

**INFORMED CONSENT FORM
AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH
INFORMATION**

Sponsor / Study Title: EyePoint Pharmaceuticals, Inc. / “A Phase 3, Multicenter, Prospective, Randomized, Double-Masked, Parallel-Group Study of EYP-1901, a Tyrosine Kinase Inhibitor (TKI), Compared to Aflibercept in Subjects with Wet AMD”

Protocol Number: EYP-1901-301

Principal Investigator: John Carlson, MD
(Study Doctor)

Telephone: 909-335-8940 (24 Hour)

Address: Retina Consultants of Southern Ca
1895 Orange Tree Lane
Suite 204
Redlands, CA 92374

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns “you” and “your” should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject’s representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

Key Study Information:

Purpose	The main goal of this study is to learn how well EYP-1901 works compared with EYLEA® (aflibercept).
Risks	The most common risks include broken blood vessels in the eye and worsening of neovascular age-related macular degeneration.
Benefits	Your condition will be checked as long as you are in the study, and the study drug may help to relieve your symptoms.

Other Options	Other therapy options include other eye injections given at different timepoints, specific combination light plus dye treatments to the eye or eye laser treatments.
---------------	--

You are invited to take part in a research study because you have neovascular (Wet) age-related macular degeneration (Wet AMD). Your participation is voluntary and requires your written consent. If you decide not to take part in this study, you can continue with your current medical care. A decision to stop study participation will not impact your regular medical care or benefits to which you are entitled.

This study involves research. Participating in a research study is not the same as getting regular medical care. The purpose of a research study is to learn about a possible medical treatment; the purpose of regular medical care is to improve your health. Being in this study does not replace your regular medical care, but you may have other tests or changes in your treatments during the study.

EyePoint Pharmaceuticals, Inc. is sponsoring this global study, and it will take place in approximately 150 sites with up to 610 people with Wet AMD participating.

Before agreeing to participate in this study, it is important that you read and understand this informed consent form. It explains the purpose, procedures, benefits, risks, discomforts, and safeguards of this study. It also explains the different choices that are available to you, and your right to withdraw from this study at any time. Please read this information carefully and ask the study doctor or study staff for an explanation if you have any questions. You can take home an unsigned copy of this informed consent form to think about it or talk about it with your partner, family, or friends before deciding whether or not to take part in this study.

The Sponsor may need to let your personal doctor know that you are participating in this study. You will be asked if you agree to this on the signature page of this informed consent form.

If you choose to participate in this study, you will be asked to sign this informed consent form. You will receive a copy of this form to keep.

1. Why is this study being done?

EyePoint Pharmaceuticals, Inc. has begun a study of an investigational drug called EYP-1901 as a possible treatment for Wet AMD. An investigational drug is one that has not been approved by regulatory agencies, such as the US Food and Drug Administration (FDA), European Medicines Agency (EMA), or others. The main goal of this study is to learn how well EYP-1901 works compared with EYLEA® (aflibercept). EYP-1901 is an insert that is placed inside the eye using a needle and is designed to slowly dissolve over time, allowing the controlled release of a study drug called Vorolanib. EYLEA® (hereafter aflibercept) is an injection given in the eye and is FDA approved to treat Wet AMD.

Vascular endothelial growth factor (VEGF) and Platelet-derived growth factor (PDGF) are the proteins found in the eyes that trigger the protein pathways, leading to Wet AMD. Vorolanib works by blocking these proteins.

From here on, EYP-1901 and aflibercept will be referred to as the “study drug”.

2. How long will my participation in this study last?

You will be in this study for approximately 99 weeks (1 year and 11 months) (including the screening period), and you will need to come to the study center at least 26 times over this period.

3. What will happen during this study?

The study is divided into two periods: a screening period and a study treatment period. During each study period, you will have 1 or more visits with your study doctor at the center. The screening visit will last between 3.5 and 5 hours, but all other visits will last between 2 to 5 hours. Unscheduled visits may be added as necessary during the study.

Before any study-related tests and procedures can be done, you will be asked to read and sign this informed consent form, and then the study will begin with a screening visit. The purpose of the screening visit is to see whether or not you meet the requirements to take part in this study. If you do not meet the requirements, the study doctor will explain why and will discuss other treatment options with you.

