IRB APPROVED
AS MODIFIED
Dec 16, 2024

# Information Sheet and Consent Form

**TITLE:** A NON-INTERVENTIONAL, OBSERVATIONAL STUDY TO EVALUATE TREATMENT PATTERNS AND SAFETY OF AVACINCAPTAD PEGOL (ACP/IZERVAY™) IN ROUTINE CLINICAL PRACTICE IN PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION

**PROTOCOL NO.:** 3021-MA-3543
WCG IRB Protocol #20243504

**SPONSOR:** Astellas Pharma Global Development, Inc.

**INVESTIGATOR:** John P. Carlson, MD
1895 Orange Tree Lane
Suite 204
Redlands, California 92374
United States

**STUDY-RELATED PHONE NUMBER(S):** 909-335-8940 (24 hours)

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

## RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

**How long will I be in this research?**
We expect that your taking part in this research will depend on how long you are treated with IZERVAY™ but will not be longer than 3-5 years.

**Why is this research being done?**
The purpose of this research is to better understand patient experiences, treatment, management and safety of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) when treated with IZERVAY™ eye injections.

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**What happens to me if I agree to take part in this research?**
If you decide to take part in this research study, the general procedures include collection of your medical history, medications and procedures from approximately 5 years before starting treatment with IZERVAYTM and during treatment follow-up. At some visits, you will be asked questions about your vision.

**Could being in this research hurt me?**
The most important risks or discomforts that you may expect from taking part in this research include the risk of accidental disclosure of your personally identifiable information and you may feel uncomfortable, sad, or embarrassed by some of the questions.

**Will being in this research benefit me?**
It is not expected that you will personally benefit from this research. Information learned from the study may help other people in the future.

**What other choices do I have besides taking part in this research?**
Your alternative is to not participate in this research.

**What else should I know about this research?**
Other information that may be important for you to consider so you can decide whether to take part in this research is your information collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies, unless you consent to this.

## DETAILED RESEARCH INFORMATION

Dear Potential Study Participant,

You have been asked to take part in this research study. The sponsor of the study is Astellas Pharma Global Development, Inc. (Astellas).

To help you decide, this **informed consent form** will explain what to expect.

**Informed consent** means agreeing to take part in this study after you fully understand what that means.

Before you decide if you want to take part in this study, please read this informed consent form carefully. It explains what is involved if you choose to participate.

After that, if you want to take part in this study, **you must sign** this informed consent form. You will be given access to a copy of this signed Consent form and Authorization for your records. You will not lose any of your legal rights if you sign and consent to join this study.

If you choose not to take part, you will not face any penalties or lose any benefits. You are also **free to leave** at any time after joining. You do not have to give a reason why.

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It is your choice to take part in this study, and you should not feel pressured. You can speak with your **study team** about any questions and concerns you might have.

Thank you for considering this study.

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An Institutional Review Board (IRB) is an independent group of people who review research to protect the well-being and rights of participants. This study has been reviewed and approved by an IRB. They did not raise any objections to the study on ethical grounds.

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# STUDY OVERVIEW

**Why is this study being done?**
This study is being done to better understand patient experiences, treatment, management and safety of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) when treated with IZERVAY™ eye injections.

**How long will the study take?**
Your participation in the study will depend on how long you are treated with IZERVAY™ but will not be longer than 3-5 years from when you sign the consent form. Your participation may continue even if you end treatment with IZERVAY™.

**How many people will take part in this study?**
Roughly 1000 people in the US will take part in this study.

**How do I know if I can take part in the study?**
You may be able to take part in this study if:

1. You have GA secondary to AMD.
2. You and your doctor have already decided to begin treatment with IZERVAY™ injections in at least one of your eyes for the first time. IZERVAY™ is not being given to you by the sponsor as part of this study.

You will not be able to take part in this study if:

1. You are not able to be safely treated with IZERVAY™. Your doctor will talk to you about this.
2. You are in an investigational program with interventions outside of routine clinical practice.
3. You have already received IZERVAY™ in both eyes.
4. You have received any medication similar to IZERVAY™ (such as Syfovre®) in either eye within the last 90 days.

**What happens if I do not take part in this study?**
Your participation in this study is completely voluntary. You can decide to take part or not to take part. If you decide not to take part, you will not face any penalties, it will not affect your rights, your treatment or your relationship with your doctor. You will continue to receive routine care from your doctor without being in a study.

