Patient Preferences of Hand Sanitizers

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Acknowledgements

I want to recognize those people who helped me finish this outstanding project. From a professional standpoint I want to first acknowledge my advisor Timothy Landers who assisted me from the beginning of this project. He motivated me to push myself and go past my comfort level. I would also like to thank Abrea Johnson who assisted greatly in IRB approval of this project. Finally, I would also like to recognize The Pressey Honors Endowment Fund presented by The Ohio State University Honors and Scholars Department that helped fund the research within this project. Personal acknowledgements include my classmates within the nursing program and of course my family who make me strive for greatness in everything that I do.
Abstract

Hand washing and the use of alcohol-based hand rubs are recognized as the best ways to prevent infection. While prior work has emphasized the role of hand hygiene for healthcare workers, there is increasing evidence that patients may also be important in transmitting infection. However, no prior studies have considered patient preferences for these products and patients may have different perspectives on features of these products that make them acceptable for use. The goal of this study was to evaluate hospitalized patients’ preferences for hand sanitizers.

A tool was developed to assess important characteristics of hand sanitizers from the perspective of the patient.

Twenty patients compared two hand sanitizers each using a standardized survey and rated product characteristics. After rating two hand sanitizers, patients were asked to select a product to keep at the bedside to determine final preference. Patients ranged in age from 27 years old to 77 years old (mean 51.1, SD 16.8). Eleven males (55%) and 9 (45%) females participated. The majority (70%) of patients worked at least part time and 5% had at least some college education. Seven (35%) patients preferred gel products and 13 (65%) patients preferred foam hand sanitizers. For the patients under the age of 50, 80% preferred foam compared to 20% who preferred the gel. In contrast, in patients over age 50, 50% preferred the foam over the gel.

The presence of rashes, hobbies, work related activities, occupation, gender, and presence of a skin condition were not related to preference.

Ease of use and application of the product were significantly different between foams and gels. The mean ease of use rating for gel was 4.50 compared to 4.96 for foam (p-value=0.04). Gels were rated lower in application compared to foam (4.21 vs. 4.85; p=0.005). Demographic variables were not
associated with patient preferences in hand sanitizers, however ease of use and application influenced patient product ratings.

We have demonstrated the usefulness of a modified version of the World Health Organization’s method of evaluating hand hygiene product preference in patients. Further work should use a larger sample size in order to determine which products patients prefer and test a broader range of products.
Background

Hand hygiene is widely recognized as one of the most important measures in the prevention of infection. Health care associated infections are a major cause of death and disability. Hand hygiene is the best way to prevent the spread of pathogens and to reduce infections (Allegranzi, Sax, & Pittet, 2013; Benedetta Allegranzi et al., 2013). New technologies and products are able to kill germs more efficiently then cleaning with soap and water with many options for hand sanitizer products (Boyce, 2013; Ellingson et al., 2014; CDCRiskInstrument).

The use of alcohol based hand rubs is preferred over hand washing as it is simple, effective, and well tolerated. In 2002 and 2009, The World Health Organization and U.S. Center for Disease Control provided guidelines for hand hygiene and measured the effectiveness of these hand sanitizers(World Health Organization 2009; Center of Disease Control 2002). In most situations, it is thought that the quickest and most effective way to kill germs and reduce infections is through the use of hand sanitizers.

The Food and Drug Administration considers hand sanitizers and their many forms (gels, liquids, foams, wipes) to be over the counter drugs. To meet the criteria for being over the counter drugs there are many different kinds of standards and a hand sanitizer must be considered “generally recognized as safe and effective” (GRASE) to meet the requirements of the Food and Drug Administration. This is much different than cosmetics which are not considered by The Food and Drug Administration. Cosmetics are required to be “safe” through lab testing but no claims are made to the effectiveness at reducing bacteria.(Kendall, Landers, Kirk, Young 2012)
Hand sanitizer formulations include active and inactive ingredients. Inactive ingredients may include items like water and polyacrylic acid which is a thickening agent that gives gel hand sanitizers its structure (Boyce J.M., 2013). Many hand sanitizers utilize inactive ingredients to add a fragrance or color to the sanitizer.

The Food and Drug Administration only recognizes two active ingredients that are GRASE – alcohol and providine-iodine (Centers Disease Control and Prevention, 2002). Providine-iodine is not commonly used and alcohol formulations have been widely adopted (WHO, 2009).

In contrast to formulation, the form includes gels, foams, liquids and wipes. Individuals may prefer one form over the other. Different forms of hand sanitizers are shown in Table 1.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid</td>
<td>Water-like sanitizer that can be put in to a spray</td>
<td>Rapid dispersal across surfaces, can present concern about dripping</td>
</tr>
<tr>
<td>Gel</td>
<td>Jelly-like colloid dispersed in a semi-solid form</td>
<td>Commonly used, well tolerated, can leave “stickiness” on the hands</td>
</tr>
<tr>
<td>Foam</td>
<td>A mass of small bubbles formed from the infusion of air in to solution</td>
<td>Created during manual activation of a dispenser or air pressurized canister</td>
</tr>
<tr>
<td>Wipe</td>
<td>Small cloth or fabric soaked in antimicrobial solution</td>
<td>Effective at removing dirt and foreign material from the hands</td>
</tr>
</tbody>
</table>

Table 1. Hand Sanitizer Forms.

Both the formulation and form that yield the best effectiveness or result for the user. Thus, it is both the formulation and form that yield the best overall effectiveness.
Two products were selected by the researchers for a head to head comparison. Because of their wide adoption, availability and brand recognition this project evaluated the use of alcohol based hand rub gel compared to a foam. In this study, Purell Gel (PURELL® Advanced Instant Hand Sanitizer, 3659-12, GOJO Industries, Akron OH) and Purell Foam (PURELL® Advanced Instant Hand Sanitizer Foam, 5792-04, GOJO Industries, Akron OH) were used along with Avaguard Foam (AVAGARD™ FOAM, 38-9019-2712-9, 3M Healthcare, Saint Paul MN).

Research on the various forms and formulations has primarily been done on health care workers but there has been increased attention in the role of patient’s own hands in acquiring infections (Aiello E., 2002; Larson, 1995; Welsh, Flanagan, Hoke, Doebbeling, & Herwaldt, 2012). In contrast to health care workers, patients may require use of hand sanitizer less frequently; thus the ideal formulation and form may be different for patients compared to health care workers.
Literature Review

Research has shown that transmission of pathogens in healthcare settings are spread mainly through the hands. While many studies have shown that hand hygiene is the single most important factor in prevention of infection, compliance with hand hygiene remains low. The reasons for poor hand hygiene compliance are complex (Boyce, 2013 Ellingson 2014). These factors include preferences, underlying attitudes, prior education, knowledge and the availability of products (Kirk, Landers, Young 2012).

Many hand hygiene improvement programs have focused on healthcare worker compliance. However, emerging evidence suggests that patients’ hands harbor important disease-causing bacteria that may later cause an infection (Landers, 2012). Despite this evidence, the literature suggests that very little attention is given to patient hand hygiene when compared to healthcare workers (Burnett, 2009).

Purpose

In order to address this gap, the purpose of this project was to measure patient preference for the form and formulation of hand sanitizer products. We hypothesize that the most desirable forms and formulations of hand sanitizers will be different for patients compared to health care workers (Ellingson, 2014).

The World Health Organization has outlined methods to evaluate hand sanitizer products, but these have been developed for use in healthcare workers. This project aims to identify the features of hand sanitizer that patients prefer including important characteristics such as color,
smell, texture, irritation/stinging, drying effect, ease of use, speed of drying, and application of the product. Patient-reported skin condition after use was also evaluated.

