Consent for Participation in a Research Study

Study Title: A Double-Masked, Placebo-Controlled, Randomized, Phase II Clinical Trial To Assess The Efficacy Of SCH1 In The Treatment Of Acute Infectious Conjunctivitis

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Sponsor: David Ritterband, MD

About this research
You are being asked to participate in a research study.

This consent 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.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this study is to find out whether a combination of two medicines will be useful to treat the problem that you have (infectious conjunctivitis, also known as "pink eye"). Each component of *combination investigational medicine* (SCH1) has been used in treating eye infections in the past, but this is the first test of a 'combination eyedrop' in humans.
What will happen to me during the study?	You will be randomly assigned to either *the combination investigational medicine* or the control and current standard of care *artificial tear eye drops*. You will need to put one drop of your study medicine in your affected

	eye every two hours while you are awake the first day, and then four times daily the following four days. You will also need to write down on a special form that we will give you exactly when you took the medicine. You will also need to write down any side effects you may experience when you take the medicine
How long will I participate?	You will be asked to spend 5 days in this study.
Will taking part expose me to risks?	▪ The treatment might not help. ▪ Right now we do not know for sure if it will help. If it does not help, your condition/disease may get worse. ▪ There may be side effects. These are listed below according to the two separate medications that make up *the investigational combination medicine*. or an increase in intraocular pressure. If you experience any of these side effects, your doctor will treat them, and the medication will be discontinued. ▪ ***Minor side effects of Prednisolone acetate 1% include:*** ▪ *Stinging/burning/itching/irritation of the eyes for 1 to 2 minutes after application* ▪ *Temporary cloudy vision* ▪ *Increased sensitivity to light* ▪ *Visual disturbance (blurry vision)* ▪ *Feeling like something is in your eye* ▪ *Minor allergic reaction* ▪ ***Rare but serious side effects of prednisolone acetate 1% include:*** ▪ *Pain behind your eyes* ▪ *Sudden vision changes* ▪ *Severe headache* ▪ *Sudden eye irritation,* ▪ *Blurred vision* ▪ *Tunnel vision* ▪ *Seeing halos around lights* ▪ *Signs of new or worsening eye infection (such as swelling, draining, or crusting of your eyes)* ▪ *Elevated intraocular pressure* ▪ ***Minor side effects of 0.2% Chlorhexidine include:***

	▪ ▪ *Stinging/burning/itching/irritation of the eyes for 1 to 2 minutes after application* ▪ *Increased sensitivity to light,* ▪ *Visual disturbance (blurry vision),* ▪ *Feeling like something is in your eye, and* ▪ *Minor allergic reaction* ▪ ***Rare but serious side effects of Chlorhexidine 0.2% may include:*** ▪ *Pain behind your eyes* ▪ *Sudden vision changes* ▪ *Headache* ▪ *Sudden eye irritation* ▪ *Blurred vision* ▪ Eye pain ▪ *Seeing halos around lights* ▪ *Signs of new eye infection (such as swelling, draining, or crusting of your eyes)* ▪ There is always a chance that any medical treatment may cause you some discomfort or harm and the drugs/procedures in this study are no different. We will do everything possible to keep you from being harmed. There may be other risks or side effects that occur which we do not know about at this time. It is important for you to tell us when you experience such a side effect.
Are there any benefits to participation?	We do not know if you will get any health benefits by taking part in this study. We do not know if *the investigational combination medicine* will help infectious conjunctivitis. That is why we are doing this study. By volunteering you are helping us learn more about conjunctivitis. We will learn more about what does or does not help. What we learn may help others with the disease you have.
What are my alternatives to participation?	You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study doctor or the research staff.

	If you decide not to take part: • You will not be in trouble or lose any rights you normally have. • You will still have the same health care benefits. • You can still get your regular treatments from your regular doctor.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?

