The iD2: A Smart Eye Drop Cap Monitor for Eye Drop Adherence

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LEGACY HEALTH

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R Young

Rebecca Young – Research Regulatory Specialist

Consent and Authorization Form for Research Study Approved by Institutional Review Board

Study Title: The iD2: A Smart Eye Drop Cap Monitor for Eye Drop Adherence
Name of Investigator: Steven Mansberger MD, MPH
Phone Number: 503-413-8495
Study Sponsor: Universal Adherence LLC

1. **Why have I been asked to take part in this research study?**

You have been invited to take part in a research study (the "Research Study" or "Study") being done by Legacy Health. You have been invited because you have an eye condition called glaucoma, which is a group of eye diseases that can cause a buildup of fluid in your eye, causing increased pressure. This pressure can cause vision loss and blindness by damaging a nerve in the back of your eye called the optic nerve. You have also self-reported poor adherence when taking glaucoma eye-drop medication.

Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so that you can make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. You may have a copy of this form to review at your leisure or to ask advice from others.

The study doctor or study staff will answer any questions you may have about this form or about the study. Please read this document carefully and do not hesitate to ask anything about this information. This form may contain words that you do not understand. Please ask the study doctor or study staff to explain the words or information that you do not understand. After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

2. Who is doing the study?

This study is sponsored and funded by Universal Adherence LLC and the National Institutes of Health (NIH).

Research will be done at a single location. Dr. Steven Mansberger MD, MPH will be the lead investigator at the Legacy Devers Eye Institute, located at the following address:

1040 N.W. 22nd Ave., Suite 200
Building 2, Legacy Good Samaritan Medical Center campus
Portland, OR, 97210-3049
Phone: 503-413-8202
Fax: 503-413-6937

The investigators involved in this study are part owners of the company that has developed the device being tested. This financial interest may create a potential conflict of interest. However, all efforts will be made to ensure that the study is conducted with integrity and that your rights and welfare as a participant are protected. You are encouraged to ask any questions you may have about this disclosure before agreeing to participate.

3. Why is this study being done?

Glaucoma damage to the optic nerve is permanent. The usual approach to care for glaucoma is the reduction and maintenance of intraocular pressure, or IOP, to prevent further damage. This can be done through the use of one or more medications, such as latanoprost, and through surgical interventions, such as laser treatments. Multiple treatments may be used, as some are more effective in certain individuals than others.

Most patients with a diagnosis of glaucoma use eye drops to lower intraocular pressure. However, poor adherence to prescribed eye drop regimens can lead to significant loss of vision-related quality of life. This study will test the iDrop Device (iD2), a device-on-cap electronic platform designed to accurately track when a research participant removes an eye drop bottle cap, wirelessly communicate usage data to a database accessible to researchers, and send on-demand alerts when a medication is due. A device capable of tracking eye drop usage and sending dosage alerts will test the hypothesis that electronic reminders improve medication adherence and help research subjects improve their eye drop taking behavior. While our primary focus is on glaucoma adherence, this device could also benefit those with other chronic eye conditions requiring regular eye drop treatment, such as dry eyes, corneal endothelial disease, eye infections, and uveitis.

The trial includes 4 stages: Stage 1) a 30-day run-in period using the ID2 without any reminders; Stage 2) a 45-day period with 1:1 random assignment to determine the effect of no reminders vs. smart cap reminders if the drop is not used within the designated time window; Stage 3) A 45-day period in which all participants receive the reminders using the smart-monitor; and Stage 4) A 30-day period using the iD2 without any reminders.

Total estimated duration for your involvement in the study is 150 days (~5 months). This study will enroll 100 participants. All participants will be enrolled and tested at the Legacy Devers Eye Institute.

4. What will happen if I take part in this Study?

If you decide to be in this study, you will be given the iD2 for at-home electronic reminders and dosage tracking. You will have a random chance (1:1 randomization, like a coin flip) to either receive reminders or not during Stage 2 of the study. You and the study staff will be aware which study group you are in.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor or study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Return the iD2 device to the study center at the end of the study.