Significance

This study is important to determine the factors that determine hand sanitizer preference. In this study we believe that products that are better tolerated will be more widely accepted and lead to better compliance. Effectiveness is associated with reduction in the bacterial load present on the hands. If an alcohol based sanitizer is more comfortable to use for the consumer and has good germ killing properties then in real world setting it is more likely to be used.

Theory

There are many factors that contribute to infection (Welsh, 2012). These factors are illustrated in what is considered the “chain of infection.” This “chain” shows how an infectious disease enters and infects a susceptible host (Tweeten 2014). The components of this chain of infection begin with the reservoir and causative agent. Important causative agents include bacteria such as MRSA, viruses, and parasites. The chain continues with the susceptible host and the causative agent passing through a portal of entry. A portal of entry could be an area of impaired skin integrity or vulnerable mucous membrane. Finally, the chain of infection continues with the mode of transmission which includes coughing, sneezing, touching hands. The process can start over with the causative agent and reservoir.

Hand sanitizers are especially important in breaking this chain of infection. They work at every level of infection. For example, they decrease reservoirsin which causative agents can live and are effective at reducing transmission. Working across the chain of infection, hand sanitizers are a vital part of infection prevention programs.
Research Questions

The research question that will be examined within this project is what are patient preferences in hand sanitizers?

Based on prior clinical and anecdotal experience, we hypothesized that patients will prefer the foam hand sanitizer over the gel hand sanitizer. We believe that when asked to complete our evaluation of the products the foam hand sanitizer will average a score higher in all of our evaluation areas than the gel hand sanitizer.

Research Design

This was a head-to-head comparison of two forms of alcohol based hand rubs, gels and foams. This study was reviewed by The Ohio State University Institutional Review Board. If any adverse events became apparent they were to be immediately reported to the PI.
staff was trained in data management and responsible research practices. All data was be kept in a secure location so that identifiable information will not be linked with informed consent forms.

To verify consent with the test subjects/patients, verbal consent was given by the patient before the test was conducted. (Appendix A) The process by which patients were recruited were as follows: Following preliminary discussions with nurse managers on potential units we identified a 27 bed Hepatology and Infectious Disease Unit. A “facilitation review” was conducted by the Ohio State University Medical Center. Nurses on the unit made patients aware of the study. Flyers and recruitment materials were made available for patients. When patients indicated their willingness to participate they were approached for eligibility, the study procedures were described and patients were asked if they were interested in participating. If candidates were interested, research staff (e.g., study research assistant) obtained consent and answered any questions participants had. Research assistants reviewed procedures and eligibility criteria with potential participants to ensure that they meet the inclusion and exclusion criteria.

Human Subjects

Consent is important to obtain from test subjects as it identifies those test subjects that understand the risks and benefits of such study. The risks of this study include potential skin irritation from hand sanitizer products and mild discomfort when applying the products to the hands. However, it must be noted that there is minimal risk for the patient to participate in this study as all of the products are FDA approved and therefore are very safe for humans to use. In this study potential benefits outweigh the risks. First, if patient hand hygiene is an effective way to reduce the presence of pathogens, this could provide evidence for the widespread adoption of patient hand hygiene protocols. For example, patients could be instructed to perform hand
hygiene at key moments when they are at highest risk of acquiring an infection. Adoption of these protocols would require inclusion of hand hygiene as part of the curriculum in nursing and health care provider training programs. Finally, these findings would introduce patient hand hygiene as an infection prevention measure. In addition to improving health and preventing serious infections, this project has the potential to highlight the role that nurses play in healthcare safety. By advocating the adoption of a patient hand hygiene program, nurses can provide an important contribution to the health of their patients.

Population and Sample

Our population and sample came from eligible subjects from The Ohio State University Wexner Medical Center who were able to understand English, were alert and orientated and were able to give verbal consent.

Data Collection Procedures and Instruments

The survey instrument was developed using a consensus-based product evaluation tool developed by WHO (2009). This tool was revised for use in patients and included product characteristics as well as patient demographics and beliefs about hand hygiene. Patients were provided a copy of the tool and were asked to provide their answers to research staff. After using each product, participants completed a questionnaire about the products. After completing the tool, patients were asked to select one of the test products that they were allowed to keep. This selection was identified as the “product choice” as it is thought to reflect patient’s true preference.
The product evaluation tool was pilot tested in a sample of 5 undergraduate students in the Technology Learning Complex (TLC) in the College of Nursing. Following completion of the interviews, feedback was solicited about the item contents and revised. Through the pilot testing, specific steps were developed for use in the final protocol. Revisions made to the protocol during this process include presenting the products in a random order, preparing the products by priming each container, placing test products on a table in a uniform manner with dispenser spout pointing toward the patient and standardizing the patient selection question. In order to reduce bias, after the second product was evaluated, it was removed from the table and patients were asked, “To thank you for your participation, I would like to leave one of these products for you. Which one would you like to keep?”

Data analysis methods

Demographic variables were collected for each subject and compared for those who preferred gel vs. those who preferred foams. Mean rating for each product was calculated and compared using a t-test for paired variables. Statistical significance was set at p<.05 for all analyses.

Results

Twenty subjects completed the study. Participant characteristics are shown in Table 1.

Patient characteristics by preference of foam or gel are shown in Table 2 and mean ratings of each product by category are shown in Table 3.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>(Mean(SD)) Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>(51.1 years(16.8))21-77</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Number (%)</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>Male</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (45%)</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
</tr>
<tr>
<td>Christian</td>
<td>18 (90%)</td>
</tr>
<tr>
<td>Atheism</td>
<td>2 (10%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>High School</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Some College</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>College Graduate</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Grad School</td>
<td>2 (10%)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
</tr>
<tr>
<td>Full Time</td>
<td>12 (60%)</td>
</tr>
<tr>
<td>Part Time</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>None</td>
<td>6 (30%)</td>
</tr>
<tr>
<td><strong>Work Related</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>No</td>
<td>16 (80%)</td>
</tr>
<tr>
<td><strong>Non-Work Related</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>No</td>
<td>13 (65%)</td>
</tr>
<tr>
<td><strong>Rashes</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>No</td>
<td>13 (65%)</td>
</tr>
</tbody>
</table>

Table 1. Participant Characteristics (n=20)
The majority of both males and females preferred foam hand sanitizers over gels. However, what is interesting is that the majority of subjects that have above a high school education preferred the foam hand sanitizer, while in contrast those with a high school education or below preferred the gel hand sanitizer (Table 2). Looking at the results within Table 2 patients reported a preference for the foam sanitizer over the gel sanitizer. When comparing preferences within the categories of whether or not the subjects had rashes, work related activities that could cause damage to the skin, or non-work related activities that could cause damage to the skin, patient preference was always slighted towards the foam hand sanitizer. Due to a small sample size, statistical significance testing was not performed.
When looking at Table 3 there are two significant p-values that stand out. The p-value for the ease of use category and the p-value for the application category. The p-values within these categories are considered statistically significant when looking at the preference of hand sanitizers. The foam hand sanitizer was rated the highest. Even though the foam hand sanitizer was rated the best overall, patients still rated gels highly.

Chapter V: Conclusion

To be placed on today’s market, hand sanitizing products must be tested in order to determine their safety and efficacy in consumer hands. The combination of efficacy, safety and preference is what makes certain hand sanitizers stand out among the rest. This study tested the preference of hand sanitizers with the notion that the products were FDA approved and had demonstrated efficacy and safety using FDA criteria. While testing for the preference of certain hand sanitizers the tolerability of each product was evaluated as well because tolerability factors largely into a person’s preference in hand sanitizers.