If the study doctor decides that you meet all the requirements to be in this study, you will be enrolled and randomly assigned (like flipping a coin) to one of the following study treatment groups to receive the study drug in the “study eye”. If you have Wet AMD in 1 eye, that will be your study eye. If you have Wet AMD in both eyes, the eye which is most affected will be your study eye. Both groups will receive aflibercept at the beginning of the study then will be randomized to receive one of the following.

- EYP-1901 study treatment group: EYP-1901 (2686 micrograms)
- Aflibercept study treatment group: will receive aflibercept (0.05 mL)

You will have a 50% (1 in 2) chance of being placed in the EYP-1901 study treatment group and a 50% (1 in 2) chance of being placed in the aflibercept study treatment group. Both study treatment groups will also receive sham injections. A sham injection is an imitation of an eye injection using a blunt cannula, and no study drug is given (like a placebo [an inactive substance]). A blunt cannula is a small, thin tube without a sharp point. Researchers use a sham injection to see if EYP-1901 works better or is safer than taking nothing.

You, the study doctor, the Sponsor, and many other people involved in the study will not be told which study treatment group you are in. However, some of the study staff will know which study

treatment group you are in. This information will also be given to the study doctor if it becomes necessary for your safety.

Description of the procedures and assessments

- **Demographics and medical history**: Includes questions about your demographics (for example: race, ethnicity, and age), your medical history, and any medications you have taken in the last 30 days. You will also be asked about contact use and eye injuries.
- **Eye examinations**: During the screening visit and throughout the study, you will have several eye tests. Both the front and back of your eye will be examined. Some of these tests may occur on both eyes. Eye drops may be used to make your pupils (center part of your eye) look larger (dilated) and easier to look through. These drops can make your vision blurry and sensitive to light for a few hours. You should protect your eyes from bright light after dilation. You should bring sunglasses to your appointment to protect your eyes from bright light while your pupils are dilated, and you should arrange for someone to drive you home after your test or the study staff can arrange a taxi for you. If you do work that requires clear vision, such as operating heavy machinery, you should also arrange to take the rest of the day off.
 - **Best Corrected Visual Acuity (BCVA)**: You will sit in front of an eye chart to read the letters and test the sharpness and accuracy of your vision.
 - **Color Fundus Photography**: A study-certified photographer will take color photos of the back (retina and optic nerve) of both eyes.
 - **Dilated Ophthalmoscopy**: The study staff will shine a bright light into your eyes to view the back of your eyes (retina) after dilation of the pupils.
 - **Endothelial Cell Count**: The cells in the front part of your eye (cornea) will be examined for quantity, shape, and size. This will only be performed if your study center has the required equipment. The study doctor will let you know if this applies to you.
 - **Fluorescein Angiography**: A dye called fluorescein will be injected into a vein in your arm (intravenous, IV) and then a camera is used to take pictures of the blood flow in the retinal layers at the back of the eye.
 - **Optical Coherence Tomography**: You will look at a light while a safe laser scans the back of your eyes to take pictures of the retinal layers.
 - **Optical Coherence Tomography with Angiography**: A series of advanced 3D scans of the back of the eye and blood vessels around the retina will be taken. This will only be performed if your study center has the required equipment. The study doctor will let you know if this applies to you.
 - **Slit lamp biomicroscopy**: The front of your eyes will be examined with a special magnifying microscope (called a slit lamp).
 - **Fundus Autofluorescence**: Your eye will be examined to view and map the healthy and unhealthy sections of the back of your eye using bright light. This will only be performed if your study center has the required equipment. The study doctor will let you know if this applies to you.

