TITLE: **Icare tonometry effects on K readings, topography and corneal staining**

PRINCIPAL INVESTIGATOR:

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SPONSOR: **Icare USA**

Introduction

You are being asked to take part in a research study. This consent form is only a part of the informed consent process. It will give you detailed *written* information about what will take place during the study.

Take the time to read this form carefully. After reading this form and having this study explained to you by someone conducting the research, you can decide if you want to participate in it.

You may have questions this form does not answer. If you do not understand something about the research study or if you have any additional questions, please ask the researcher for an explanation before you sign this form.

If you choose to participate in this research study, then you should sign this *consent* form. If you do not want to take part in this research study, you should not sign this form. Your decision whether or not to participate will have no effect on your medical care.

Why is this research study being done?

The purpose of this study is to determine the effect of obtaining the measurement of pressure caused by the continuous renewal of fluids in the eye which is called intraocular pressure (IOP) using the i-Care tonometer on other factors in the eye exam. The i-Care tonometer has been approved by the FDA for use in obtaining the IOP. Your doctors believe that because the i-Care tonometer does not require any anesthetic or any other drops to be placed in the eye, and has minimal contact with the eye surface, it may be used on any patient at any time in the exam without affecting other testing during the eye exam. This may allow for significant improvement in patient flow in the office and save patients from the cost and time of extra visits. You were selected to participate in this study because you are scheduled to undergo a routine eye examination today. Sixty patients will be asked to participate in this study.

What does this study involve?

If you agree to participate in this research study, you will undergo a few measurements of your eyes and a brief eye examination. Your participation in the study is complete at the end of your examination.

What are the possible risks, side effects, and discomforts of this research study?

There are no additional risks to you for participating in this research study.

What are the possible benefits from taking part in this research study?

The possible benefit to you from being in this study is that your doctor may discover the best method for obtaining your intraocular pressure. Your participation in this study will allow researchers to obtain data that may change the way other people are tested for IOP in the future.

What if I decide not to take part in this research study?

Should you decide not to participate in the study, you will still undergo your normal eye exam.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

There will be no additional costs to you or your insurance provider for participating in this research study. The cost of the eye examination will be billed to your insurance provider because it is not being done for the purpose of this research study.

Will I be paid if I take part in this research study?

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

What if I am injured as a result of being in this study?

Side effects directly related to participation in this research study are not expected. If you are injured or become ill because of this study, additional treatment(s) and medical care (including hospitalization) may be necessary. Your health insurance may pay for these additional treatments. If costs of care related to such an injury are not covered by your insurance, you may be responsible for these costs.

What are my rights as a study participant?

As a research study participant you have the right:

- To be told about the nature and purpose of the study;
- To be given an explanation of exactly what will be done in the study;
- To be given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- To ask questions you may have about the study;
- To decide whether or not to be in the study without anyone misleading or deceiving you;
- To stop taking part in the study; and
- To receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not to take part in or leave the study, your medical care will not be affected and you will not lose any of the benefits you would have received normally.

How will my confidentiality be maintained?

Your participation in this study will be kept as confidential as possible. All records related to your involvement in this research study will be securely stored. Your identity will not be shared.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity however will not be disclosed.

How is the privacy of my medical information maintained and what information about me may be released?

No private medical information about you will be shared. Only your doctor will have access to your private records. Results of this study that will not contain any private information about you that could identify you as a participant may be shared with:

- The research team including the Principal Investigator and other research staff.
- Mount Carmel's Institutional Review Board or Office of Research Affairs.
- The Sponsor of the study, i-Care, USA
- Food and Drug Administration (FDA).
- The Office for Human Research Protections in the U.S. Department of Health and Human Services.

Can I withdraw my consent for participation in this research study?

You can withdraw from this research study at any time. If you decide to withdraw from the research study, you will still receive medical care.

How can I get more information?

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, you should contact the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

If at any time you want to discuss your participation in this study with someone who is not directly involved with the study, or if you feel undue pressure to enroll in or to participate in this study, you may contact the:

- Mount Carmel Institutional Review Board Chairperson by telephone at (614) 546-4325, or by writing
- IRB Chairperson, c/o Institutional Review Board, Office of Research Affairs, Mount Carmel Health System, Corporate Services Center, 6150 E Broad Street, Columbus, OH 43213

In the event that you would require the number of a disinterested third party to whom complaints regarding this study may be addressed, you may contact Risk Management, Mount Carmel (614) 234-5862.

Statement of Consent and Authorization

I confirm that I have read the preceding information or it has been read to me. I confirm that I understand its contents. All my questions regarding this study and my participation in it have been answered to my satisfaction. I have been informed of the risks involved. I have been informed of my rights as a research subject. I understand that if I decide not to be part of this study or withdraw my consent, I will still receive treatment at Mount Carmel or from the researcher. I will receive a copy of this signed and dated consent form. By signing this consent form, I give permission for the use and disclosure of my protected health information for the purposes of this study, and I have not waived any of the legal rights to which I otherwise would have as a subject in a research study.

_____ _____

Subject's/Guardian's Signature* Date

_____ _____

Subject's/Guardian's Printed Name Time of Consent

_____ _____

Name of Principal Investigator Date

_____

Signature of Principal Investigator

If this consent form is signed by a legal representative of the patient/research subject (for example, the parent, or legal guardian if the research subject is a minor), a description of such representative's authority to act for the patient/research subject must also be provided.

Provide description of authority:_____