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**Who is leading this research?**
The study doctor listed above is running this study at your study site and receiving payment through a contract with Astellas.

Astellas is working with IQVIA, a contract research organization, to coordinate the day-to-day management of this study across multiple study sites in the US.

# STUDY DETAILS

**What will happen to me if I take part in this study?**

- Participating in this study will not affect your doctor's choice of treatment, and your doctor will decide what treatment you will receive. You will visit your doctor as usual (as arranged by your doctor). Whether or not you decide to participate in the study will not affect the medicine/treatment your doctor selects for you.
- If you take part in this study, your study doctor will provide information to a database about your medical history, medications and procedures, how you are feeling, results of your eye exams and reasons why you chose to start or switch to new medications. Information about your medical history, medications and procedures will be collected from approximately 5 years before starting treatment with IZERVAY™ and during treatment follow-up.
- Your study doctor will also provide any eye images taken as part of your routine care, but only if you consent to future research.
- Your study doctor will collect this information when you first join the study and at each visit you make to the doctor's office.
- At some visits, you will be asked about 16 questions about your vision.
    - For example, the questions will ask about how bad your vision loss has been over the past 7 days, how blurry your vision is, how difficult it is to see in low light or how difficult it is to drive. Your answers to these questions will also be entered in the database.
    - These questions will be asked when you visit your study doctor at roughly 6, 12, 18, and 24 months after you sign consent and then yearly until the end of the study.
- If the study team is unable to reach you, the study team may follow up with your family doctor unless you withdraw your consent to collect your personal information.

**What if I want to stop taking part in the study before it is finished?**
You can stop taking part in the study at any time. You should tell your study team about your choice.

Furthermore, the entire study or your participation in the study could be stopped at any time without your consent for any reasons by the study team or the sponsor.

# RISKS AND BENEFITS

**What are the possible risks?**
There will be no treatment administered as part of the study. You may feel uncomfortable, sad, or embarrassed by some of the questions. If you become uncomfortable with any of the study questions, you can always decline to answer, or stop participation at any time.

There are non-physical risks associated with taking part in this study, such as the risk of accidental disclosure of your personally identifiable information. However, steps have been taken to help ensure this will not happen. You will read more about the protection of your information later in this form.

There could be risks associated with the administration of IZERVAY™, which is prescribed by your doctor. Your doctor has discussed these risks with you before prescribing IZERVAY™. You can find more information in the IZERVAY™ patient information leaflet. If you have any questions or concerns regarding the risks or safety of IZERVAY™, please speak with your doctor.

**What are the possible benefits of taking part?**
You will not get any benefits from taking part. This study is purely for research purposes. Information learned from the study may help other people in the future.

# YOUR CHOICES

**What choices can I make?**
**As a study participant, you can make the following choices:**

- **You can choose to stop taking part in this study at any time** by talking to your study team. You do not have to give a reason why. You will not face any penalties.
- **You can choose to stop the study team from collecting, using, and sharing any new or additional personal information.** However, if you leave this study early without withdrawing access to your personal information, your study team might still continue to collect it. If you have experienced a side effect, we may have to share your personal information for safety reasons.
- **You can choose to see and copy your own study information after the study,** for as long as the study doctor/study team holds it.

**You cannot:**

- stop your study team from sharing and using personal information they have already collected,
- stop your study team from looking at your personal information if you experience a side effect,
- take part in this study if you do not let the study team see, use, and share any of your personal information.

# PRIVACY AND PERSONAL INFORMATION

**Authorization to use and disclose protected health information for research:**

The U.S. government issued a rule to protect the privacy of individuals (the Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). This section is referred to as an "Authorization," and it explains how your PHI will be used and disclosed (shared) for purposes of the research study and describes your rights with respect to such information.

If you agree to take part in this study, your personal information will be processed as set out in this information sheet and consent form. Processing includes, for example, collecting, using, and disclosing your personal information.

You do not have to sign this Authorization, but if you do not, you cannot participate in this research study. You may choose to withdraw this Authorization to Use and Disclose Protected Health Information for Research at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to the address indicated at the beginning of this document.

**What kind of information will be collected from me?**
Your study team will collect, share, and use the following types of **personal information** from you:

- information about your identity such as your name, address, and phone number,
- your age, ethnic origin, racial background, gender, sex at birth, height and weight,
- your medical information, including information from other hospitals/institutions, such as your physical health, mental health, and past treatments,
- your test results,
- images taken of your eyes, if you consent to optional future (secondary) research and
- other information you give to the study team, which may include insurance information and limited financial information e.g., such as your debit card number, in case you want to receive payment to your bank account.