In our review of the literature, we found that most hand hygiene methods and practices have been focused on healthcare workers and the facilities that they work in. With more and more research in this area there is increasing appreciation that patients should also be engaged in hand hygiene interventions (Sunkesula, Kundrapu, Macinga, Donskey 2014). This study demonstrates that patients may have different criteria for rating hand hygiene products and product selection in patient-centered programs should be carefully targeted toward their specific preferences.
We have also shown within this study that the World Health Organization method for evaluation of hand sanitizers that is usually used with health care workers can be used with patients. However, it is important to have measurements that are validated in patients and to pilot test evaluation protocols. This is very important for the prevention of infection as ill patients within the hospital are most susceptible to the spread to infection.

There were some limitations to this study. One of the main limitations was our sample size in which we surveyed only 20 subjects. To get more definitive results for our hypothesis, testing more subjects would be the first step in achieving this. A larger sample size would have provided more power to detect differences.

One study recovered MRSA on 82% of subject’s hands and found that the use of hand sanitizer decreased this number from 82% to 33% of positive cultures within the subject field (Sunkesula, Kundrapu, Macinga, Donskey 2014). These findings demonstrated that efficacious products that are well tolerated and available to patients can play an important role in the prevention of infection.

This study evaluated preference and tolerability of two forms of hand sanitizer products. It may be that other factors such as name brand recognition may be important. However, a great number of products are commercially available and FDA-approved. Other studies have shown the importance of proving the efficacy of certain hand sanitizing products in particular healthcare settings.

Future studies should evaluate the efficacy of additional types of product formulations using various methods to determine if all are equally adept at differentiating between products (Edmonds-Williams, Campbell, Macinga 2015). Thus, another limitation of our study was the
fact that there were only two products evaluated in two forms. To have a better, more clear understanding of patient preferences of hand sanitizers, the use of other forms of hand sanitizers could have been initiated. Other forms could have included wipes, lotions, etc. with different brands in each form.

One of the most surprising conclusions within our study was the fact that the more difficult bottle to use, the foam bottle, was rated the highest. This is not what was expected. The expectations were that an easier to use bottle such as the gel bottle would have been rated higher. With that said another surprising conclusion within our results is that smell was determined to be the lowest ranked category meaning that subjects didn’t like the smell of either alcohol sanitizer. This finding is especially important if smell impacts the use of these products. To better control this category, this study could have educated patients before the use of these sanitizers. All alcohol-based hand rubs have a characteristic alcohol odor in the first 10-15 seconds after application as the alcohol evaporates. This study could have told the subjects that the initial smell, which is a more aggressive smell, will go away. Along with this education it would be important to tell the subjects to use the hand sanitizer and then smell their hands after use and then evaluate the smell after the hand sanitizer was completely used. Patient education could have been important in reporting accurate smell characteristics for both products.

In this pilot study, we did not identify one specific variable or category that influenced patient preference of hand sanitizers the most. The key point to take from this study is that the methods used to evaluate hand sanitizers in health care workers can be transferred to patients in the health care setting. This study showed the modified tool was easy to use, well tolerated, and the patients appeared to understand the content of the questions. This suggests that this tool is appropriate to use with patients of varying ages, backgrounds, and underlying health problems.
There were also some limitations within this study that if improved may have influenced patient preference and the results thereof.

The consistent theme in the research literature is that hand hygiene and its products are the most important key to prevention of infection. As demonstrated in this study, it is critically important to evaluate product efficacy along with preferences and tolerability testing in the intended audience and setting. Improving hand hygiene programs in this manner is essential to preventing infection, providing a safe environment of care, and improving patient outcomes.
Appendix A

Recruitment Script
Hello, We are conducting a research study about hand sanitizer products and were hoping that you would be willing to participate. We are trying to determine the kinds of hand sanitizers that patients prefer. If you would like to do it, it takes about 10 minutes for me to show you two kinds of hand sanitizers, for you to use them both and then answer a few questions. There are no foreseeable risks to using the hand sanitizers. This project will help us understand what patients think about hand sanitizers. It is voluntary, so you do not have to do it. If you do not wish to participate, you will still receive usual care and there is no penalty or loss of benefits to you. You can stop doing the study at any time. We will not collect names or any other identifying information- it will be completely confidential anonymous. If you have questions about your participation or your rights as a subject, I can give you the contact information for the lead researcher, Dr. Timothy Landers. (If desired, leave business card.) Would you be willing to participate in this study? If “no” or unable to answer: Thank you for your time. Have a nice day. If “yes”: That is great. I would like to show you a hand sanitizer, have you use it and ask you some questions about it. (Show product #1) Thank you. I would like to show you a second product and ask you the same questions. (show product #2) I have just a few final questions (show demographic questions) (When completed with product comparison, make observations about hand condition.)
Appendix B

Survey Instrument
Questionnaire – Part 2: Background Information

1. Age: _________

2. Gender: □ Female  □ Male  □ Other

3. Religion: □ Christianity □ Judaism □ Islam □ Buddhism □ Hinduism □ Atheism □ Other

4. Highest Level of Education Completed:
   □ Less than High School □ High School □ Some College □ College Graduate □ Graduate School □ Trade School

5. Occupational Field: _____________________________
   □ Full time □ Part time

6a. Do you have work-related activities likely to cause damage to your skin?
   □ No
   □ Yes Please list: ____________________________________________

6b. Do you have NON-work-related activities likely to cause damage to your skin?
   □ No
   □ Yes Please list: ____________________________________________

7. Do you develop rashes?
   □ No
   □ Yes

8. Do you have a skin condition?
   □ No
   □ Yes

9. How important do you think it is to use alcohol-based hand rubs?

   | Not Important | □ | □ | □ | □ | Very Important |

10. Which of the following would prevent you from using alcohol-based hand rubs?
    □ Don’t have time
    □ Damaged skin
    □ Not easily accessible
    □ Don’t want to use chemicals
    □ Don’t think about it

Thank you for your participation!
I would like to show you a product and ask you to use it.

**Questionnaire – Part 1: Product Evaluation**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1. What is your opinion of the test product?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Very Unpleasant</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Smell</td>
<td>Very Unpleasant</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Texture</td>
<td>Very Sticky</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Irritation/Stinging</td>
<td>Very Irritating</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Drying effect</td>
<td>Very Drying</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Very Difficult</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Speed of drying</td>
<td>Very Slow</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Application</td>
<td>Very Unpleasant</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Overall evaluation</td>
<td>Very Dissatisfied</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

2. Do you think the test product could improve your hand hygiene compliance?

- Yes, absolutely: □ □ □ □ □
- No, not at all: □ □ □ □ □

**Evaluation of Skin Condition**

3. Please self-assess the skin on your hands after using the test product:

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Abnormal</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>(red, blotchy, rash)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intact</strong></td>
<td>Abnormal</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>(abrasions, splitting)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moisture content</strong></td>
<td>Abnormal</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>(dryness)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sensation</strong></td>
<td>Abnormal</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>(itching, burning)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. How would you assess the overall condition of the skin on your hands after using the test product?

- Abnormal: □ □ □ □ □
- Normal: □ □ □ □ □
Appendix C

Institutional Review Board Application & Approval
December 15, 2014

Protocol Number: 2014H0413
Protocol Title: PATIENT PREFERENCES FOR HAND SANITIZERS, Timothy Landers, Nursing
Type of Review: Initial Review – expedited
IRB Staff Contact: Jenna Mowil-Hufkowski
614.688.2208
mowil-hufkowski.1@osu.edu

Dear Dr. Landers,

The Biomedical IRB APPROVED BY EXPEDITED REVIEW the above referenced research. The Board was able to provide expedited approval under 45 CFR 46.110(b)(1) because the research meets the applicability criteria and one or more categories of research eligible for expedited review, as indicated below.

Date of IRB Approval: December 14, 2014
Date of IRB Approval Expiration: December 14, 2015
Expedited Review Category: 7

In addition, the research has been approved for a waiver of documentation of the consent process.

