail:
A consent has been prepared for the P. Acnes study and is uploaded. Individual sites may add material but may not delete material thought to be necessary for informed consent. Clinical sites may reformat and reword information to conform to their local requirements. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. Copies of the signed consent forms will be given to the patient, and this fact will be documented in the patient's record.

Once eligibility has been confirmed, the informed consent process will be completed by the Research Coordinator and the attending surgeon. Patients will be approached about potential participation in the study as soon as is feasible following determination of eligibility.

Participants will be approached and given the opportunity to enroll after surgery has been indicated. Patients often will have time to discuss the study with others prior to making a final decision to participate. Patients and their families will be provided with a pamphlet describing the study, the risks and benefits of participation and what will be expected of them if they choose to participate. Consent will be obtained in accordance with principles of GCP and ICH guidelines.

All study materials will be provided in English.

The patient him or herself (as opposed to a proxy) should be consented.

The research staff will endeavor to answer all questions posed by the patient and his/her family to ensure their understanding of the protocol. A limited number of questions will be asked of all patients after they are introduced to the study and have reviewed the consent form. These questions assess the person's understanding of the study and what it means to participate, their appreciation of the consequences of participation, and their ability to consider alternatives to participation. If the Research Coordinator is at all unsure about the patient's ability to consent s/he will consult with the study site PI. No LARs will be used, if a patient cannot consent then they will be excluded from the study.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

● **Yes** ○ No

4 * Describe who will obtain Informed Consent:
Attending surgeon and co-ordinator

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A

6 * Describe the setting for consent:
Private office clinic with door closed or in private lab setting for volunteers

7 * Describe the provisions for assessing participant understanding:
The patient him or herself (as opposed to a proxy) should be consented.The research staff will endeavor to answer all questions posed by the patient and his/her family to ensure their understanding of the protocol. A limited number of questions will be asked of all patients after they are introduced to the study and have reviewed the consent form. These questions assess the person's understanding of the study and what it means to participate, their appreciation of the consequences of participation, and their ability to consider alternatives to participation.

The Research Coordinator will ask the questions and determine the appropriateness of the responses. If the Research Coordinator is at all unsure about the patient's ability to consent s/he will consult with the study site PI. If the patient cannot consent, then they will be excluded from the study.

8 * Describe the consideration for ongoing consent:
Recognizing that consent is an ongoing process, the study team will encourage the participants to ask additional questions that may arise during the course of their participation in the study.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
RESEARCH CONSENT FORM Healthy volunteer updated 2-21.docx	1/5/2017 3:28 PM	2/22/2017 3:59 PM
RESEARCH CONSENT FORM Modification 11.3.docx	11/3/2015 9:55 AM	1/29/2017 10:55 AM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date

There are no items to display

2 Upload any HIPAA authorization forms here:

HIPAA Form.docx	3/30/2015 11:50 PM	3/30/2015 11:50 PM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates:
http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Orthopedics

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ● **Yes** ○ No
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● **No**

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● **No**

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

Institutional Biosafety Committee Review Required

1 **NOTE**: based on your answers to questions on a previous page (see below) review by the Institutional Biosafety Committee (IBC) is required. This will involve extra steps on your (study team) part. Clicking the Continue button will result in the system creating a blank IBC Submission form for you. You will be required to fill out and submit this IBC form before you will be able to submit the Protocol form. The IBC Submission workspace and form can be reached by clicking the appropriate button on the left hand side of the Protocol submission's workspace (web page) after exiting the Protocol form.

2 **Question** - answered on IBC RSC review requirements page:

Yes

3.1 Does the research involve human gene transfer? - OR - Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.
3.2 Does the research involve: a) the exposure of human subjects to pathogenic microorganisms, or b) the potential exposure of UMB research staff to infectious materials through the sampling or processing of materials from patients with known infectious disease or from environmental surfaces?
3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

If the answer to this question is wrong, an IBC submission is not required, use the Jump To menu or your browser's <

3 * **Confirm** - you have read the above information and understand that in addition to the IRB Protocol form, you will fill out and submit the IBC Submission form :

● **Yes** ○ No

ID: VIEW4E1AF91ED4C00
Name: v2_Institutional Biosafety Committee Review Required

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission		
IBC Submission: Skin Prep P. Acnes	Workspace	SmartForm

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Orthopedics	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

Additional Documents

1 Upload all additional documents here:

Name	Created	Modified Date
Evaluation to Sign Consent.docx	6/15/2015 9:35 AM	6/17/2015 10:15 AM
Benzoyl Peroxide Instructions Final.docx	6/11/2015 3:58 PM	6/11/2015 3:58 PM
Chlorhexidine Instructions Final.docx	6/11/2015 3:58 PM	6/11/2015 3:58 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Orthopedics	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission		
IBC Submission: Skin Prep P. Acnes	Workspace	SmartForm

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
Samir Kaveeshwar

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a financial interest related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Has been brought up to speed regarding project and sites.

Add a Team Member

1 * Select Team Member:
Ashley Klein

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a financial interest related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Ashley is a student at UMSOM with research experience on campus.

Add a Team Member

1 * Select Team Member:
Katrina Williams

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a financial interest related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Katrina is experience conducting research through multiple departments on campus.

Add a Team Member

1 * Select Team Member:
Grant Duvall

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a financial interest related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Grant is a medical student at UMSOM and will be assisting with data analysis.

Add a Team Member

1 * Select Team Member:
Ralph Henn

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a financial interest related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Henn is UMB faculty with extensive experience in clinical research

Add a Team Member

1 * Select Team Member:
Syed Hasan

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a financial interest related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Hasan is an associate professor of orthopaedics with extensive experience in clinical research.