The purpose of this research study is to find out whether a combination of two medicines will be useful to treat the problem that you have (infectious conjunctivitis, also known as "pink eye"). The individual components of SCH1, which is a combination medication, have been used in treating eye infections in the past. This is the first test of in humans as a 'combination eyedrop'.

Why is this research?

This is a research study because right now, we do not know for sure if the *combination investigational medicine* will help you. We are doing this study to find out if it will help.

SCH1 is an investigational combination medicine that has not yet been approved by the Food and Drug Administration (FDA). It is being compared to the usual treatment for pink eye which is artificial tear eye drop solution. The safety and efficacy of SCH1 is being tested in this study.

You are being asked to participate in this study because we do not know if the investigational combination medicine will help infectious conjunctivitis. That is why we are doing this study. By volunteering you are helping us learn more about conjunctivitis. We will learn more about what does or does not help. What we learn may help others with the disease you have.

How many people will take part in this study?

This research study hopes to enroll 30 participants at this site.

How long will you be in this study?
You will be asked to participate in the study, which has 3 visits that will last approximately 30 minutes for a period of 5 days.

What will happen in this research study?

In this study you will be randomized. This means that you will be assigned to a group by chance (like flipping a coin). You will have an equal chance of being in either (or any) group. The study is done this way because knowing whether you are in a group can change the results of the study. We will not tell you which group you are in. The research study staff will not know your group either. We can quickly find out which group you are in if we ever need to know for your safety.

- The investigational drop contains chlorhexidine and prednisolone acetate, a combination of two medicines already used in humans.
- The control drop contains artificial tear eye drop solution (the current standard of care), which is a liquid that does not contain any active drug ingredient.
- You will not know which one of the treatments you receive.
- Each dose of the study medicine (either the investigational drop or control drop) will be one drop.
- You will receive the first dose from your doctor today and will put the remaining doses in by yourself.

- You will need to put one drop of your study medicine in your affected eye every two hours while you are awake the first day, and then four times daily the following four days. You will also need to write down on a special form that we will give you exactly when you took the medicine. You will also need to write down any side effects you may experience when you take the

- There will be 3 visits in total. After your initial visit, you will visit your doctor on day 3 and Day 5. Safety and efficacy measurements will be taken on these visits.

- During this study there is a 1 in 2 chance that you will receive a placebo, which is a liquid that does not contain any drug (the control drop). During this time you may feel worse, or have increased symptoms such as itching, burning, or redness. Your doctor will carefully watch your condition. If your symptoms become worse and make you uncomfortable, you can withdraw from the study. You can do this at any time during the study.

Please see Table 1 below for details of the study procedures that will be done during Screen/Visit 1, Visit 2, and Visit 3.

Table 1: Schedule of Visits and Assessments:

	Screen / Visit 1	**Visit 2**	**Visit 3**
	Day 1	Day 3	Day 5
General Exams			
Obtain informed consent	X		
Review of study eligibility	X		
Medical history	X		
Vital signs	X		X
Physical Exam	X		
Patient comfort exam	X	X	X
Review of side effect	X	X	X
Review of current medication	X	X	X
Ophthalmic exams			
Best Corrected Visual Acuity (BCVA)	X	X	X
Anterior segment slit lamp exam and tonometry	X	X	X
Dilated fundus exam	X		X

Conjunctival swab
We will use a pre-packaged swab (*Visufarma Adenoplus)* to obtain a culture from your eye. This will give us information about what is causing your conjunctivitis, and allows us to better determine your response to the study medication. While the eye is still numb from the anesthetic drop used for the exam, a swab will be swept gently along the inside of your lower eyelid several times to obtain an adequate culture. You may experience mild transient discomfort.

Best Corrected Visual Acuity (BCVA)
This is a standard test of vision. You will be asked to read progressively smaller letters from a screen, one eye at a time. If you wear corrective leses, they will be worn during the test.
Anterior Segment Slit Lamp Exam and Tonometry
A slit lamp exam is an magnified examination of the front of the eye. The examiner looks through an eyepiece while you sit with your chin supported. Tonometry is the measurement of the pressure within your eye. It is performed by lightly touching a probe to the front of the eye. You may experience the sensation of mild pressure.