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for one year from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of all investigators and research staff to promptly report to the IRB any serious, unexpected and related adverse events and potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University’s OHRP Federalwide Assurance #00006378. All forms and procedures can be found on the ORIP website – www.orip.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Karla Zdunik, OD, PhD, Chair
Biomedical Sciences Institutional Review Board
C) INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH
The Ohio State University Institutional Review Boards

Office of Responsible Research Practices (ORRP)
300 Research Administration Building, 1960 Kenny Road, Columbus, OH 43210
Phone: (614) 688-8457       Fax: (614) 688-0366       orrp.osu.edu

<table>
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<th>DATE RECEIVED:</th>
<th>PROTOCOL NUMBER:</th>
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1. PROJECT TITLE

Patient Centered Hand Hygiene

2. INSTITUTIONAL REVIEW BOARD

Select the Board to review this research:

- [ ] Behavioral and Social Sciences
- [x] Biomedical Sciences
- [ ] Cancer

Final Board assignment is determined by ORRP.

3. PRINCIPAL INVESTIGATOR (or Advisor) - see Qualifications for service as a PI

<table>
<thead>
<tr>
<th>Name (Last, First, MI):</th>
<th>Timothy Landers</th>
<th>Degree(s):</th>
<th>RN CNP PhD</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Academic Title:</td>
<td>Assistant Professor</td>
<td>College (TIU):</td>
<td>College of Nursing</td>
</tr>
<tr>
<td>Department Name (TIU):</td>
<td></td>
<td>Department #: (TIU):</td>
<td></td>
</tr>
<tr>
<td>Campus Mailing Address:</td>
<td>378 Newton Hall 1585 Neil Avenue</td>
<td>University ID Number:</td>
<td>02120682</td>
</tr>
<tr>
<td></td>
<td>Columbus, Ohio 43210</td>
<td></td>
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</tr>
</tbody>
</table>

| E-mail: | Landers.37@osu.edu | Phone: | (614) 292-0309 |
|.........|--------------------|--------|----------------|

| Fax:       | 614 292 7976       | Emergency phone: | 614 264 7873 |
4. CO-INVESTIGATOR(S)

Are there any Ohio State University co-investigators on this protocol?

- Yes ➔ Complete Appendix A1
- No

Signatures of co-investigator(s) are required on Appendix A1.

5. KEY PERSONNEL

Are there any Ohio State University key personnel on this protocol?

- Yes ➔ Complete Appendix A1
- No

Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.

6. EXTERNAL CO-INVESTIGATOR(S) & KEY PERSONNEL

Are any external (non-Ohio State University) investigators or key personnel engaged in the Ohio State research?

- Yes
- No ➔ Go to Question #7

“Engaged” individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Ohio State University. See OHRP Engagement Guidance or contact ORRP for more information.

If Yes ➔ Who will provide approval for these external personnel?

- Ohio State University IRB ➔ Complete Appendix A2
- Non-Ohio State University IRB ➔ Provide a copy of the approval(s)

7. ADDITIONAL CONTACT(S)

If further information about this application is needed, specify the contact person(s) if other than the PI (e.g., study or regulatory coordinator, research assistant, etc.).

<table>
<thead>
<tr>
<th>Name (Last, First, MI):</th>
<th>Johnson, Abrea</th>
<th>Phone: 330-842-1115</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-mail:</td>
<td><a href="mailto:johnson.3195@osu.edu">johnson.3195@osu.edu</a></td>
<td>Fax: 614-292-7976</td>
</tr>
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<table>
<thead>
<tr>
<th>Name (Last, First, MI):</th>
<th>Dent, Anthony</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-mail:</td>
<td><a href="mailto:Dent.56@osu.edu">Dent.56@osu.edu</a></td>
<td>Fax:</td>
</tr>
</tbody>
</table>

All Ohio State University individuals listed on this protocol will have access to information about IRB actions and the completion status of each individual's administrative and training requirements (CITI, COI disclosure). Personal financial information provided in COI disclosures is not included.
8. EDUCATION

Educational requirements (initial and continuing) must be satisfied prior to submitting the application for IRB review. See Human Subjects Protection Training or contact ORRP for more information.

Have all Ohio State University investigators and key personnel completed the required web-based course (CITI) in the protection of human research subjects? Yes □ No □

9. FINANCIAL CONFLICT OF INTEREST

All Ohio State University investigators and key personnel must have a current COI disclosure (updated as necessary for the proposed research) before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights and royalties from such rights. For more information, see Office of Research Compliance COI Overview and eCOI.

a. Have all Ohio State University investigators and key personnel completed the required COI disclosure? Yes □ No □

b. Does any Ohio State University investigator (including principal or co-investigator), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research? Yes □ No □

10. FUNDING OR OTHER SUPPORT

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact ORRP for more information.

a. Is the research funded or has funding been requested? Yes □ No □

If Yes → Specify sponsor: Robert Wood Johnson Foundation

Provide a copy of the grant application or funding proposal. The university is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded.

b. Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study? Yes □ No □

If Yes → Specify support and provider:

11. OTHER INSTITUTIONAL APPROVALS

Check all that apply and provide applicable documentation. See websites listed below for information on obtaining approvals. IRB review cannot be conducted until required institutional approvals or exemptions are obtained, except as noted.

□ None
Clinical Research Center (CRC) Scientific Advisory Committee (SAC) – Approval required for research sponsored by the CRC. Final IRB approval will be held pending receipt of SAC approval.

Institutional Biosafety Committee (IBC) – Approval required for research involving biohazards (recombinant DNA, infectious select agents, toxins), gene transfer, or xenotransplantation.

Comprehensive Cancer Center (CCC) Clinical Scientific Review Committee (CSRC) – Approval or exemption required for cancer-related research.

Maternal-Fetal Welfare Committee – Approval required for some research involving pregnant women and fetuses.

Human Subject Radiation Committee (HSRC) – Approval required for research involving radiologic procedures for research purposes (e.g., non-clinical care X-rays, DEXA or CT scans, nuclear medicine procedures, etc.).

12. LOCATION OF THE RESEARCH

Research to be conducted at locations other than approved performance sites will minimally require a letter of support and may require another IRB’s approval if personnel are engaged. See OHRP Engagement Guidance or contact ORRP for more information.

a. List the specific site(s) at which the Ohio State research will be conducted (include both domestic and international locations).

<table>
<thead>
<tr>
<th>Location Name (or description)</th>
<th>Address (street, city and state, or country)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ohio State University Hospital East</td>
<td>1492 East Broad Street, Columbus, OH</td>
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b. Are all the sites named above on the Ohio State list of approved research performance sites?

- Yes
- No

If No → ☐ Domestic sites → Provide a letter of support, as applicable

☐ International sites → Complete Appendix U

c. Is the Ohio State PI the lead investigator or is The Ohio State University the lead site for collaborative research?

- Yes
- No → Go to Question #13

☐ Not collaborative research → Go to Question #13

i. Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.
ii. Describe IRB oversight arrangements for each collaborative site (i.e., who will provide IRB review and approval). Provide copies of the non-Ohio State approvals, as applicable. Contact ORRP if requesting that Ohio State University serve as the IRB of record.

