Study title: Utility of single-dose oral antibiotic prophylaxis in prevention of surgical site infection in dermatologic surgery
Date document approved by IRB: 8/31/20
Date uploaded: 9/09/20

CARILION CLINIC
CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE: Utility of single-dose oral antibiotic prophylaxis in prevention of surgical site infection in dermatologic surgery

INVESTIGATOR:
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SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study doctor. A brief summary of the study is provided below.

- **The purpose of the study is to assess the effectiveness of a single dose of preoperative antibiotic in reducing surgical site infections in certain dermatological procedures.**
- **Being a participant in this study may help surgeons better predict if antibiotics are needed in certain procedures.**
- **If you are willing to participate, you will be randomized to either receive a single dose of antibiotic or a placebo pill (inactive pill) before your surgery.**
- **If your surgeon feels you no longer meet the inclusion criteria of the study and require antibiotics to prevent an infection, you will be withdrawn from the study and given an antibiotic.**
- **After the surgery, you will follow up with the clinic in 1-2 weeks in person or receive a phone call around that time. You will also either follow up in person or receive a phone call about 30 days from surgery. These visits and phone calls will allow us to evaluate your surgical site, and we will also check to confirm if you have received care elsewhere for any postoperative concerns.**
- **Your participation is expected to last about 30 days after surgery.**

- You will not personally benefit from taking part in this study, but the knowledge gained may benefit others in the future by helping dermatological surgeons **better predict if antibiotics are needed in certain procedures.**
- **The most likely risks to you are slightly more than minimal. A single dose of antibiotic is very well tolerated, and most patients experience no side effects. There is a very low risk of nausea or vomiting and allergic reactions. Some patients are allergic to certain antibiotics. We will review your allergies to decrease the risk of an allergic reaction to the antibiotic.**
- **Your option other than participating is not participating.**
- **Being in the study WILL NOT cost anything. You or your insurance will be billed only for standard medical care.**

The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. Please keep in mind:

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can <u>stop at any time</u>.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

<u>Please read this consent form carefully.</u>

WHAT IS INFORMED CONSENT?

You are being asked to take part in a research study because you are having surgery for a skin cancer. This study is aimed at determining the effectiveness of a single dose of antibiotic in preventing a surgical site infection. The dermatologists running this study are Dr. Phillips, Dr. Prickett, Dr. Eikenberg, and Dr. Holliday. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research subject. Being in this study is voluntary.

Be aware that the role of the study doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem in order to help you. The study doctor treats all subjects under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you understand these different roles.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to determine whether a single dose of preoperative antibiotics can reduce the rate of surgical site infections in certain dermatological procedures. There will be a total of 1602 participants taking part in this study. The length of time you can expect to be in this research is about 30 days.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

Today you will have surgery for the removal of your skin cancer. Before your surgery, you will be randomly assigned to receive either a single dose of an antibiotic (cephalexin or clindamycin hydrochloride) or placebo (inactive) pills, which contain no antibiotics. Randomization means that the group you are in will be assigned by chance, like the flip of a coin. Your chance of receiving treatment is equal. The antibiotics cephalexin and clindamycin hydrochloride are FDA approved for the use in the study. Neither you nor your doctor will know which treatment (the antibiotic vs placebo) you are receiving. This information is available in the event of an emergency.

After your surgery is complete, we will have you follow up in 1-2 weeks or call you to ensure your surgical site is healing well. At this office visit or phone call, we will ask about your surgical site and if you have noticed any redness, drainage, swelling. We will also ask if you have been to any other physician since the surgery and received antibiotics for any reason. We will ask if you have had any other new symptoms since your surgery such as nausea, vomiting, or diarrhea. If you are seen in the clinic for this follow-up, a research team member will inspect the surgical site and ensure it is healing well. The time required to complete these questions and inspect the surgery site will take about 20 minutes in office or 10 minutes over the phone. If this follow-up is over the phone, and you have

concerns about your surgery or how you are healing, we will make an appointment for you to come to the office so we can evaluate your surgical site.

We will also call you about 30 days from surgery or have you return to care around this time to confirm your surgery site is healing well. At the visit or over the phone, we will ask about your surgical site and if you have noticed any redness, drainage, swelling. We will also ask if you have been to any other physician since the surgery and received antibiotics for any reason. If you are seen in the clinic for the 30-day follow-up, a research team member will inspect the surgical site and ensure it is healing well. If this 30-day follow-up is over the phone, and you have concerns about your surgery or how you are healing, we will make an appointment for you to come to the office so we can evaluate your surgical site.
The time required to complete these questions and inspect the surgery site will take about 20 min in office or 10 minutes over the phone.

If there is concern for an infection at any time, all standard of care procedures will be performed, and you will be prescribed antibiotics, which is standard of care. We will also perform a culture of your surgical site, which is standard of care, so that we can ensure we are giving you an antibiotic that will treat your infection. A culture uses a swab that is brushed against your surgical site, and it is sent to the lab where they use techniques to allow any present bacteria to proliferate. Some antibiotics do not work for certain types of bacteria, and a culture confirms what type of bacteria is growing and ensures we give you the correct antibiotic. It takes a few days to receive the results from the culture, so we will prescribe you an antibiotic initially, and the antibiotic may be changed if the culture grows bacteria that are not susceptible to the antibiotic we prescribed (this is standard of care for all infections). If you do acquire an infection, we will recommend a follow-up check after 1-4 weeks to confirm the infection is resolving or resolved.