- **Intraocular Pressure:** Your eye pressure is measured with a device at each visit and after an injection. A numbing eye drop may be used before the eye pressure is checked.
- **Post-injection assessment:** The eye pressure in both eyes and blood flow in the study eye will be checked after all eye injections.
- **Vital signs:** Your heart rate, breathing rate, blood pressure, and body temperature will be measured.
- **Questionnaire:** You will be asked a series of questions at the study center. Your responses will help the study doctors and Sponsor understand how your Wet AMD affects you.
- **Laboratory tests:** Blood and urine samples will be collected.
 - Blood will be taken during the study. The blood will be taken from a vein in your arm for the following:
 - 20 mL (a little over 3 teaspoons at each scheduled visit) for different blood tests to check the cells and chemicals in your blood (including blood clotting ability). If your center is participating, blood pharmacokinetic (PK) samples will be taken to examine how your body processes the study drug. If PK testing applies to you, the PK sample for Week 8 will be taken between 3 and 7 days after your Week 8 injection.
 - A urine sample will be collected to check that you are healthy and that you may safely take part in the study.
 - If you are a woman able to become pregnant, a urine sample will be collected at different timepoints, including before you receive the study drug to make sure you are not pregnant. A positive urine pregnancy test will be confirmed using a blood pregnancy test.
- **Study drug administration:** A local anesthetic will be given first to numb the eye. The injection into the eye will be administered by a study doctor.

4. **What do I have to do?**

During this study, you will have the following responsibilities:

- Tell your study doctor if you have any allergies, including drug allergies. If you are not sure, ask your family/personal doctor.
- Attend all scheduled visits.
- Follow the study doctor's instructions about whether you may continue to take your regular prescribed medications or over-the-counter medicines.
- Tell the study doctor about any changes to your current medications, illnesses or injuries, unexpected or troublesome side effects, or problems that occur.
- Tell the study doctor if you plan to have an elective surgery or any other medical treatment or procedure.
- You should take care when performing activities that require mental alertness, judgment, or physical coordination such as driving or operating machinery, or do anything that requires

you to be alert, for at least 12 hours after study treatment and for 3 hours after study visits (dilated eye exam), unless you feel secure and safe to do so.

- Report any pregnancy (a female study subject or a female partner of a male subject) to the study doctor immediately.
- You should continue to make regular visits to your family/personal doctor, regular eye doctor or any other special doctors you were seeing before starting the study because being in the study does not replace regular medical care.
- Contact the study doctor if you find you have any questions about the study after you sign this informed consent form.

5. What are the risks and possible discomforts?

Any study has risks, which may include things that could make you sick, make you feel uncomfortable, or harm you. You might experience side effects related to the study drug (and rescue medication, if applicable) while participating in the study. All subjects in the study will be watched carefully for any side effects; however, the study staff does not know all the side effects that the study drug may have on you. Because the study drug is investigational, there may be rare and unknown risks. The study staff may give you medicines to help reduce side effects. These side effects may be mild or serious. In some cases, these side effects might be long lasting or permanent and may even be life threatening.

Taking part in this study involves some risks and possible discomfort to you.

Side effects observed after ANY injection into the eye:

- Eye redness
- Eye pain
- Vision changes
- Inflammation
- Increased pressure in the eye
- Damage to the retina, choroid, crystalline lens, or cornea (structures of the eye)
- Intraocular hemorrhage (bleeding in or around the eye)

There is also the possibility of an eye infection. After the study injection, you may receive eye drops with instructions on when to use them to reduce the possibility of an eye infection occurring. Any of these complications may lead to severe, permanent loss of vision, blindness, or loss of the eye.

Possible risks/side effects associated with the study drug:

- If EYP-1901 or aflibercept do not work for you, you may see an increase in your Wet AMD symptoms.
- EYP-1901 may cause unpleasant side effects or reactions. The most commonly reported side effects in other studies of EYP-1901 were:

- Broken blood vessels in the eye
- Worsening of neovascular Age-Related Macular Degeneration
- Eye fluid leakage
- Eye discomfort
- Reduced vision

As with any drug, on rare occasions, unexpected reactions, including severe allergic reactions or immune response may occur, which may require risk of cardiopulmonary resuscitation (CPR) and even lead to death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating

The most common side effects (greater than or equal to 5%) reported in patients receiving EYLEA® (aflibercept injection) were:

- Broken blood vessels in the eye
- Eye pain
- Cataract
- Clumpy collagen fibers within the vitreous (gel like fluid that fills the eye) casting shadows on the retina
- Vitreous fibers pulling away from the retina
- Increased eye pressure

There is also a potential risk of blood leakage and bleeding from broken blood vessels and blood clotting.