13. EXPEDITED REVIEW
Are you requesting Expedited Review?  
- Yes ➔ Complete Appendix B
- No

14. SUMMARY OF THE RESEARCH
Summarize the proposed research using non-technical language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may reasonably be expected to result. Use complete sentences (limit 300 words).
Hand hygiene is the most important means of preventing the transmission of infection and increasing evidence demonstrates that bacteria on the patients’ own skin may be the source of many infections. However, few efforts have been directed at involving patients in hand hygiene. The purpose of this single-group pre-post study is to develop and pilot test an evidence-based patient hand hygiene protocol. In the first phase of the study, we will gather data on the tolerability, preferences, and acceptability of hand hygiene products among patients and collect baseline survey data. We will ask patients to evaluate several hand hygiene products using a standardized questionnaire (see attached).
Secondly, we will gather samples from the hands of approximately 75 patients on admission and 48 hours post-admission by the ‘glove juice’ method in which a liquid is used to recover bacteria from the hands. In this phase we will maintain normal hospital conditions.
Finally, we will then implement a standardized hand hygiene protocol for patients on a select unit (including the products to be used, timing, and patient education components). This protocol including hand sanitizer products and materials will be developed based on patient preferences from the first phase. We will examine the impact of the protocol in 75 patients by repeating the glove juice sampling procedure described in the first phase. We will perform descriptive analyses and culminates in testing the reduction of pathogens as a result of the patient hand hygiene intervention.
Potential risks will be minimized by using approved hand hygiene products. Benefits will include improved access to hand hygiene materials and supplies, lowering rates of hospital acquired infections.
Findings from this study will provide evidence regarding the feasibility of a hand hygiene protocol in an acute care setting with the potential to reduce the occurrence of healthcare-associated pathogens transmitted by hospital inpatients. It will also contribute to knowledge about the acquisition of pathogens on the hands of patients.

15. SCIENTIFIC BACKGROUND & LITERATURE REVIEW
Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. Use complete sentences (limit 300 words).
In order to improve patient safety and prevent infection, national and international guidelines have been developed for hand hygiene compliance by healthcare workers (HCWs) (Pittet, 2009; Boyce, 2003; Cookson, 2009). However, few studies have addressed the importance of patient hand hygiene as a means to prevent infection. (Burnett, 2008). Emerging evidence suggests that most infections may occur as a result of bacteria present within the patient’s own flora, on their skin, and bacteria present in the healthcare environment. Patients may be involved in the transmission of
pathogens and HAI risk in four significant ways: 1) through the transfer of pathogens within the environment, 2) by directly spreading pathogens to other patients, 3) cross-contamination through HCWs via direct contact, and 4) by in increasing their own risk of an infection from an endogenous source. While well-developed guidelines exist for the timing and techniques of hand hygiene in HCWs, significant questions remain about implementing patient hand hygiene programs. Although the World Health Organization’s “5 Moments for hand hygiene” are regarded as the standard opportunities for hand hygiene in patient care, similar guidelines do not exist for patients (Sax, 2007). Finally, effective hand hygiene promotion strategies require multimodal approaches, but the ideal components of the education, monitoring, product placement, feedback, and organizational strategies to promote patient hand hygiene have not been developed (Haas, 2008).

### 16. RESEARCH OBJECTIVES

List the specific scientific or scholarly aims of the research study.

The specific aims of this project are to:

1. Develop an evidence-based patient hand hygiene protocol utilizing current practice recommendations, solicitation of input from experts, and convening of patient focus groups to develop a standardized hand hygiene protocol. Since effective hand hygiene strategies must include a multimodal strategy, patient and staff education and training plan will be developed to accompany the protocol.

2. Determine the feasibility (acceptability, adaptation and demand) of an evidence-based patient hand hygiene protocol. Data will be collected in three key areas of feasibility – acceptability, adaptation, and demand. (Bowen, 2006). Evaluation of the acceptability and success of the adaptation of the protocol to hospitalized patients will be obtained using instruments designed to measure perceptions of hand hygiene products. Demand, or usage, will be measured using overall consumption and number of dispenser “hits.”

3. Estimate the effect size of the patient hand hygiene protocol on the presence of potential pathogens on the patients’ hands. The number of patients with pathogens on their hands before and after the implementation of a patient hand hygiene protocol will be determined. Samples will be obtained from hospitalized patients at baseline and 48 hours later to test for 5 common pathogens. Then, the hand hygiene protocol will be implemented and results compared.

### 17. RESEARCH METHODS & ACTIVITIES

a. Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities. **Provide description (e.g., spreadsheet or forms) of data being collected. Do not include case report forms for multi-site industry-sponsored or cooperative group studies.**

The first phase of the project will involve recruiting 40 people to develop an evidence-based hand hygiene protocol by assessing patient preference for hand sanitizer products and formulations. At Ohio State East University Hospital nurses will be asked to identify patients

If the patient indicates that they would like to hear more about the study or enroll, the research assistant will come in and inform the patient of the study and go over the consent form. Once the patient has consented to participate, the research assistant will bring in 4 hand sanitizing products. The patient will be surveyed on their impression of the hand sanitizers. See attached survey. This data will be used to develop a hand hygiene protocol. first phase of the project will involve recruiting 75 patients prior to the development of an evidence-based hand hygiene protocol. At the select unit nurses will let patients know of the availability of a research study examining patient hand hygiene.

Flyers will be available if the patient would like to read more information. If the patient indicated that they would like to hear more about the study or enroll, the research assistant will come in and inform the patient of the study, determine eligibility, and go over the consent form and HIPPA forms. If the patient has consented to participate, the research assistant will then begin the study procedure. The research assistant will conduct a glove juice procedure in order to detect the presence of pathogens on the skin. This involves the patient putting a non latex glove on their hand. Then the research assistant will pour in 75ml standardized of surfactant set at a ph of 7.5 +/- .2 and massage the hand for 60 seconds. Then the research assistant will remove 10ml out of the glove and put in in the collection tube. The tube will be coded by a unique patient code that is not related to the
patients ID, but so that it can be matched to the same patient. Usual hand sanitizers will be available for the patients during their stay. The study would like to capture the normal patient experience in the hospital. The research assistant will then return 48 hours post admission and he/she will repeat the glove juice procedure. Samples will be compared at admission and 48 hours post admission.

The third phase of the project will involve recruiting 75 patients after the development of an evidence-based hand hygiene protocol. At the selected unit nurses will let patients know of the availability of a research study examining patient hand hygiene. Flyers will be available if the patient would like to read more information. If the patient indicated that they would like to hear more about the study or enroll, the research assistant will come in and inform the patient of the study, determine eligibility, and go over the consent form. If the patient has consented to participate, the research assistant will then begin the study procedure. The research assistant will conduct a glove juice procedure in order to detect the presence of pathogens on the skin. This involves the patient putting on a non-latex glove on their hand. Then the research assistant will pour in 75ml standardized surfactant set at a pH of 7.5 ± .2 and massage the hand for 60 seconds. Then the research assistant will suction 10ml out of the glove and put it in the collection tube. The tube will be coded by a unique patient code that is not related to the patients ID, but can be matched to the same patient. The participant will be educated on the evidence based hand hygiene protocol. This phase would like to capture protocol adherence through self-reported protocol usage and open-ended questions about the acceptability and tolerability of the protocol. Automation of the dispenser will be recorded by measuring the number of “hits” on the dispenser over a 24-hour period using “smart dispensers” with built-in recording technology. Recording of total product consumption will be determined per bed (The Joint Commission, 2009). The research assistant will then return 48 hours post admission and he/she will repeat the glove juice procedure. Samples will be compared at admission and 48 hours post admission.

