Study Title: Randomized Controlled Study of Cooled Versus Room-Temperature Artificial Tears for Reducing Surface Irritation Following Intravitreal Injection

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INFORMED CONSENT DOCUMENT

Project Title: **The Effect of Cooled Artificial Tears in Reducing Ocular Surface Irritation after Povidone-Iodine Preparation of Intravitreal Injection**

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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

If you have any questions about or do not understand something in this form, you should ask the research team for more information.

You should discuss your participation with anyone you choose such as family or friends.

Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you routinely receive an intravitreal injection in your eye(s) as part of your eye care. Your eye surface is prepared with povidone-iodine (PVI) to prevent infection prior to the intravitreal injection. The povidone-iodine can cause discomfort, tearing, burning, redness, dryness and stinging sensations. After the procedure most patients receive saline (artificial drops) to rinse out the eye. This study plans to use the artificial eye drops that are either cooled down or at room temperature.

The purpose of this research study is to see if the temperature of saline eye drops used to flush out the povidone-iodine (PVI) after your intravitreal injection may improve your eye comfort level.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 200 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last 1 visit and a follow up phone call 12 to 72 hours after your clinic visit. Each will take 15 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

At your UIHC Ophthalmology Retina Service Injection Clinic appointment, you will be invited to participate in a research project prior to your intravitreal injection. If you decide to enroll in the study, the following will occur.

You will be asked a short questionnaire about your eye(s) surface comfort before your injection. After your intravitreal injection you will receive artificial tear drops to rinse your eye(s). They will are either be at room temperature or cooled down (refrigerated). You will randomly be assigned which eye drops will be given. This means the group your assigned is determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving the cooled down (refrigerated) or room temperature drops. You and the technician will know which type of eye drops you were assigned. The physician will not know. Most patients use artificial tears after injection per instruction, as needed, to alleviate any eye surface discomfort. This will take 15 minutes of you time.

A research team member will telephone you 12 to 72 hours after your clinic visit. You will be asked the questions about your eye surface comfort after the injection. You may decline to answer any questions you feel uncomfortable answering. The telephone call will take 15 minutes.

After the follow up telephone call you will have completed your participation in the study.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over. Your sample, information, and/or data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

The procedure we might want to use to study may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding eye condition, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored *without* your name or any other kind of link that would enable us to identify which sample(s) are yours. Therefore, if you give permission to store your data , it will be available for use in future research studies indefinitely and cannot be removed.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to

these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. There is a minimal risk of scratching the eye surface (cornea) during self-administration of the saline artificial drops. Most patients already use artificial tears after the injection, as needed, per instruction to alleviate any ocular surface stinging sensation.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.

The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.

If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these

records could contain information that personally identifies you.

- federal government regulatory agencies,
- the U.S. Food and Drug Administration
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will **store the research data on University of Iowa compliant device with password protection and** deidentify your data with a code that does not directly link you back to the study. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires **University of Iowa Health Care** to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research. Once **University of Iowa Health Care** has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, .

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes **University of Iowa Health Care** to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to **Dr. Jonathan F Russell or Dr. Douglas Jin, MD, University of Iowa Hospitals & Clinics, Department of Ophthalmology & Visual Sciences, 200 Hawkins Drive – PFP, Iowa City IA 52242**. However, we may still use your health information that was collected before

withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to complete the follow up telephone call.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Dr. Jonathan F. Russell or Dr. Douglas Jin at 319-356-3185; and ask for the ophthalmology fellow or resident on call and to tell operator you are a research subject.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)