Possible discomforts and risks associated with the study procedures:

- Blood samples: Taking blood from your arm may cause faintness and/or swelling, pain, redness, bruising, bleeding, or infection (infection rarely happens) at the site where the needle is inserted.
- Eye examinations: Risks of study-related eye examinations are the same as with any eye examinations you may have had in the past. Dilating drops or anesthetic drops may sting when they are first placed into your eyes. Dilation of your pupils may cause some temporary glare and blurring of vision. The drops could cause an allergic reaction, and, if they are contaminated, they could cause an infection. This problem is rare. Also, bright lights during the different eye examinations may cause temporary discomfort.

- **Eye pressure measurement:** Anesthetic drops may sting when placed in the eye. The device used to check the eye pressure may rarely cause a scratch on the front surface of your eye, called a corneal abrasion. This can result in temporary blurring of vision and rarely infection.
- **Fluorescein angiography:** The risks of the injection of fluorescein dye include temporary pain, bleeding, and bruising where the needle enters the skin. There is a small chance of fluid leaking into the surrounding tissue. Mild reactions to the fluorescein dye itself may cause skin and urine discoloration; a rash; red, itchy bumps on the skin; a whistling sound when breathing; or temporary nausea or vomiting in a small percentage of subjects. If you previously had a mild reaction when having this test, your study doctor may give you some medication before you have this test to reduce any reaction.
- **Additional unknown risks:** There may be side effects and discomforts related to study procedures that are not yet known.

6. What about birth control, pregnancy, and breastfeeding?

The study drug may involve unknown risks to a pregnant woman, an embryo, a fetus (unborn baby), or a breastfeeding infant.

Women

If you are pregnant, planning to become pregnant, or breastfeeding a child, you cannot take part in this study.

Before entering the study, a pregnancy test will be done for all women able to become pregnant. This test might not detect an early pregnancy. Pregnancy tests will be repeated during the study.

Female subjects who are able to have children must use an effective birth control method before the initial dose, during study treatment, and for at least 3 months after leaving the study.

Effective and acceptable birth control methods include: oral contraceptive pill (such as Ortho Tri-Cyclen[®]); injection (such as Depo Provera[®]); implant (such as Norplant[®]); patch (such as Ortho Evra Patch[®]); vaginal ring (such as NuvaRing[®]); intrauterine coil (such as Mirena[®] coil); intrauterine device (IUD) with or without hormones; a barrier method (such as latex condom, diaphragm, or cap) used with an additional form of contraception (such as a sponge, spermicide, hormonal contraceptive pill, or injection); a vasectomized partner; or abstinence (if in line with your usual or preferred lifestyle).

If you become pregnant during the study, you should tell the study doctor as soon as possible. You should continue your participation in the study only if the study doctor determines it to be safe and beneficial. The Sponsor may want to receive updates on the progress of the pregnancy and its outcome.

Men

There are no birth control requirements for male participants in this study. If your partner is planning to become pregnant, you should discuss it with your study doctor.

7. What are the benefits of being in this study?

There is no guarantee that you will receive any benefits. However, you will be helping others by contributing to medical research. You may feel that you are benefiting in the following ways:

- Your condition will be checked as long as your participation in the study lasts. However, services provided, and evaluations carried out as part of the study should not be seen as a substitute for a careful evaluation, ongoing medical care, or follow-up by your family/personal doctor.
- The study drug may help to relieve your symptoms.

You have the right to be informed of the overall results of this study.

8. What other options are available if I do not take part in this study?

You do not have to take part in this study to treat your Wet AMD. There are other therapy options, such as other eye injections given at different timepoints, specific combination light plus dye treatments to the eye or eye laser treatments. The other eye injections have similar risks to the ones already listed. The light/dye treatment may cause itching, chest or back pain, shortness of breath, light sensitivity, and an increase in blood pressure. The eye laser treatment involves an extended duration of the use of bright light, may cause pain or soreness in the eye during and after the treatment, and may cause decreased vision afterwards.

Your family/personal doctor, your regular eye doctor or the study doctor can answer any questions that you have about other treatments. You can also contact your personal eye doctor to ask about other research currently being done in the treatment of Wet AMD.

9. What if I get harmed or injured during the study?

In the event that any study-related activities result in an injury, diagnosis and treatment will be made available by the study doctor, including first aid, emergency care, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company.