We will then perform descriptive analyses and culminates in testing the reduction of pathogens as a result of the patient hand hygiene intervention prior to the protocol development and after the protocol implementation. Findings from this study will provide evidence regarding the feasibility of a hand hygiene protocol in an acute care setting with the potential to reduce the occurrence of healthcare-associated pathogens transmitted by hospital inpatients.

b. Check all research activities that apply:

☐ Anesthesia (general or local) or sedation
☐ Audio, video, digital, or image recordings
☐ Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
☒ Biological sampling (other than blood)
☐ Blood drawing
☐ Coordinating Center
☒ Data, not publicly available
☐ Data, publicly available
☐ Data repositories ➔ Complete Appendix C
(future unspecified use, including research databases)
☐ Deception ➔ Complete Appendix D & Appendix M1
☐ Devices ➔ Complete Appendix E
☐ Diet, exercise, or sleep modifications
☐ Drugs or biologics ➔ Complete Appendix F
☐ Magnetic Resonance Imaging (MRI)
☐ Materials that may be considered sensitive, offensive, threatening, or degrading
☐ Non-invasive medical procedures (e.g., EKG, Doppler)
☐ Observation of participants (including field notes)
☐ Oral history (does not include medical history)
☐ Placebo
☐ Pregnancy testing
☐ Program Protocol (Umbrella Protocol)
☐ Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) ➔ Complete Appendix V
☐ Randomization
☐ Record review (which may include PHI)
☐ Specimen research
☐ Stem cell research
18. DURATION

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

Phase 1 (standard hospital condition pre/post test) will last 30 minutes for participants. Phase 2 (hand sanitizing product feedback survey) will consist of a 15 minute product survey. Phase 3 (hand hygiene protocol implementation pre/post test) will consist of a short educational component and then the pre/post procedure lasting a total of 40 mins. No long-term follow-up will be conducted.

19. NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

a. Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University IRB approval. 250

b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).

The sample size calculation was develop based on up to 100 patients in the product evaluation group and 75 in each phase of the hand hygiene protocol group (total of 150 in hand hygiene protocol group).

For the control/intervention groups, it was assumed that 40% of patients would have one of the five bacteria present at the end of 48 hours which is consistent with the existing studies. Using a hypothesized reduction in the number of patients positive for pathogens of 40% with the 40% population prevalence, a final sample size of 49 subjects would achieve .80 power at alpha = .05, to detect a 50% reduction using a two-sided binomial test. A final sample size of 49 subjects would achieve .83 power at alpha = .05, to detect a 50% reduction (a change in Prob(Y=1) from the value of 0.40 to .20) in a logistic regression model. Although prior studies have found a high rate of participation, accounting for a 20% attrition rate, 75 subjects should provide a sufficient sample.

c. Is this a multi-site study?
20. PARTICIPANT POPULATION

a. Specify the age(s) of the individuals who may participate in the research:

   Age(s): \( \geq 18 \text{ years old} \)

b. Specify the participant population(s). Check all that apply:

   - Adults
   - Children (< 18 years) \( \rightarrow \) Complete Appendix I
   - Adults with decisional impairment \( \rightarrow \) Complete Appendix W
   - Non-English speaking \( \rightarrow \) Complete Appendix J
   - Student research pools (e.g., psychology, linguistics)
   - Pregnant women/fetuses \( \rightarrow \) Complete Appendix K
   - Neonates (uncertain viability/nonviable) \( \rightarrow \) Complete Appendix K
   - Prisoners \( \rightarrow \) Complete Appendix L
   - Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program protocols)

   Specify: ____________________________

   c. Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

   **Inclusion criteria:** Men and women, age's \( \geq 18 \) years old, admitted to the OSUWMC, able to understand English, awake, alert and can provide verbal consent for the study procedures.

   **Rationale for Inclusion Criteria:** Patients ages > 18 years are adults and can provide their consent for participation. Participants must be English speaking because intervention materials, instructions, and surveys/measures are written in English. The study is small and not practical/feasible for translator, etc.

   d. Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status? \( \checkmark \) Yes

   **If Yes \( \rightarrow \) Explain the criteria and reason(s) for each exclusion. Consider the study's scientific or scholarly aims and risks.**

   **Exclusion Criteria:** patients ages < 18 years and non-English speaking, inability to sample at least one hand due to the presence of dressing, bandages, or open wounds on both hands.

   **Rationale for Exclusion Criteria:** patients ages < 18 years are not legal adults; Intervention materials and surveys/measures are written in English. The study is small and not practical/feasible for translator, etc.
e. Are any of the participants likely to be vulnerable to coercion or undue influence? **Consider students, employees, terminally ill persons, or others who may have limited autonomy.** □ Yes □ No

If Yes → Describe additional safeguards to protect participants’ rights and welfare. **Consider strategies to ensure voluntary participation.**

21. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Provide evidence that you will be able to recruit the necessary number of participants to complete the study.

Preliminary discussions with nurse managers on potential units have indicated their willingness to participate and that the proposed number of subjects could be easily obtained. The proposed hospital, University Hospital East, is a 404-bed acute care hospital providing the full range of acute care services.

While willing and interested units have been identified, a “facilitation review” is required by the Ohio State University Medical Center which is dependent on IRB approval.

b. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

Nurses on the unit will make patients aware of the study. Flyers and recruitment materials will be available for patients. If the patient would like to know more about the study, agree to be approached for eligibility, or enroll, the study staff will approach potential participants, describe study procedures and ask if they are interested in participating. If candidates are interested, research staff (e.g., study research assistant) will obtain consent and answer any questions participants may have.

c. List the names of investigator(s) and/or key personnel who will recruit participants.

   Timothy Landers, Kurt Stevenson, Study Research Assistant (TBD), Anthony Dent

d. Describe the process that will be used to determine participant eligibility.
Research assistants will review procedures and eligibility criteria with potential participants to ensure that they meet the inclusion and exclusion criteria. Consultation with PI will occur for any questions. See above for inclusion/exclusion criteria.

e. Describe the recruitment process; including the setting in which recruitment will take place. Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).

A study flyer with information about the objectives and PI contact information will be available. Study participants will be made aware of the study in the selected unit. As described above, participants will be approached by study staff about participation in the study.

f. Explain how the process respects potential participants’ privacy.

Only potential participants who indicate their willingness to discuss the study will be approached. Identifiable information will not collected until participant consents to participate in study. Potential participants will be informed that by choosing not to participate in this study, their medical care will not change in any way. Once participants consent, identifiable information will be stored in a separate and locked filing cabinet with PI. Participants will be made aware that there is a follow-up visit at 48 hours post admission and that the study staff will approach them at that time for a second test. The study staff will be sure to make sure the time is acceptable for the participant when they return.

22. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study?  
Compensation plans should be pro-rated (not contingent upon study completion) and should consider participant withdrawals, as applicable.

<table>
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<th>Yes</th>
<th>No</th>
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If Yes ➔ Describe the incentive, including the amount and timing of all payments.

Participants will keep the hand hygiene products ($25 value).

23. ALTERNATIVES TO STUDY PARTICIPATION

Other than choosing not to participate, list any specific alternatives, including available procedures or treatments that may be advantageous to the subject.

None, patients/families may find the hand hygiene materials helpful.
24. INFORMED CONSENT PROCESS

Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. Provide copies of documents and/or complete relevant appendices, as needed. See Consent for Research for templates, HRPP policies Informed Consent Process and the Elements of Informed Consent, Documentation of the Informed Consent Process, and Assent and Parental Permission or contact ORRP for more information.

<table>
<thead>
<tr>
<th>Document/Process</th>
<th>Appendix/Section</th>
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</thead>
<tbody>
<tr>
<td>Assent – Form</td>
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<tr>
<td>Assent – Verbal Script</td>
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<tr>
<td>Informed Consent – Form</td>
<td>Appendix M2</td>
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<td>Informed Consent – Verbal Script</td>
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</tr>
<tr>
<td>Waiver of Consent Documentation</td>
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b. List the names of investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.

Timothy Landers, Kurt Stevenson, Study Research Assistant (TBD), Anthony Dent

N/A

c. Who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)?

The patient will provide informed consent.

N/A

d. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.

Nurses on the unit will identify eligible participants (by adhering to inclusion and exclusion criteria described in a subsequent section). Nurses will approach eligible participants and ask if candidates are interested in participating. If the patient is interested, research staff (e.g., study research assistant) will obtain consent and answer any questions participants may have. The consent form will be signed and a copy made for the participant.

N/A

e. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

Participants (or potential participants) will be informed that their participation in this study will not alter their hospital care in any way. Additionally, they will be informed that they can leave the study at any time, with no penalty.

