VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: Corticosteroid for Diabetic Macular Edema (DME) Study
Version Date: 04MAR2026
PI: Stephen Kim, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

What we have learned so far:

We have safely and successfully recruited all patients for the study and there have been no negative side effects from the study. We want to continue to follow the patients for a longer period of time to better understand factors that are associated with diabetic retinopathy progression in this large and well characterized cohort.

Key information about this study:

You are being asked to take part in this research study because you previously participated in the INflammatory MediatorS in the PathophysIology of Diabetic (INSPIRE) study. Dr. Kim and Dr. Gangaputra want to continue to follow patients for a longer period to better understand factors that are associated with diabetic macular edema. Nearly 300 million individuals have diabetes worldwide and the prevalence is rising. Over one-third of diabetic patients will develop diabetic retinopathy (DR). 5% to 10% of these individuals will suffer from vision-threatening complications. DR progresses in many patients despite preventable measures such as blood sugar and blood pressure control. DR remains the leading cause of legal blindness among working-age adults. Current diagnostic tests fail to identify early disease stages or predict disease progression. Consequently, new biomarkers and therapeutic strategies are needed.

We have previously enrolled 164 adult type II diabetic patients, aged 18 years or older in the INSPIRE study. We have also enrolled 100 patients in the same age group without diabetes who underwent retinal surgery in one eye for conditions such as, macular hole or epiretinal membrane. The purpose for this extension study is to evaluate the effects of a long-acting vs short acting corticosteroid (Iluvien vs Ozurdex).

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You will see either Dr Kim or Dr Gangaputra every 1-2 months for the next 12 months (1 year). On your first visit after consenting, you will undergo a complete eye examination, including vision, intraocular pressure measurement, dilation and imaging per standard of care. You will then receive an eye injection in your study eye of either Iluvien or Ozurdex to treat your diabetic macular edema (DME). Diabetic macular edema (DME) is a complication of diabetes where fluid accumulates in the macula, the central part of the retina responsible for sharp, central vision. This swelling can lead to blurred or distorted vision, and if left untreated, can cause permanent vision loss. Additionally, we will be taking some fluid from the front of both of your eyes (Aqueous Biopsies) to store for testing.

At each follow up visit, you will undergo a full exam to evaluate for any adverse events and repeat eye exam, any clinically indicated imaging and aqueous biopsies, as well as HbA1C testing as needed at the local lab per standard of care.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
You will be questioned about side effects at each study visit. Corticosteroid injections have been FDA approved to treat diabetic macular edema. Side effects include discomfort on the day of injection, possible worsening of cataract, possible increase in intraocular pressure, possible bleed on the surface of the eye, possible infection risk with possible loss of vision.

Aqueous biopsies are performed routinely and are generally considered minor procedures. Risk of bleeding and infection can occur but are rare. The principal investigator Dr Stephen Kim and co-investigator Dr. Sapna Gangaputra are well experienced in this procedure having performed over 1000 of them collectively in the standard care of patients with retinal disease and ocular inflammation.

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This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the "Confidentiality" section below for more information.

Please let the principal investigator or co-investigator know of any current or planned use of prescription systemic NSAIDs or regular use of nonprescription NSAIDs including aspirin.

Risks that are not known:
The following risks may include: the injection may be uncomfortable temporarily. Your doctor will numb your eye to make the procedure more comfortable. Other risks include an allergic reaction if you are allergic to fluorescein (dye) or proparacaine (numbing drop).