If you cannot be seen by the study doctor, get the medical care that you need right away and inform the healthcare professional treating you that you are participating in this study. Contact the study doctor listed on the first page of this form.

If you require medical treatment for an illness or injury that is a direct result of the study or from procedures done for the purpose of this study (and not the result of natural disease progression), you may be entitled to reimbursement for reasonable and necessary costs of such treatments that are not covered by your medical insurance or any other third-party coverage. You will need to provide the Sponsor with medical documentation supporting the diagnosis and need for treatment, as well as receipts for out-of-pocket medical expenses for such treatments not covered by your medical insurance.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare

By signing this document, you will not lose any of your legal rights or release anyone involved in the study from responsibility for mistakes or negligence.

10. What are the costs for participation and will I be paid?

This study is being funded by EyePoint Pharmaceuticals, Inc., who appreciates your involvement in the study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company. You will receive no direct payment for taking part.

However, for your time and inconvenience related to your participation in this study, you will be reimbursed according to the following:

\$125 for Visits 1, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, Early Termination (ET), and Week 9 PK visit.

\$187.50 for Visits 2, 3, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26.

You will be paid after each completed visit in the study. If you do not complete the study, for any reason, you will only be paid for the study visits you do complete. If you have any questions regarding your compensation for participation, please contact the study doctor at the telephone number listed on page 1 of this consent document.

Optional travel service

The Sponsor is offering support with travel arrangements for participants thereby reducing the burden of taking part. Travel expenses will be booked through Broadway Elite or Lyft so you will not pay out-of-pocket for these.

The study staff will schedule transportation for you and provide additional information about how to contact these services should you require support from either travel provider.

If you choose to use Broadway Elite or Lyft, you will be required to provide personal details such as your name, phone number, home address and email address. This information will be held securely and used to manage your travel, accommodation and expense claims for each study center visit.

Please note that travel services are optional and if you choose not to use the service at any time, this decision will not affect your participation in the study itself.

11. May I or someone else stop my participation after the study has begun?

Taking part in this study is voluntary. You can leave the study at any time for any reason, and your regular medical care or benefits to which you are entitled will not be impacted.

If you are considering or have already decided to leave the study, you should contact the study doctor to discuss the safest way to leave the study. This may involve completing some final tests and examinations. You should also contact your family/personal eye doctor so they can provide you with the best course of action for your continued care.

If new findings that could affect your safety and willingness to participate in this study are identified while you are in the study, you will be told as soon as possible so you can decide whether to stop or continue participating in the study. If this happens, and you decide to continue participating in the study, you will be required to sign a new informed consent form.

Sometimes the study doctor or EyePoint Pharmaceuticals, Inc. may decide it is best for you to stop the study drug or remove you from the study (even if you do not agree). They will discuss this with you. Possible reasons for doing so include the following:

- It is in your best interest.
- You have a side effect that requires you to stop participating in the research study.
- You need a treatment that is not allowed in this research study.
- You become pregnant.
- The research is canceled by the FDA or the Sponsor.
- You are unable to take the study drug.
- You are unable to keep your scheduled appointments.

12. What medical care will I receive when my participation in this study ends?

When you leave the study, you will be under the care of your regular eye care provider, who will decide the best way to treat your Wet AMD. EYP-1901 will no longer be available to you.

13. What will happen to the samples that I provide?

The blood and urine samples that you give will be sent to a central laboratory and used only for the tests specified in this document and destroyed after the tests are completed.

No other analyses will be performed without your approval and the approval of the ethics committee. You have the right to refuse permission for these tests to be done, and you may (at any time) request that your samples be destroyed (if they have not yet been processed). In this event, your samples will not be used for any new tests; however, the information already gathered from your samples will be retained for the integrity of the study.

14. What happens with my data and other personal information?

A description of what will happen to your data and other personal information is included in the authorization that you should read and sign to be able to participate in this study. The authorization for this study is attached as Appendix 1 (below). Your identity will not be disclosed unless required by law.

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the Sponsor or persons working on behalf of the Sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on <http://www.ClinicalTrials.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 Web site at any time.