N/A
f. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?
   - Yes
   - No

   - Yes → Provide copies of these tools

   - No

25. PRIVACY OF PARTICIPANTS

a. Describe the provisions to protect the privacy interests of the participants. Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.

   The Principal Investigator and research staff will oversee data collection and maintenance throughout the duration of this project. If any adverse events occur, they will immediately be reported to the PI.

   Research staff will be trained in data management and responsible research practices.

   Informed consent forms will be kept in a separate and locked filing cabinet in the PI's office. All data will be kept in a separate location so that identifiable information will not be linked with informed consent forms.

b. Does the research require access to personally identifiable private information?
   - Yes
   - No

   - Yes → Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

   Informed consent forms will contain participant's legal name. These will be kept in a locked filing cabinet in the PI’s office. Additionally, participants will sign a HIPPA Authorization form so that research staff can utilize medical records to determine name, date of birth, date of admission, current medications, and occurrence of infection. Name and DOB will be collected in order to identify where the patient is located upon the 48 hours post admission time. Current medications and current infections are mediators that will need to be controlled for in data analysis.

26. CONFIDENTIALITY OF DATA

a. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see Policy on Institutional Data and Research Data Policy.
Informed consent forms will be kept in a separate and locked filing cabinet in the PI's office. All data will be kept in a separate location so that identifiable information will not be linked with informed consent forms.

Participant surveys (and other data) will record only study identification number and no identifying information.

b. Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected. ☒ N/A

c. Will you be obtaining an NIH Certificate of Confidentiality? ☐ Yes ➔ Provide a copy before you begin the research ☒ No

See HRPP policy Privacy and Confidentiality for more information.

d. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality. ☒ N/A

e. Indicate what will happen to identifiable data at the end of the study. Primary research data should be retained for a minimum of five years after final project closeout. For more information, see the university's Research Data Policy. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)

☐ Identifiable data were not collected
☒ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
☐ Identifiable or coded/linked data will be retained and stored securely (as appropriate)
☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

27. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study?

☐ No
☒ Yes ➔ Check all that apply:
28. **REASONABLY ANTICIPATED BENEFITS**

a. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. *Compensation is not to be considered a benefit.*

Patient hand hygiene protocol has the potential to reduce the presence of pathogens and transmission of organisms that may reduce HAI during the patient's hospital stay.

b. List the potential benefits that society and/or others may expect as a result of this research study.

These findings have important implications for nursing. First, should patient hand hygiene be an effective way to reduce the presence of pathogens, this could provide evidence for the widespread adoption of patient hand hygiene protocols. For example, patients could be instructed to perform hand hygiene at key moments when they are at highest risk of acquiring an infection. Adoption of these protocols would require inclusion of hand hygiene as part of the curriculum in nursing and health care provider training programs. Finally, these finding would introduce patient hand hygiene as an infection prevention measure. In addition to improving health and preventing serious infections, this project has the potential to highlight the role that nurses play in healthcare safety. By advocating the adoption of a patient hand hygiene program, nurses can provide an important contribution to the health of their patients.

29. **RISKS, HARMS, & DISCOMFORTS**

a. Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. *Consider the range of risks, including physical, psychological, social, legal, and economic.*

Patient may experience skin irritation or other adverse reactions while using the hand hygiene products and/or during the 'glove juice' sample collection procedure.

b. Describe how risks, harms, and/or discomforts will be minimized. *If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders, etc.), address timing and method of testing; include how positive test results will be handled.*

If irritation occurs, the patient will be instructed that they may request at any time to stop participation in the study.
30. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described in Question #29 beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)?

- [ ] Yes
- [x] No

If Yes → Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

31. ASSESSMENT OF RISKS & BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

The risk of potential patient skin irritation is a reasonable risk in light of the potential decreased risk for a patient HAI.

32. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

None

b. List any costs to participants that will be covered by the research study.
33. APPLICATION CONTENTS

Indicate the documents being submitted for this research project. Check all appropriate boxes.

- [x] Initial Review of Human Subjects Research Application
- [x] Appendix A1: Ohio State University Co-Investigators & Key Personnel (questions 4 & 5)
- [ ] Appendix A2: External (non-Ohio State) Co-Investigators & Key Personnel (question 6)
- [x] Appendix B: Expedited Review – Initial Review (question 13)
- [ ] Appendix C: Data Repositories (question 17b)
- [ ] Appendix D: Deception (question 17b)
- [ ] Appendix E: Devices (question 17b)
- [ ] Appendix F: Drugs or Biologics (question 17b)
- [ ] Appendix G: Genetic Testing (question 17b)
- [ ] Appendix H: Storage of Biological Materials (question 17b)
- [ ] Appendix I: Children (question 20b)
- [ ] Appendix J: Non-English Speaking Participants (questions 20b and 24a)
- [ ] Appendix K: Pregnant Women/Fetuses/Neonates (question 20b)
- [ ] Appendix L: Prisoners (question 20b)
- [ ] Appendix M1: Waiver or Alteration of Consent Process (questions 17b & 24a)
- [ ] Appendix M2: Waiver of Consent Documentation (question 24a)
- [ ] Appendix N: Waiver or Alteration of HIPAA Research Authorization (question 27)
- [ ] Appendix U: Research in International Settings (question 12)
- [ ] Appendix V: Radiation (question 17b)
- [ ] Appendix W: Adults with Decisional Impairment (question 20b)
- [x] Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question 24a)
- [x] HIPAA Research Authorization Form(s) (question 27)
- [ ] Data Collection Form(s) for Investigator-Initiated Studies (question 17a)
- [ ] Data Collection Form(s) involving protected health information (Appendix N)
- [ ] Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 21d)
- [ ] Script(s) or Information Sheet(s), including Debriefing Materials (question 24)
- [x] Instruments (e.g., questionnaires or surveys to be completed by participants) (question 17b)
- [ ] Other Committee Approvals/Letters of Support (questions 11 & 12)
- [x] Research Protocol
Complete Grant Application or Funding Proposal, as applicable

Drug Manufacturer’s Approved Labeling/Investigator’s Drug Brochure (Appendix F)

Device Manufacturer’s Approved Labeling (Appendix E)

Other supporting documentation and/or materials

For Multi-Site Clinical Trials supported by DHHS, the submission will also include:

DHHS-approved Sample Informed Consent Document (if one exists)

DHHS-approved Protocol (if one exists)

34. ASSURANCE

PRINCIPAL INVESTIGATOR (or Advisor)

I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators, including, but not limited to, the responsibilities described in HRPP policy Responsibilities of Principal Investigators, Co-Investigators and Key Personnel.

I verify that the information provided in this Initial Review of Human Subjects Research application is accurate and complete. I will initiate this research only after having received notification of final IRB approval.

______________________________  __________________________
Signature of Principal Investigator (or Advisor)  Date

______________________________
Printed name of Principal Investigator (or Advisor)

DEPARTMENT CHAIR (or Signatory Official)

As Department Chair (or Signatory Official) for the Principal Investigator, I acknowledge that this research is in keeping with the standards set by our unit and that it has met all Departmental/College requirements for review.

If the PI or any co-investigator is also the Department Chair, the signature of the Dean or other appropriate Signatory Official, such as the Associate Dean for Research, must be obtained.

______________________________  __________________________
Signature of Department Chair  Date

______________________________
Printed name of Department Chair
Appendix D

Pressey Honors Grant Application
Application for Student Research Grant or Student Travel Grant

PRESSEY HONORS ENDOWMENT

University Honors & Scholars Center

Autumn, 2013

The purpose of the Pressey Honors Endowment Grant Program is to assist students who are candidates for graduation with honors research distinction. The grant money must be used for budgeted items or travel specifically related to the research project. For example, laboratory expenses, computer time, and mailing costs are appropriate, while tuition, thesis duplication expenses or living expenses are not. The maximum amount for which students may apply is $300.00, and we are able to fund just one request per student. A faculty committee will review all requests and make recommendations.

