RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Impact of nasal antisepsis on *Candida auris* colonization
Sponsor(s): The Centers for Disease Control and Prevention (CDC)

Name of Participant: _____

Note: If you are a parent, guardian or legal representative of a person who is not able to consent (give permission) for themselves, the terms "you" or "your" refer to the research participant.

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future. This consent (permission) form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to determine whether a common and safe antiseptic called povidone iodine can be used to decrease the germ *Candida auris* (a type of fungus) on your skin and in your nose. *Candida auris* can live on your skin or in your nose without causing problems. In these cases, it does not need to be treated. *Candida auris* can sometimes move from the skin or nose into a person's body and cause infections that do need to be treated. Having *Candida auris* on your skin or in your nose makes you more likely to get an infection with *Candida auris* or spread it to other people. Getting rid of *Candida auris* from your skin and nose is expected to prevent infections. Povidone iodine has been available over the counter (anyone can buy it without a prescription) in the United States since 1955.

If you agree to participate in this study, your participation may last up to 28 days and you will be asked to complete up to 10 study visits (1-2 screening visits and up to 8 visits after randomization). During these visits, we will check your nose and skin for *Candida auris*. Your participation in the study will end when you leave the hospital, regardless of how long you have been in the study or how many study visits have occurred.

If you agree to participate in this study, you may receive either a topical antiseptic (*povidone iodine*) or no treatment (*control*) to the inside of your nose. Most people have no side effects when using povidone iodine. With antiseptics like povidone iodine that are applied to the surface of the skin or nose, the most common side effects are mild discomfort and/or irritation at the site of application (in the nose). In a

recent study of 7,388 people who used povidone iodine in their noses, only one person reported a mild sore throat. No other side effects were reported. There is also a risk of loss of confidentiality, but precautions will be taken to prevent this from happening.

You may or may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit people with *Candida auris* in the future. Your only other option to participating in this study is not to participate.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
You are being asked to participate in this study because you have had *Candida auris* on your body or in your nose.

How many participants will take part in this study?
About 120 participants are expected to take part in this study across all sites. This includes participants at three different healthcare facilities in the Chicago area. About 40 participants are expected to enroll at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?
If you agree to be in this study, you may be chosen randomly (assigned by chance, like flipping a coin) to get povidone iodine or no treatment in the nose twice a day for 5 days. We will check your body for *Candida auris* by gently rubbing just inside your nose and on your skin with a rayon-tipped swab (a "Q-Tip"). The places on the skin that will be checked include the hands, armpit, groin, between the toes, and next to the anus. We will test your nose and skin again several times to see if we can still find *Candida auris* on your body. Samples will be collected five times during the first week, then once a week until you are discharged. The longest possible duration of participation in the study is 22 days (up to 8 study visits) after randomization. Your participation in the study will end when you are discharged from the hospital, regardless of how long you have participated or how many study visits have occurred.

What do you need to know regarding the collection of biospecimens?
Biospecimens are materials that come from your body. Skin and nose swab samples collected from you are considered *biospecimens.* We will analyze the samples only for germs, including *Candida auris*. We will not analyze any human cells containing your DNA that may be on the swab.

Will your information or biospecimens be used for research in the future?
Information collected from you for this study may be used for future research or shared with other researchers. We will save the original samples (biospecimens) and any germs that grow from your body. If we use your information in future research, we will remove all information which could identify you. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
Skin and nose swabbing are painless and have no known side effects to you.

Most people have no side effects when using povidone iodine. With products like povidone iodine that are applied to the surface of the skin or nose, the most common side effects are mild discomfort or irritation at the site of application (in the nose). In a recent study, only 1 person out of 7,388 people who used povidone iodine in the nose developed a side effect of a mild sore throat.

There is a potential risk of breach of confidentiality (your health information), but precautions will be taken to prevent this from happening. There may be other risks that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?
Generally, activities performed for research purposes are not meant to provide clinical information, but your results can be shared upon your request. Results may be requested from the study investigator in writing upon conclusion of the study.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. The researchers and Sponsor also have the right to stop your participation in this study without your consent if they believe it is in your best interests or if the study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold (keep back) or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study.

By signing this document, you voluntarily authorize (give permission to) Dr. Hayden, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information (the personal information we collect about you) for the study described in this document.

During the study, Dr. Hayden and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use for this research includes: your age, sex, gender, medical conditions, history of infections, presence of medical devices, and medications.

Dr. Hayden and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. We will not release any information that can be used to identify you. The persons who receive your health information may not be required by federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used by or disclosed to: The study Sponsor (CDC) and its representatives.

While you participate in the study you will have access to your medical record, but Dr. Hayden is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept permanently. Your identity will not be revealed on any report, publication, or at scientific meetings. You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Hayden at 1750 W. Harrison St., Chicago IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/ entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. To ensure privacy, your name and other directly identifying information will not be attached to records or samples. Instead, your information will only be identified by a code. Only the study doctor and authorized personnel will be able to connect this code to your name. If the results of the study are published, your identity will remain confidential.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time, with identifier NCT06282510.

What are the costs to participate in this study?
All costs for the required study supplies, sample collection, and laboratory procedures will be paid by the Centers for Disease Control and Prevention.

You or your insurance will be responsible for paying for the cost of any routine medical care that you would receive whether you participate in this study or not, unless you are told that such item or service will be supplied at no cost.

Will you be paid for your participation in this study?
You will not be paid for being in this study.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Hayden at telephone number 1-312-942-5865.

If you do seek medical treatment, you or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Hayden at 1-312-942-5865 or email her at mhayden@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Hayden in writing at the address on the first page. Dr. Hayden may still use your information that was collected before your written notice.

SIGNATURE BY THE PARTICIPANT OR THE PARTICIPANT'S LEGAL REPRESENTATIVE:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

Name of Legal Representative

Signature of Legal Representative	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant or the participant's legally authorized representative. I further attest that all questions asked by the participant or the participant's legal representative were answered to the best of my knowledge.

Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative and the person signing the form has done so voluntarily.

Name of Witness

Signature of Witness	Date of Signature