15. Who can I contact if I have a question?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By mail:

Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044

- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00081476

16. Emergency contact information

The study staff/Sponsor needs an emergency contact if they are unable to reach you to discuss important information about the study or in case of an emergency. Please provide the name and phone number of a person the study staff Sponsor can contact:

Name: _____

Relationship to Subject: _____

Phone Number: _____

Consent to Participate

By signing this informed consent form, I agree to the following:

- I have read and I understand this informed consent form.
- I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.
- I understand the risks of taking part in this study as described in this informed consent form.
- I freely consent to receive the study drug under the study doctor's care. I understand that there is no guarantee that I will receive any benefits from taking part in this study. By voluntarily consenting to participate in this study, I will follow the study doctor's instructions.
- I understand that I am free to withdraw from the study at any time for any reason. I will tell the study doctor if I decide to withdraw so that my participation may end in an orderly manner and my future care can be discussed. I understand that my study doctor can stop my participation in the study at any time. Withdrawing from participation at any time will not cause any penalty or consequences to my quality or standard of care.
- I understand that I will be told of any new information that might relate to my willingness to continue in the study.
- I understand that relevant personal data may be used for the purpose of this research study. The monitor(s), auditor(s), institutional review board/independent ethics committee, and regulatory authority(ies) will be granted direct access to my original medical records for verification of research study procedures and/or data, without violating my confidentiality, to the extent permitted by applicable laws and regulations. By signing this written informed consent form, I or my legally authorized representative authorize such access.
- I understand that I cannot participate in another research study while taking part in this study.
- I understand that I will receive a signed and dated copy of this informed consent form for my records.
- **I consent to have the study doctor contact my personal doctor(s). Yes No**

My consent to participate in this study does not take away any legal rights in the case of negligence (carelessness) or other legal fault of anyone who is involved with this study.

Name of subject (print)

Signature of subject

Date (dd/Mmm/yyyy)

Person conducting consent (STAFF CONFIRMATION)

By signing below, I show that:

- I have explained the study to the potential study subject and what their participation will involve.
- I have given the potential study subject the chance to ask questions and I have answered them to his/her satisfaction.
- I have given the potential study subject enough time to think and decide whether or not he/she wants to take part in the study.
- I confirm that the subject freely provides his/her consent, without signs of dissent.
- I explained that he/she may talk with others before making a decision.
- A copy of this informed consent form has been provided to the study subject.

Name of study doctor or person administering consent (print)

Signature of study doctor or person administering consent

Date (dd/Mmm/yyyy)

Legally Authorized Representative Consent

As the legally authorized representative for _____, I have read this informed consent form. I have been given the chance to ask any and all questions that I had about the study, and all questions that I asked were answered to my satisfaction. I understand the risks and benefits of taking part in the study, as described in this informed consent form. I affirm that I have the legal right to sign this form on behalf of _____.

I give my consent for _____ to take part in this study under the conditions stated above.

Name of legally authorized representative (print)

Signature of legally authorized representative

Date (dd/Mmm/yyyy)

Authority of legally authorized representative to act on behalf of Subject

Impartial Witness (If Applicable)

I am an impartial witness and I confirm that I was present during the entire informed consent discussion. I attest that the information in this informed consent form was accurately explained and apparently understood, and that the consent to participate was given freely.

Name of subject (print)

Name of impartial witness (print)

Signature of impartial witness

Date (dd/Mmm/yyyy)

Appendix 1: Authorization To Use And Disclose Protected Health Information

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Syneos Health.
- Representatives of EyePoint Pharmaceuticals, Inc.
- Representatives of the Institutional Review Board (IRB) that reviews this study.
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and Sponsor and need to access your information to conduct this study.
- Other study doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs/devices.
- For other research activities related to the study drug.

Except for instances above, your health data will not be shared with others unless required by law.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Printed Name of Subject

Signature of Subject

Date

Printed Name of Legally Authorized Representative

Signature of Legally Authorized Representative

Date

Authority of Legally Authorized Representative to act on behalf of Subject

Name of study doctor or person administering authorization

Signature of study doctor or person administering
authorization

Date (dd/Mmm/yyyy)

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (IF APPLICABLE)

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

Printed Name of Impartial Witness

Signature of Impartial Witness

Date