Your study doctor will hold your personal information in a medical file in their office. Astellas, its representatives, and competent authorities will be able to access your medical file only to monitor and help run the study properly. Astellas will not get or keep a record of your direct personal identifiable information.

Your study doctor will also record information from your medical file in the Study Records. These Study Records will identify you with a code instead of your name or other direct identifying information (such as your address). The code with your name can be matched only at the study site.

Your medical files may also be reviewed remotely (outside of the study site) in order to check the information and verify the clinical study procedures, without breaking your confidentiality. If your medical files are reviewed remotely, the records will include your code but will not include your name or other directly identifiable information, unless these records will be reviewed directly through the study site's secure electronic medical records portal or through other secure viewing platform where permitted by local regulations and health authority guidance.

Astellas needs to use your coded medical information from the Study Records to run the study and to use and publish the results of the study.

Your study doctor and the study team at the study site need to use personally identifying information such as your name, address, and phone number to check that your information is correct.

Astellas needs your permission (or "consent") in order to use your data, and by signing this form, you are consenting to this use. If you do not consent to your personal information being collected, shared, and used, you will not be able to take part in the study.

**How will my personal information be used?**
Your Study Record, including your coded medical information, will be used for:

- running the study,
- seeing if the study is running properly, safely, and legally.

Your Study Record will be kept by Astellas for 5 years after the study ends (i.e., after the final report). If eye images are collected from you for future research, they will be kept by Astellas for 5 years after the end of the future (secondary) research.

Astellas may also use your Study Record for:

- sharing with researchers of this study, its affiliates, other researchers, companies and institutions,
- use in reports or public scientific presentations, and
- optional use in secondary research, now or in the future where these uses may include but are not limited to activities related to quality, safety, development, innovation, training, testing, evaluation of artificial intelligence systems, medical devices, and digital health applications. Your images will only be included in the Study Record if you consent to secondary research.
- However, Astellas will not reveal your identity if your Study Record is used for these purposes.

**You can decide if you want your Study Record to be used for future (secondary) research towards the end of this document.**

**Who will be able to see my personal information?**
As mentioned above, personally identifiable information will be accessible only to the study doctor and the study team to conduct the study. Non-medical personnel acting on behalf of the sponsor who are bound by a duty of confidentiality as well as health authorities such as, the Department of Health and Human Services, and Institutional Review Boards may also be given access to this personal information only to monitor and verify that the study is carried out in compliance with legal and quality requirements.

The following people will be able to see your personal information:

- Astellas and its present or future affiliates,
- research, collaboration, and licensing partners
- study monitors appointed by Astellas or Astellas' service providers to check how the study is going,
- auditors/inspectors appointed by Astellas or Astellas' service providers or by health and regulatory authorities to check that the study is being run properly,
- members of the Institutional Review Board.

Some of the parties above may not be located in the country where you live. If your personal information is shared with another country:

- Data protection laws may not be as strict as in the country where you live,
- The personal information may be shared with another party not listed above, and
- the people and organizations that get your personal information may not be legally required to protect the privacy of your personal information.

Astellas is taking proper safeguards to protect your personal information. One of these safeguards is special contract clauses, known as Standard Contractual Clauses. They make sure that personal information that is shared between companies in the Astellas group is safe. Astellas is taking similar safeguards with third party service providers and partners. We can give you more details about these contracts if you want.

**What are my rights in relation to the processing of my personal information?**
You may have the right to see and copy your personal information for as long as the study doctor or the study team holds it.

However, you may not be able to see some of your personal information until after the study is finished (because knowing about the details can influence the outcome of the study).

You can withdraw consent and stop your study team from collecting, using, and sharing your personal information. If you withdraw from the study and withdraw your Authorization to Use and Disclose Protected Health Information, they will not collect any new information about you.

However,

- information they had already collected will still be used in order to comply with legal obligations and to support the purpose of the study, and
- you will not be able to take part in the study anymore.

If you withdraw consent, we will still protect your personal information under the law. Your decision to withdraw consent or not to participate will not involve any penalty or loss of benefits to which you are entitled.

You may also add, correct, update, change, and delete parts of your personal information or ask the restriction of processing or object to such processing. However, you may not be able to if:

- these rights conflict with legal and/or official duties (such as documentation and reporting)
- the clinical study would become impossible or very difficult as a result.

