CONSENT FORM FOR OFF-LABEL USE OF BETADINE 5% FOR EPIDEMIC KERATOCONJUNCTIVITIS

Name of Subject:_____

Purpose
You have been asked to participate in an off-label treatment because you have epidemic keratoconjunctivitis (EKC). The purpose of the treatment is to provide you the opportunity to be treated with Betadine 5%® (Alcon, Inc., Fort Worth, TX). Off-LABEL means that Betadine 5% has not been specifiacally labeled by the U.S. Food and Drug Administration (FDA) for the treatment of EKC. Betadine 5% is FDA approved for irrigation of the ocular surface, and is routinely used for pre-operative antisepsis. There are no known antimicrobial treatments for EKC, however, there is medical evidence to support the use of Betadine 5% for EKC. This protocol is intended to conform with good medical practice and the best interests of the patient. This protocol is undertaken in the interest of public health. There are no commercial sponsors and no financial interests.

Procedures to be Followed
The eye(s) suffering from EKC will be irrigated with Betadine 5%. Follow-up visits at (2-3 days, 4-5 days, and 1-2 weeks) will be arranged to monitor your response.

Risks and Discomforts
The possible discomforts and risks attendant to this procedure are: conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis, chemosis, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain, eyelid edema, headache, red eye, reduced visual acuity and taste disturbance.

Potential Benefits
It is possible that the administration of Betadine 5% may result in expeditious resolution of EKC. We are, however, unable to guarantee a cure as a result of receiving this off-label treatment. We can give no guarantee that the use of this agent will be beneficial to you.

Alternatives to Participation
Other options may exist for the treatment of your EKC, including symptomatic relief without the use of anti-microbial pharmaceuticals. Your physician will discuss these alternative options in detail, at your request. Significant new findings about Betadine 5% which may affect you, or your willingness to continue, will be made available

Patient Protection / Protected Health Information

Study related records will be held in confidence. Your consent to receive this off-label therapy includes consent for your doctor and assistants to review all your Protected Health Information (PHI, i.e. medical records and other pertinent health information) as may be necessary for purposes of this participation. Your PHI may

also be inspected by governmental agencies such as the Food and Drug Administration, authorized representative(s) of the study sponsor (including its agents and/or contractors) and the Institutional Review Board (a committee for the protection of study participants).

Participation is Voluntary
Your participation is entirely voluntary and you may refuse, or discontinue your participation at any time without any penalty or loss of benefits to which you may otherwise be entitled.

I have read the above informed consent document and have had the opportunity to ask questions concerning the procedures to be used. I wish to participate in this experimental therapy. By signing this form, I am authorizing the use and disclosure of my PHI collected in connection with my participation. If I wish to revoke my authorization, I may do so at any time in writing. I shall receive a copy of this consent. My consent is valid for the duration of this study.

_____ _____
(Signature of Patient or Legal Representative) (Date)

_____
(Witness, cannot be the Researcher)

I have offered an opportunity for further explanation of this procedure to the individual whose signature appears above.

_____ _____
(Signature of Investigator) (Date)

_____ _____
(Signature of Person Obtaining Consent if other than Investigator) (Date)