Dilated fundus exam
This is a magnified examination of the back of the eye. Your pupil will be dilated with an eye drop so that the back of your eye will be visible to the examiner.

If you are a woman of child-bearing potential: *The investigational medicine* may cause side effects we do not know about. After you have consented to participate in the study, you will be asked to give a urine sample at Visit 1 to check if you are pregnant. If the urine test results indicate that you are pregnant, you will not be able to stay in the study.

Tell one of the study doctors right away if:

* You are pregnant
* You get pregnant

Drugs and Devices

- The study drug SCH1 is a combination anti-infective / steroid eye drop. The product contains two FDA-approved active ingredients: prednisolone acetate and chlorhexidine gluconate.

- SCH1 is registered with the FDA as an IND (*Investigational New Drug)* so that it can be studied in clinical trials.

Birth Control

The drugs in this study may affect a baby, before or after the baby is born. As a result, women should not be in this study if they are:

- pregnant,
- breast-feeding, or
- trying to become pregnant.

If you are a woman of childbearing age, you should use birth control for the entire time you are in the study. Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

If you are a man, you should not have unprotected sex with your partner while on this study. You and your partner should use birth control for the entire time you are in the study. Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

What are the risks of the research study? What could go wrong?

- The treatment might not help.
- Right now we do not know for sure if it will help. If it does not help, your condition/disease may get worse.
- There may be side effects.
- You may have problems because of the experimental drug used in this study. These problems are called side effects. Some side effects are just a bother. Others could harm you. There may be some side effects that we don't know about yet.
- You may experience an allergic reaction if you have an allergy to any of the components of the investigational medication, which include chlorhexidine gluconate and prednisolone acetate. Please note that having a known reaction to either of these components disqualifies you from participating in this study.

Here are the known side effects that could happen with this experimental drug:
One of the components of the investigational medicine has sometimes caused an increase in the pressure inside the eye. This happens very rarely and almost never when used for only 5 days. But it has occurred in some people even after one day. We will check your eye pressure at each visit and if it increases we will stop the medication at once. This is usually all that is needed to reduce the eye pressure. However, if the pressure remains high after we stop the medicine we can give you other treatments (drops, pills) to bring the pressure down.

Another component of the investigational combination medicine has rarely caused some irritation such as itching, burning and foreign body sensation in people who have used it alone. If that happens to you we can stop the medicine or we can continue the treatment if you think these effects are tolerable. There has never been a case where either component has caused damage to the cornea of the eye at the doses you will be receiving.

Additional potential side effects are listed below, broken down by the two component medications that make up the study drug:

- ***Minor side effects of Prednisolone acetate 1% include:***
- *Stinging/burning/itching/irritation of the eyes for 1 to 2 minutes after application*
- *Temporary cloudy vision*
- *Increased sensitivity to light*
- *Visual disturbance (blurry vision)*
- *Feeling like something is in your eye*
- *Minor allergic reaction*

- ***Rare but serious side effects of prednisolone acetate 1% include:***
- *Pain behind your eyes*
- *Sudden vision changes*

- *Severe headache*
- *Sudden eye irritation,*
- *Blurred vision*
- *Tunnel vision*
- *Seeing halos around lights*
- *Signs of new or worsening eye infection (such as swelling, draining, or crusting of your eyes)*
- *Elevated intraocular pressure*

- ***Minor side effects of 0.2% Chlorhexidine include:***

- *Stinging/burning/itching/irritation of the eyes for 1 to 2 minutes after application*
- *Increased sensitivity to light,*
- *Visual disturbance (blurry vision),*
- *Feeling like something is in your eye, and*
- *Minor allergic reaction*

- ***Rare but serious side effects of Chlorhexidine 0.2% may include:***
- *Pain behind your eyes*
- *Sudden vision changes*
- *Headache*
- *Sudden eye irritation*
- *Blurred vision*
- *Eye pain*
- *Seeing halos around lights*
- *Signs of new eye infection (such as swelling, draining, or crusting of your eyes)*

If you have a dormant herpes eye infection, it is possible that one of the components of the investigational combination could cause the infection to reactivate. Please note that any history of such infection disqualifies you from participating in this study.