If you wish to withdraw consent, change your personal information, or ask any questions, you can talk to:

- your study doctor, or
- the study team, or
- the data protection officer.

They can contact Astellas for you if needed.

If you withdraw from the study but do not withdraw your Authorization to Use and Disclose Protected Health Information, new protected health information may be collected until this study ends.

For sites in California, Delaware, Indiana, Illinois, and Washington, this permission will be good until December 31, 2070. For all other sites, this Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

You may also contact the sponsor's Data Protection Officer at privacy@astellas.com with questions about the use and protection of your Personal Information in this study.

# MORE INFORMATION

**Where can I find more information about this study?**
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.

**Who can I talk to for more information about this study?**
If there is anything you do not understand in this document or if you have other questions about this study, you can talk to:

- your study team,
- your study doctor and nurse.

If you have any questions, concerns or complaints about the study or questions about your rights as a study participant, contact:

- WCG IRB at 855-818-2289 or clientcare@wcgclinical.com

**Will I be paid for taking part in this study?**
Yes, you will be paid for taking part in this study.

To thank you for your time and any inconvenience related to the screening procedures and answering the questionnaires in this study, you will be offered $25 USD for completing screening and $5 USD each time you complete both questionnaires. Compensation will be provided to you by a third-party vendor who has access to your personal information (full name and email address) and what payment you are owed. They receive no information on your study results. Depending on which payment modality you choose, you may need to provide your debit card number or your phone number.

**Will it cost me anything to take part in this study?**
There is no cost to you to take part in this study.

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# PROVIDING YOUR CONSENT

The original signed version of this form will be filed with the study doctor. You will receive a signed copy of this statement of consent and Authorization, as well as a signed and dated copy of the Experimental Subject's Bill of Rights.

By signing below, I agree that:

- I have read this entire document and understood it.
- I have had time to ask questions to my study team and study doctor and all my questions were answered.
- I will not lose any of my legal rights by signing below.
- I grant my consent that my personal information can be processed, used, and shared as described in this document including any possible transfer of this information to other countries as mentioned above. In those countries, data protection laws may not be as strict as in the country where I live.
- If I am taken out of this study before it is finished, the study team can follow up with my family doctor to ask about side effects.
- If I stop allowing my study team to collect my personal information, information that was already collected may still be used.
- I authorize the release of my medical records and protected health information related to this study.
- **I choose to take part in this study, and it is my own decision.**

| **Name of participant:** | **Signature:** | **Initials** | **Date (dd/MMM/yyyy):** |
|---|---|---|---|
| | | | |
| **Name of person obtaining informed consent:** | **Signature:** | **Initials** | **Date (dd/MMM/yyyy):** |
| | | | |

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WITNESSED ORAL ICF: IF APPLICABLE
I have witnessed that this document was read to the potential participant, and they have had the chance to ask questions. I confirm that the potential participant has given consent and it is their own decision.

| **Name of participant:** | **Signature:** | **Initials** | **Date (dd/MMM/yyyy):** |
|---|---|---|---|
| | | | |
| **Name of witness:** | **Signature:** | **Initials** | **Date (dd/MMM/yyyy):** |
| | | | |
| **Name of person obtaining informed consent:** | **Signature:** | **Initials** | **Date (dd/MMM/yyyy):** |
| | | | |

| (OPTIONAL) CONSENT ADDENDUM FOR FUTURE (SECONDARY) RESEARCH USING STUDY RECORDS: | **YES** [initials below] | **NO** [initials below] |
|---|---|---|
| My study data/study records can be used by Astellas, its affiliates, other researchers, companies, and/or institutions without another informed consent as described in this document for future (secondary) uses (e.g. activities related to quality, safety, development, innovation, training, testing, evaluation of artificial intelligence systems, medical devices, and digital health applications). | | |

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# AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

## What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

## Who may use and give out information about you?

The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

## Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

## Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

## Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

**What if I decide not to give permission to use and give out my health information?**
Then you will not be able to be in this research study.

**May I review or copy my information?**
Yes, but only after the research is over.

**May I withdraw or revoke (cancel) my permission?**
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**Is my health information protected after it has been given to others?**
There is a risk that your information will be given to others without your permission.

**Authorization:**
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

**AUTHORIZATION SIGNATURE:**

| | |
|---|---|
| **Signature of Participant** | **Date** |