



Medical College of Wisconsin Advanced Ocular Imaging Program (AOIP) Bank ~Information Sheet~

Researchers at the Medical College of Wisconsin (under the direction of Dr. Joseph Carroll) are creating a bank through the Advanced Ocular Imaging Program. The purpose of this form is to provide an overview of the bank in order to help you determine if you are interested in participating. You will not be enrolled in the bank without your consent, and you do not have to participate in the bank. This does not provide every detail of the banking study; rather it highlights some of the more frequently asked questions about the study. You will be told more about the study and given an opportunity to ask questions when AOIP Bank staff contact you as well as during the informed consent process.

WHAT IS THE ADVANCED OCULAR IMAGING PROGRAM (AOIP)?

The Advanced Ocular Imaging Program (AOIP), co-directed by Dr. Joseph Carroll and Dr. Alfredo Dubra, provides an infrastructure to promote the development and use of translational ocular imaging tools to improve detection, diagnosis, and management of eye disease. Partnering with collaborators around the world, AOIP members include vision scientists, clinicians, and engineers at the Medical College of Wisconsin.

WHAT IS BANKING AND WHAT IS A BANK?

“Banking” is storing health information and/or blood or tissue for future research studies. A “bank” is the place where it is stored. Multiple institutions will be contributing data to this bank.

WHY IS THIS BANKING STUDY BEING DONE?

Dr. Carroll is creating this bank in order to help learn about many different eye diseases and conditions. The Advanced Ocular Imaging Program has high-resolution imaging tools that allow researchers to see the tissues of the eye with single-cell resolution. By combining high-resolution ocular images with standard health information and genetic information, it is hoped that researchers will be able to develop a better understanding of various eye diseases. Ultimately, it is hoped that this information can be used to help improve health and develop new treatments.

WHY AM I BEING ASKED ABOUT THIS BANKING STUDY?

You are being given this information sheet because your doctor thinks you may be a good candidate for participating in the bank. Dr. Carroll is interested in adding as much data as possible to the bank, from individuals with normal vision, as well as individuals with a wide variety of eye conditions. Dr. Carroll is hoping to recruit individuals of all ages, even as young as 5 years of age.

WHAT ARE THE COSTS OF BEING IN THE STUDY?

There are no costs to you or your insurance company for any of the procedures in this banking study.

WILL I BE PAID FOR BANKING MY OCULAR IMAGES, HEALTH INFORMATION, AND GENETIC RESULTS?

You will be paid \$15/hour for your time spent completing the study, though to pay you, we need to collect your social security number. Any payment may be reportable as income on your taxes. If you do not wish to provide your social security number, you can still participate in the study, however we cannot pay you.

WHAT WILL HAPPEN IF I DECIDE TO PARTICIPATE?

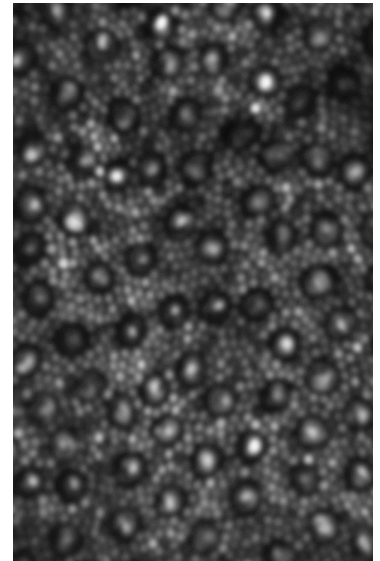
The AOIP Bank staff will contact you to schedule an appointment at a time that is convenient for you. Upon arrival at the AOIP, the AOIP Bank staff would obtain your informed consent to participate and have you sign an informed consent form. You will be provided with a signed copy of this document for your records.

The data we collect is only for the purpose of banking. Not all tests will be done on all subjects, this will be based on a review of your condition and will depend on whether you recently had similar tests done as part of your regular eye care. We will need to dilate your eye(s) during your study visit(s).

We may collect a brief ocular history questionnaire, perform a variety of vision tests that allow us to understand how well you see, and perform an eye exam. Various instruments routinely used in clinical exams may also be used to collect data from your eye (including optical coherence tomography, and in some subjects, fluorescein angiography). For many subjects we may take a sample of blood (up to about 3 tablespoons). The blood would be sent to a laboratory and used to examine various genes and proteins related to your vision.

We may also perform **Adaptive Optics Imaging**. This imaging test corrects for the imperfections in the front part of your eye, allowing us to see your retina with very high resolution. Nothing will touch your eye and you will be asked to either place your chin on a chin-rest and forehead in a forehead-rest or to bite on a custom dental impression on a bite bar. This is to help keep your head still. You will see different color lights, which are used to collect pictures from your retina.

Shown here is an image of the human retina taken with adaptive optics. Each circle is a single photoreceptor, the large ones are cones (which help you see in the daytime) and the small ones are rods (which you use at night). By using this imaging tool, it may be possible to see disease much earlier than currently possible and to track disease progression with high sensitivity.



WHAT ARE THE RISKS ASSOCIATED WITH THE PROCEDURES?

It is important that you understand the possible risks associated with the banking study. They will be discussed in detail with you during the informed consent process, and if you are uncomfortable with any of the risks or tests, you do not have to participate. There are risks associated with genetic testing (bruising from the blood draw or accidental release of confidential information), with having your eyes dilated (increased intraocular pressure or allergic conjunctivitis), and with having fluorescein angiography done (nausea and discomfort can occur and though uncommon, allergic reactions can also occur and can include hives, itching, and possible life-threatening allergic reactions). We take many precautions to minimize your risk, and will describe these during the informed consent process. The lights used in the tests are not brighter than those you would be exposed to during a typical visit to the eye doctor.

WHO CAN I CONTACT IF I HAVE QUESTIONS?

A member of the AOIP Bank staff will contact you, however if you need to reach the AOIP you can do so with email (aoip@mcw.edu) or by phone: 414-456-AOIP (2647).