CONSENT TO TAKE PART IN A RESEARCH STUDY:

“A prospective single-blind placebo-controlled trial to establish the efficacy and tolerability of 10% Povidone-Iodine for nasal *S. aureus* and MRSA decolonization among patients undergoing same-day surgery”.

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Title of Study: A prospective single-blind placebo-controlled trial to establish the efficacy and tolerability of 10% Povidone-Iodine for nasal *S. aureus* and MRSA decolonization among patients undergoing same-day surgery.

Principal Investigator: Dennis Grech, MD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this study. It is your choice whether to take part or not.

The **purpose of the research** is: to determine if the use of preoperative (before surgery) Povidone-Iodine nasal swab can help decrease MRSA bacteria colonization in the nares (nostrils) and decrease the rate of surgical site infections. If you take part in the research, you will be asked to provide nasal cultures from both nares before, during, and after the surgery and to allow us to swab the nares with either saline solution (salt solution) or Povidone-Iodine (medication) solution before surgery. At the Pre-operating room and PACU, you will be asked a few questions about the tolerability of applied investigational drug. Your time in the study will take from when you arrive at the preoperative area until you are discharged after your surgery.

Possible harms or burdens of taking part in the study may be minor discomfort from the nasal swabs and possible benefits of taking part may be decreased rate of surgical site infections and contributing to medical knowledge.

Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Dennis Grech is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Dennis Grech may be reached at (973) 972-0470 at 185 South Orange Avenue (Room E-547), Newark, NJ 07101.

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: Rutgers, Anesthesiology Department (PDI Healthcare is funding the study)

Why is this study being done?
The purpose of this study is to determine if the use of Povidone-Iodine nasal swab before surgery can help decrease MRSA bacteria colonization in the nares and decrease the rate of surgical site infections.

Who may take part in this study and who may not?
Any patient presenting to University Hospital for a same day outpatient surgery may participate in this study as long as they meet the following inclusion criteria and do not meet the exclusion criteria.

Inclusion criteria include:

- community-based English or Spanish speaking patients ages 18-80
- willing and able to consent
- American Society of Anesthesiology (ASA) rating of 1, 2, or 3 as determined by anesthesiologist
- undergoing an outpatient surgery for at least 1 hour and up to 6 hours duration

Exclusion criteria include:

- pregnancy
- allergy to povidone-iodine
- infectious indication for surgery or preexisting known infection/wound
- immunocompromised state
- use of chemotherapy or steroids within 30 days prior to surgery
- use of antimicrobial therapy within 30 days prior to surgery
- surgeries where field avoidance prevents intraoperative access to the nares

Why have I been asked to take part in this study?
Your participation in this study will help in progressing our understanding of surgical site infections and in assessing the efficacy of a novel method of preventing them.

How long will the study take and how many subjects will take part?
The study will last 2 years, but the patient's participation in the study lasts only until discharge from University Hospital Same Day Surgery after their surgery. 200 subjects will take part in this study.

What will I be asked to do if I take part in this study?
If you decide to participate, a nasal culture will be obtained from both nares. You will then receive a nasal swab in both nares while in the preoperative holding area. This swab may contain either saline (placebo) or Povidone-Iodine solution (medication). Additional nasal cultures will be taken during the surgery as well as in the PACU recovery area. We expect those who receive the Povidone-Iodine swabs to have a decreased rate of surgical site infections. At the Pre-operating room and PACU, you will be asked a few questions about the tolerability of applied drugs as burning/itching, pain, irritation, epistaxis, runny nose and others.

Your electronic medical records will be accessed before surgery to ensure that you are eligible for the study, and members of the research team will gather sociodemographic (age, XXXX) and pertinent medical data, ensuring that any data that is collected is deidentified (removal of name, Date of birth, gender, address) and kept confidential. Your electronic medical records will also be accessed at 7 and 30-day post-operative (after surgery) intervals to assess for any surgical site infections that may have occurred postoperatively.

What are the risks of harm or discomforts I might experience if I take part in this study?
The risks of this study are minimal except for minor discomfort from the nasal swabs. In rare cases, there may be some bleeding from the nares. In addition, as with any clinical trial, there is a risk of breach of patient confidentiality, though we do not expect this to occur.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be decreased risk of surgical site infections. However, it is possible that you may not receive any direct benefit from taking part in this study. Your participation will contribute to medical knowledge.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take Part in this study?
There will not be any cost to you to take part in this study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

Who might benefit financially from this research?
Neither the university, the hospital, nor the investigators are expected to directly benefit financially from this research.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All data will be kept on encrypted and password-protected computers and transmitted only via secure means. The computers will be located in a secure area only accessible by the research team. The only identifying data that will be kept will be the medical record number and the date/type of procedure. The research team will only be using a separate ID number apart from the medical record number to identify data. These ID numbers will also ensure that subjects remain anonymous. The study will end after approximately 2 years and the data will be used in writing and publishing the manuscript, which will occur in the months following the end of the data collection period. The content will be published in a peer-reviewed scientific journal. Deidentified data will not be destroyed. The link (identifying code) to the personal identifiers will be kept for six years after study completion.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board.
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The scientific Community.

A description of this clinical study will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the study is over?
After information that could identify you has been removed, de-identified information/biospecimens collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, as identified above. In addition, it is possible that during the course of this study, new adverse effects of Povidone-Iodine nasal swabs that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you. Even if you withdraw from taking part in the study, outcome data will continue to be collected about you, such as medical course or lab results obtained through medical chart review. Public records may also be consulted, such as those establishing survival status.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Dennis Grech, Anesthesiology department, (973) 972-0470.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Director at Newark Health Sciences IRB, 65 Bergen St., SSB 511, Newark, NJ 07107, (973)-972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-3608 or (732) 235-9806, email us at human-

subjects@research.rutgers.edu., or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- Hospital discharge summaries
- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)
- Dental records
- Emergency Medicine reports
- Progress notes from outpatient follow-up visits

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary for Clinical Care: University Hospital

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannottake part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind and Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Dennis Grech at 185 South Orange Avenue (Room E-547), Newark, NJ 07101

How Long Will My Permission Last?
Your permission for the use and sharing of your health information will last until the end of the research study.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____Date: _____