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

There are minimal risks to being a participate in this study. Antibiotics can have side effects such as nausea, vomiting or diarrhea, although this is less likely with a single dose of antibiotics. Vomiting would be uncommon after a single dose of antibiotics. If nausea does occur, it is most commonly mild and resolves without

intervention. Additionally, antibiotics can cause allergic reactions. This is also rare as we will review your allergies carefully to confirm you do not have an allergy to the antibiotics being used in this study. Courses of antibiotics are associated with antibiotic induced colitis with organism including C. difficile, but C. difficile colitis has not been reported in dermatologic studies after a single dose of antibiotic.

The following are risks of any standard of care dermatologic surgery: scarring, infection, bleeding, or need for surgical revision.

There is a low risk of potential breach of your confidentiality. We take extensive measures to minimize this risk as we keep the information collected for this research separate from information that would identify you. We will do everything we can to protect your privacy and confidentiality.

There is also a small inconvenience to answering the questions we will ask at your follow-ups or phone calls. Most of the questions we will ask are questions you would normally be asked at any postoperative visit. The additional questions are about your visits to other doctors for your surgical site and if you have been prescribed antibiotics since surgery.

The study may have additional risks that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?
You will not personally benefit from taking part in this study, but the knowledge gained may benefit others in the future by helping dermatological surgeons **better predict if antibiotics are needed in certain procedures.**

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?
The other option is to choose not to be in the research study, in which case the decision to use antibiotics will be up to the dermatological surgeon.

WHAT ABOUT CONFIDENTIALITY?
The research records will be kept private in a locked file cabinet and on a password-protected computer in a locked office. All research data will be coded with a unique number. Your name and medical record number will be linked to

the code number on a master list. This master list will be kept separately from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report. Your protected health information will not be shared with anyone outside of the study team and will not be given to any other organization.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers such as name or medical record number.
- Information related to your Mohs surgery, such the location of your surgery and the size of the surgical wound.
- Information obtained at your dermatological follow-ups or phone calls within 37 days of your dermatological surgery.

- Results of physical exams, laboratory tests, and other diagnostic procedures.
- Current and past medications or therapies.
- Information from surveys or questionnaires done for this study.

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research, or to do accounting and billing.
- The Food and Drug Administration or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.
- Researchers at the following non-Carilion facilities: Virginia Tech Carilion School of Medicine
- The following company (known as a contract research organization) that manages the research at Carilion and other sites: Virginia Tech

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

WHAT WILL TAKING PART IN THIS RESEARCH STUDY COST OR PAY?

You or your insurance company may be billed for any standard of care treatment that you receive while taking part in this research study. Billing will be in the usual and customary manner. You will not be charged for the antibiotic.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

In the unlikely event that you develop a medical problem that happens because you are in this study, you will be able to get treatment. The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

You will not be paid for taking part in this research.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part, or you may stop at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion. The researchers may take you out of the research study for any reason, without your consent, if they feel it is in your best interest. The reason for any exclusion will be explained to you.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

This study does not have any sponsors. It does not have any funding. None of the investigators or research staff will receive money or other types of payment from this study.

WHO ARE THE CONTACT PERSONS?

If you have questions about the research study, you may contact Dr. Mariana Phillips at (540) 561-0170. If you have questions about your rights as a research subject, you may contact staff of the Carilion IRB at (540) 224-5878.

IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research subjects. One job of the IRB is to make sure the research is done in a way that is respectful to subjects. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.

_____ No, I do not want Carilion IRB to send me such a survey.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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

CONSENT SIGNATURES:

- **Research Subject Box** must be completed unless the subject cannot read or is physically unable to sign the form. Separate boxes are provided for these exceptions.
- **Person Obtaining Consent Box** must always be completed.

RESEARCH SUBJECT: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time. I will receive a signed copy of this consent form.

_____

Printed Name of Research Subject (18 years or older)

_____ _____

Subject's Signature Date

PERSON OBTAINING CONSENT: I certify I was present for the informed consent discussion. The subject had an opportunity to ask questions about and appeared to understand the information presented. The subject agreed to take part voluntarily in the research and I obtained his/her signature.

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

WHEN THE SUBJECT IS PHYSICALLY UNABLE TO SIGN OR MAKE A MARK:
I certify the subject gave verbal consent to take part in this research study and gave me permission to sign on his or her behalf.

_____
Printed Name of Person Signing for Subject
(This person cannot be part of the study team)

_____ _____
Signature of Person Signing for Subject Date

WHEN SUBJECT CAN'T READ:

I was present during the consent process. The material in the consent form was explained to the research subject. Consent was given voluntarily.

_____
Printed Name of Research Subject

_____
Printed Name of Witness to Consent Process
(This person cannot be part of the study team)

_____
_____
Signature of Witness to Consent Process Date