This application should be submitted to Anne Krabacher, University Honors & Scholars Center, 220 West 12th Avenue. For students applying for funding in Autumn semester, 2013, the application should be submitted by Tuesday, October 1, 2013. Please note that given limited funding, we will not be able to award as many grants as we have in the past. Applications received after the deadline will not be considered. We will notify applicants of the results no later than Monday, October 13, 2013.

Please print or type. Date September 25, 2013

Name Smedes Kristopher Allen Student ID 20076440

Last First Middle

Telephone Number: 7404173184 Email address: smedes.1@osu.edu

Project Title: Patient Preferences for Hand Sanitizers

Project Advisor: Dr. Timothy Landers
Project Advisor’s E-mail Address: landers.37@osu.edu

College of Enrollment: Nursing Total Credit Hours: 80

Major: Nursing Cumulative Point Hour Ratio: 3.787

For what semester have you planned your project for graduation with honors research distinction?

AU □ SP X SU □

Expected Graduation Semester: Spring Year: 2015

Amount Requested $300.00

Semester Funding is Desired Spring 2014

Credit Hours for Semester Funding is Desired 13

Please attach the following: 1) Project Summary (maximum of three pages); 2) Project Budget; 3) Letter of Support from Project Advisor

Rev. 08/15/12
Project Summary for Pressey Honors Endowment: 
Patient Preferences for Hand Sanitizers

Student Name: Kristopher Smedes 
Junior, Honors Program, College of Nursing

Advisor: Dr. Timothy Landers, RN, PhD 
Assistant Professor, College of Nursing

I. Background

The importance of hand hygiene in the prevention of infection is an important topic in health care. Health care associated infections are a major cause of death and disability. Hand hygiene is the best way to prevent the spread of pathogens and to reduce infections. New technologies and products are able to kill germs more efficiently than cleaning with soap and water with many options for hand sanitizer products. It is thought that the quickest and most effective way to kill germs and reduce infections is through the use of hand sanitizers.

The Food and Drug Administration considers hand sanitizers and their many forms (gels, liquids, foams, wipes) to be over the counter drugs. To meet the criteria for being over the counter drugs there are many different kinds of standards and a hand sanitizer must be considered “generally recognized as safe and effective” (GRASE) to meet the requirements of the Food and Drug Administration (1). This is much different than cosmetics which are not considered by The Food and Drug Administration. Cosmetics are known to be “safe” through lab testing but no claims are made to the effectiveness at reducing bacteria.

Hand sanitizer formulations include active and inactive ingredients. Inactive ingredients may include items like water and polyacrylic acid which is a thickening agent that gives gel hand sanitizers its structure. Many hand sanitizers will put inactive ingredients into the formulation to add a fragrance or color to the sanitizer. The Food and Drug Administration only recognizes two active ingredients that are GRASE — alcohol and providine-iodine. Providine-iodine is not commonly used and alcohol formulations have been widely adopted. We plan to use alcohol based hand sanitizers in our project.

In contrast to formulation, the form includes gels, foams, liquids and wipes. Individuals may prefer one form over the other. There may be different combinations of ingredients that could be coupled with different forms of hand sanitizers that would yield increased effectiveness in reducing bacteria on the skin and lower infection risk. Thus, it is both the formulation and form that yield the best effectiveness or result for the user.

Research on the various forms and formulations has primarily been done on health care workers (2,3), but there has been increased attention in the role of patient’s own hands in acquiring infections. In contrast to health care workers, patients may require use of hand sanitizer less frequently; thus the ideal formulation and form may be different for patients compared to health care workers.

II. Study purpose

The goal of this project is to measure patient preference for the form and formulation of hand sanitizer products. We believe that the most desirable forms and formulations of hand sanitizers will be different for patients compared to health care workers.
III. Methods

We plan to test a range of formulations and forms with a patient population within the Ohio State University Wexner Medical Center. We will obtain data about patients' preferences of various types of hand sanitizers based on unique characteristics of each formulation and form and measure product usage.

In our study we are going to use the World Health Organization's Second Method from "The Protocol for Evaluation and Comparison of Tolerability and Acceptability of Different Alcohol Based Handrubs" (2). Our sample size will be approximately 40 volunteer participants (patients) within the Ohio State University Wexner Medical Center. Each person that is involved in our study will try two samples of hand sanitizers. Each patient will get a combination of two formulations/forms of hand sanitizer. To test patient preference we will include a survey that will evaluate each test product. We will also measure usage of the product by weighing the remaining portion after a 24-hour period.

Evaluation of the test product

What is your opinion of the test product for hand hygiene?

<table>
<thead>
<tr>
<th></th>
<th>Unpleasant</th>
<th>Pleasant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smell</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Texture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irritation (stinging)</td>
<td></td>
<td>Not irritating</td>
</tr>
<tr>
<td>Drying effect</td>
<td></td>
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</tr>
<tr>
<td>Ease of use</td>
<td></td>
<td>Very easy</td>
</tr>
<tr>
<td>Speed of drying</td>
<td></td>
<td>Very fast</td>
</tr>
<tr>
<td>Application</td>
<td></td>
<td>Very pleasant</td>
</tr>
<tr>
<td>Overall evaluation</td>
<td></td>
<td>Very satisfied</td>
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</tbody>
</table>

We will compare patient’s ratings of different forms and formulations using standard statistical techniques. We will compare patient ratings of product characteristics to actual usage over a 24-hour period and product usage by form (gel, foam, liquid, or wipe).
IV. Importance of results

These results will provide information about the best product for patient hand hygiene. We will be able to recommend a product based on patient preferences. In the future of this project we plan to look at the efficacy of these products in reducing the amount of bacteria on patients’ hands.

IV. Timeline

October - December 2013

IRB application approved and submitted

January - February 2014

Identify units within hospital and obtain unit consent

March - May 2014

Perform hand sanitizer tests

June - August 2014

Data analysis

September, 2014

Presentation at Fall Undergraduate Research Forum

V. References


# Project Budget

**Project Title:** Patient preferences for hand sanitizers  
**Student:** Kristopher Smedes  
**Advisor:** Timothy Landers, RN, PhD

<table>
<thead>
<tr>
<th>Item</th>
<th>Number Needed</th>
<th>Cost</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Debmed Foam</td>
<td>20</td>
<td>$3.25</td>
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<tr>
<td>Ecolab Gel</td>
<td>20</td>
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<td>VioNex Towelette</td>
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<td>Purell Wipes</td>
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**Total:** $295.00
September 24, 2013

Anne Krabacher  
University Honors & Scholars Center  
The Ohio State University  
220 W 12th Avenue  
Columbus, OH 43210

Dear Ms. Brabacher:

I am pleased to provide this letter of recommendation for Kristopher Smedes’ application to the Pressey Honors Endowment. As his honors advisor in the College of Nursing, I have been working with him for the past year and a half on his planned honors research project.

His proposal to assess patient acceptance of different forms of hand sanitizer products will provide interesting insights that will help develop and design strategies to encourage patients to perform hand hygiene. Since we know that the majority of infections originate from bacteria on patient’s own skin, this is an interesting, and surprisingly understudied approach to infection prevention. The project flows our discussions over the past year as well as his own study and observations in clinical rotations.

I will be happy to continue to work with Kris in order to complete this project. He has demonstrated enthusiasm for the field of infection prevention and I believe that he will work diligently to complete the project as outlined. I will ensure that he has access to the resources and expertise to complete the research.

Thank you for your consideration of Kris Smedes’ proposal. We look forward to sharing the results of his work at the Undergraduate Research Office poster presentation.

Sincerely,

Timothy Landers, RN, CNP PhD  
Assistant Professor
References