After you sign this form, the study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- Demographic Questions: Ask you to give personal information, such as your name, gender, date of birth, race, and eye color.
- Health and Medication Questions: Ask you to answer questions about your health, your medical history, and the medications you take.
- Vision Test: Measure how well you see to evaluate your vision.
- Eye Examination: The study doctor will use a special microscope called a slit lamp that shines a light into your eye to examine the structures of your eye.
- Gonioscopy Examination: If you have not had this test done within the past 6 months, the study doctor will place anesthetic (numbing) drops in each eye and touch a special mirrored instrument to the surface of each eye to evaluate the internal drainage system of the eye (the anterior chamber angle), where the fluid inside the eye drains out.
- Pachymetry: The study doctor will place anesthetic (numbing) drops in each eye and touch a device called an iPac to each cornea to measure the thickness of your cornea.
- Visual Field Testing: Visual field testing will be done to evaluate the sensitivity of your peripheral vision (side vision). This test involves staring straight ahead into a machine that will flash a light around the edges of your field of vision.
- Optical Coherence Tomography (OCT): The OCT tests gather special pictures using a dim beam of light to measure the thickness of your retina (the back of your eye). For this test you will sit at a machine, look straight ahead and be asked to focus on colored targets. The light beam of the OCT reflects from the retinal tissue and is detected by the OCT machine, which is then used to produce a picture of your retina.

- Questionnaires: You will be asked to fill out the following questionnaires, which will provide information about your general health, demographics, mental health, and vision:
  - MOCA (Montreal Cognitive Assessment)
  - GTCAT (Glaucoma Treatment Compliance Assessment Tool)
  - CESD-R-10 (Center for Epidemiologic Studies Depression Scale Revised)
  - NEI VFQ-25 (National Eye Institute-Visual Function Questionnaire)
  - REALM-SF (Rapid Estimate of Adult Literacy in Medicine-Short Form)
  - SDOH (Social determinants of health)
  - SF-12 (Short Form-12)
  - Study close out visit questionnaire

5. What are the possible side effects and risks from being in the study?

There are possible risks, side-effects or discomforts that might happen if you take part in the Study; these have been explained to you. You have had a chance to ask your doctor and staff all the questions you have about the risks in this Research Study.

There are some slight risks from the dilating drops (eye drops used to open up your pupils for the purpose of examining your eyes). The use of these drops includes a very small risk of an allergic reaction. Allergic reactions to these drops, when they occur, are usually local (affecting the eye with itching, redness, etc.) rather than generalized (throughout the body). Also, your vision may be blurred and bright light might bother you for several hours afterwards. You should protect your eyes with sunglasses in bright light while your pupils are dilated. If you do not bring a pair of sunglasses with you to the study visits, the study staff will provide you with a pair. You should not drive or engage in any hazardous activity until your vision returns to normal.

There is also a risk, though unlikely, of the dilating drops causing an acute rise in your eye pressure (angle closure glaucoma). If angle closure glaucoma occurs after the dilating drops are given, treatment is available by the study doctor.

There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

6. What are the possible benefits of this study?

You may benefit from improved medication adherence, but there is no guarantee that being in this study will help you. Information from this study might help researchers to better understand glaucoma adherence to help others in the future.

7. What are my other choices if I do not take part in this study?

You do not have to be in this study to receive treatment. Your health care provider can provide an approved medication to treat your glaucoma. These include medicated eye drops to lower pressures within the eye. Surgical interventions may also be used for glaucoma management.

8. What are the costs of taking part in this study?

The costs of the device and procedures in this Study will be paid by the Study Sponsor: Universal Adherence LLC and the NIH. You and/or your health-care payer/insurer will not be billed for the costs of the study device, study visits, or procedures and tests that are described in this form. You and/or your healthcare payer/insurer will be billed for the cost of the eye drops you use to treat your glaucoma.

9. Will I be paid for being in this study?

The sponsor will pay you for taking part in the Research Study. If you complete all study visits you will be given a total of $300, split between $150 given at the enrollment and exit visits.