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:
- Delayed onset and progression of Diabetic Retinopathy and Diabetic Macular Edema

Procedures to be followed:
You will undergo a complete ophthalmic examination of both eyes including best corrected visual acuity (how well your eyes can see with corrective lenses, if needed, intraocular pressure (IOP) measurement (measure of the pressure inside the eye using numbing drops and a special device that gently touching the front surface of the eye), slit-lamp examination (the doctor will take a close look at your eye with a bright light and a special microscope, dilated funduscopic examination (eye drops will be placed inside both eyes to enlarge the pupil and the doctor will look at the inside back surface, or retina, of your eye with a bright light and a special lens), Spectral Domain Optical Coherence Tomography (SDOCT: a certified ophthalmic photography technician will obtain images of the inside back surface, or retina, of your eye at a resolution equivalent to a low-power microscope. It is effectively 'optical ultrasound', imaging reflections from within tissue to provide cross-sectional images, optical coherence tomography angiography (OCTA: similar to SDOCT that will be used to help assess the health of the blood vessels in the back of the eye), Optos (Optomap Retinal Exam) color fundus photograph y of the macula peripheral retina (color photographs will be taken of the inside back surface, or retina, of your eye), . You will have HbA1c tested at the local lab as needed and will undergo bilateral aqueous fluid biopsies. The aqueous fluid biopsy tap will occur in clinic with all aseptic precautions. The aqueous fluid is the fluid inside the eye that is constantly being produced and drained within the eye itself and occupies the front chamber of the eye from the cornea (the front clear covering of the eye) to immediately behind the pupil and around

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the lens. This area of the eye is also called the anterior chamber. During the biopsy/tap procedure your eye will be numbed with a numbing drop and sterilized with an antibiotic drop. The doctor will then remove a very small amount of aqueous fluid from the anterior chamber of the eye with a small needle and syringe through the cornea, or clear part of the eye. This aqueous humor sample will be stored in Dr. Kim's lab.

You will be randomly selected to either get a short acting corticosteroid injection, dexamethasone 0.7mg (Ozurdex) or a long-acting injection, fluocinolone acetonide 0.19mg (Iluvien). You or your physician will not be able to select the medication of choice, and the determination will be purely by chance. Both medications are safe and approved by FDA for treatment of diabetic macular edema.

You will follow with Dr Kim and Dr Gangaputra every 1-2 months for the next 12 months. At each follow up visit, you will undergo a full exam to evaluate for any adverse events and repeat all testing that was done at baseline - best corrected visual acuity, intraocular pressure (IOP) measurement, slit-lamp examination, dilated funduscopic examination, any imaging determined clinically necessary, HbA1c at the local lab as needed and bilateral aqueous biopsies.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Kim, and the core research team will have access to your name.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.
Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

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Payments for your time spent taking part in this study or expenses:
The study will provide $25 dollar gift cards to patients to cover their travel cost. Patients will receive a $50 gift card to compensate for the longer appointment times or longer travel times.
The study will provide compensation for co-pays.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.
You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Stephen Kim at 615-936-2020. If you cannot reach the research staff, please page the study doctor at 615-936-2020

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

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What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. 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 Web site at any time.

Confidentiality:
The investigators/study team will take all appropriate measures to ensure that the anonymity will be maintained according to Good Clinical Practice (GCP). You will be identified by your patient identification number, only, on case report forms or other documents submitted to the sponsor. Documents that will not be submitted to the sponsor (e.g., signed Informed Consent Forms/subject ID log) will be kept in strict confidence and under lock and key in the Clinical Trials Department office.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. It does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

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At any time, you may ask to have your sample destroyed. You should contact Dr. Stephen Kim at 615-936-2020 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no cost to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Study Results:
Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done.

Authorization to Use/Disclose Protected Health Information What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use all your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

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Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY
I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

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Legally Authorized Representative (if applicable):

_____ _____
Date Signature

_____
Relationship to subject

Impartial witness (if applicable):

_____ _____
Date Signature

Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood and aqueous samples for genetic research. What we learn about you from this sample will not be put in your health record.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

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To prevent this, these samples will be given a code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only study staff will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Giving samples for research is your free choice and you may be in the study even if you do not want your samples used or stored for gene research.

At any time, you may ask to have your sample destroyed. You should contact Dr. Kim at 615-936-2020 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

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Please check Yes or No to the questions below:
My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____

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