There is always a chance that any medical treatment may cause you some discomfort or harm and the drugs/procedures in this study are no different. We will do everything possible to keep you from being harmed. There may be other risks or side effects that occur which we do not

know about at this time. It is important for you to tell us when you experience such a side effect.

Your group may receive less effective treatment or have more side effects than the other group.

Risks to Women of Childbearing Potential and Pregnant Women

We do not know the effects of SCH1 on fertility or a fetus. For this reason, if you believe you are pregnant or have a chance of becoming pregnant, you should not take part in this study. A urine pregnancy test will be performed prior to the start of study procedures. If you are pregnant, you will not be allowed to be in the study.

If you do take part in this study, you must use a medically recognized form of birth control for one month before entering the study, while in the study, and for at least one menstrual cycle after stopping the study. If you become pregnant during the study, you will be immediately withdrawn from the study and closely monitored through your entire pregnancy.

The side effects of this experimental procedure on newborns are also not known; therefore, if you are currently breastfeeding you cannot be in this study.

What are the benefits of this research study?

The possible benefits you may experience from the investigational combination medication described in this study include releif from the symptoms of infectious conjunctivitis, however, we do not know if you will get any health benefits by taking part in this study. Because this is a randomized study, it is also important to remember that you might receive a placebo.

We do not know if the investigational combination medicine will help infectious conjunctivitis. That is why we are doing this study. By volunteering you are helping us learn more about conjunctivitis. We will learn more about what does or does not help. What we learn may help others with the disease you have.

Will I receive my results?

Clinically relevant results will be discussed at the scheduled visits.

Drug Availability After Completion of Study

The study drug may become available at a later date, but not at this time.

If you do not want to take part in this research study, what are your other choices

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study doctor or the research staff.

If you do not join this study, you have other choices for treatment. Talk to your doctor about your choices. Your other choices may include:

- Standard treatment
- No treatment
- Comfort care

If you decide not to take part:

- You will not be in trouble or lose any rights you normally have.
- You will still have the same health care benefits.
- You can still get your regular treatments from your regular doctor.

Are there any costs for being in this research study?

You will not be responsible for any cost related to research-specific visits or procedures.

This research study is funded by David Ritterband, MD. You will not have any added costs from being in this study. All study related visits, procedures and medications will be given to you at no cost. Neither you nor your insurance company will be billed for your participation in this research.

Will you receive any payments for participating in this research study?

You will not receive any compensation for participating in this research study.

What happens if you are injured while participating in this study?

If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What will happen with the information we collect as part of this research study?

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- study sponsor and/or its agents,
- other researchers
- data safety monitoring board
- clinical staff not involved in the study who may be involved in participant's treatment

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as the FDA
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Jacqueline Dauhajre MD
82-11 37th Avenue, Ste 604
Jackson Heights, NY 11372

or

Dr. David Ritterband, MD
210 E. 64TH St
New York, NY 10065

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Will my information be used for research in the future?

Information or specimens collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent.

Does the investigator of this study receive money if you take part?

The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by Dr. David Ritterband. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?

If you have any questions about the study, you may call David Ritterband MD 212-702-7313. If you have questions about side effects or injury caused by research you should call Isha Mehta DO 302-983-0280. If you need emergency care, dial 911 or go to the nearest Emergency Room.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of witness Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

_____
Witness's Signature Date

Witness's Printed Name:_____

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature Date

_____
Investigator's printed name