10. What happens if I am injured or hurt because I took part in this study?

If you have an injury or illness, you should seek medical care for it and tell the study doctor. If you become sick or hurt while taking part in this Research Study, medical treatment will be available; this might be first aid, emergency treatment or follow-up care as needed. Legacy Health will bill your health insurance for the cost of such care. If your insurance does not pay for that care, or pays only a part of the cost, Legacy Health may bill you for any unpaid amounts. By providing or making available medical care for injuries or illness, Legacy Health and the people doing this Research Study are not admitting fault for injury or illness.

11. What are my rights in this study?

Taking part in this Research Study is voluntary; it is your choice. You are free to decide not to take part; and you can decide to stop taking part at any time. Your decision will not affect your relationship with or treatment at Legacy Health. It will also not lead to any penalty or loss of benefits that you would have outside of the Research Study.

You can decide to stop being in the study at any time. If you decide to stop for any reason, tell study doctor as soon as possible. Also, you can decide whether the study doctor can continue to collect your medical information for the study.

New information learned during the Research Study could affect whether you still want to take part. New findings will be explained to you, and your written agreement to stay in the study may be needed.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available that suggests the study is not right for you
- If you are not able to meet the study requirements
- If the study is stopped by the sponsor

13. Who can answer my questions about this study?

If you have questions, concerns or complaints about the research study or you experience a research-related injury, please contact Dr. Mansberger or the study staff at 503-413-8495.

You have a right to know about the risks, benefits, alternative procedures, and your rights as a research participant. If at any time you believe you have not been well informed, or if you feel pressure to take part in the study even if you do not want to, you can talk to a Research Specialist. Legacy Health's Research Regulatory Specialist is available by phone during weekday working hours (8:30 a.m. to 5:00 p.m.) at (503) 413-2474.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

14. Who will see my medical information?

For this Research Study, your doctor and research staff will need information from your medical records. This information about you is called Protected Health Information (PHI). PHI includes any part of your health records that could be used to identify you, such as name, address, birth date, etc. With this Consent Form, you allow Legacy Health to use and share your PHI only for the purposes of this Research Study.

WHO: You authorize (give permission to) Legacy Health to provide your PHI to these people and agencies:

- The study sponsor (or sponsor representatives such as monitors and/or auditors)
- The U.S. Food and Drug Administration (FDA)
- Legacy Health Institutional Review Board (IRB)
- The Department of Health and Human Service (DHHS)/NIH
- Other government agencies in other countries
- Other doctors, health care professionals or research staff who are involved in the study

FOR HOW LONG: You authorize (give permission to) Legacy Health to use and share your PHI for the purposes of this Research Study until you cancel that permission at any time in writing.

We will keep your information as secure as we can. But once Legacy Health gives PHI to the people or agencies listed above, Legacy Health cannot guarantee they will keep it private. They might give PHI to other people who are not limited by the terms of this Consent Form; and it might be used in ways that you did not intend.

You may change your mind and cancel this authorization at any time. To cancel this authorization, you must write to:

Steven Mansberger
1040 N.W. 22nd Ave., Suite 200
Building 2, Legacy Good Samaritan Medical Center campus
Portland, OR, 97210-3049

Phone: 503-413-8202

If you cancel this authorization, you may no longer be able to take part in the Study. But the information already collected by Legacy Health and Universal Adherence LLC may be used and shared as allowed by this authorization and consent form.

You will receive a copy of this Consent Form.

My signature agreeing to take part in this Research Study

I have read this Consent Form or had it read to me. I have talked about it with the study doctor, and my questions have been answered.

I agree to take part in this Research Study. I know I can change my mind and can stop being part of it at any time.

I also give my permission to Legacy Health to use and share my Protected Health Information (PHI) for the purposes of this Research Study, as described in this Consent Form.

Signature of Research Participant	Date
Printed Name of Research Participant	
Signature of Legal Representative of Research Participant (if applicable)	Date

The research participant has been informed of the purpose and procedures of this Research Study. This includes the risks involved in the study and the use of Protected Health Information. The participant's questions have been answered to the best of our ability. A copy of this Consent and Authorization has been given to the participant.

Signature of Investigator or Designee	Date