UNIVERSITY OF WASHINGTON

CONSENT FORM

AI READY AND EQUITABLE ATLAS FOR DIABETES INSIGHTS (AI-READI)

Researchers:

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24-hour emergency telephone number: 206-744-3000 – ask for eye doctor on call

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

PURPOSE OF THE STUDY

The purpose of this study is to collect information on type 2 diabetes in people with and without diabetes from diverse racial and ethnic backgrounds. After removing the information that may give away your identity, we will place the data we collect from you, along with that from thousands of other volunteers like you, into a database. The database will be publicly accessible to anyone who is interested in studying type 2 diabetes and used for scientific discovery. You may decide to participate based on what data are publicly available and what is controlled and would need permission to access. Controlled access would mean that data access requests are reviewed by a committee comprised of all AI-READI investigators and would require legal agreement and privacy protection measures to be put in place with interested researchers before the data are shared. The table below explains which information will be publicly accessible and which will be held under controlled access.

List of publicly accessible data		List of data held under controlled access	
Survey data	Retinal Images	5-digit ZIP code	Genetic sequence
Blood and urine lab results	ECG	Race/ethnicity	Sex
Fitness activity levels	Blood sugar levels	Past health records	Traffic & accident reports
Clinical measurements (monofilament & cognitive function testing)	Home air quality		

STUDY PROCEDURES

Your study participation will consist of one in-person study visit followed by approximately ten days of at-home study participation. Your total active study participation is expected to be approximately 11 days. At the end of the home study participation, you will be expected to return several study items. The study payment is contingent upon the successful return of all devices.

IN-PERSON STUDY PARTICIPATION

Sample Collection

We will collect a urine sample and about 3-4 spoonfuls of blood (50-60mL). You will not need to be fasting. We will use these samples to aid in assessing your general health.

Demographics

We will ask you about your racial and ethnic background and collect other basic demographic information, and to fill out several questionnaires related to general health, diabetes, and social factors associated with health and disease. You do not need to answer any question you are uncomfortable with.

Additional Testing

We will test your memory and other thinking processes, measure your vital signs such as blood pressure, height, and weight, and perform an ECG (electrocardiogram) to see how your heart works. We will also use thin bendable wires to evaluate how well you can feel the sense of touch on the bare soles of your feet. This is called a monofilament test and it is important for people who have diabetes because this disease often changes the ability to sense touch in some areas of the body.

Eye Testing

We will test and image your eyes, part of this process may be similar to tests you had when visiting an optometrist or ophthalmologist in the past. We will test your glasses prescription and your vision by asking you to read letters under normal and reduced light. We will also take images of the back of your eyes using several different cameras. We will need to apply eye drops to enlarge your pupils and get better pictures of your eyes. If you are sensitive to the drops, we may choose to use only one type of eye drops or take the pictures without using the drops.

Glucose Monitoring

We will attach a continuous glucose monitoring device, also known as a CGM, to the skin of your stomach. The CGM has a sticker that keeps it in place on your stomach and a small sensor that will go under your skin to monitor your blood glucose. To get the sensor under your skin, you will push a button on the CGM and you will feel a slight pinch when the sensor goes into your skin. The study personnel will be present with you during the entire set up.

AT HOME STUDY PARTICIPATION

Glucose Monitoring

It will be important for our research study to understand how your glucose levels change during your daily activities. You will wear the continuous glucose monitor (CGM) device for 10 days. The CGM sensor will need to be returned at the end of the study as described below.

Physical Activity Tracking

We will provide you with a physical activity tracker to wear for 10 days on your wrist to check how much time you spend walking, sitting, sleeping, or exercising, which also assesses your heart rate and oxygen level in your blood. The fitness tracker will not record any GPS data. It will be your responsibility to charge the device every day (evening recommended). The physical activity tracker must be returned at the end of the study as described below.

Air Quality Monitoring

We want to explore the connection between air quality and diabetes. We will also provide you with a small sensor to keep in your house for 10 days. This sensor is for us to collect information on the air, light, temperature, and particles at home. You will not need to do anything besides place this device somewhere in your home. This sensor does not have a camera or microphone. It cannot collect any video, photographs, or sound from your home.

Returning the Devices

After 10 days, you will peel off the glucose monitoring device and you may notice a small dot on your skin where the sensor was for 10 days (instructions on removal and study contact information in case you need help at home will be provided). The CGM sensor that you peeled off, the physical activity tracker, and the environmental sensor will be mailed back to the study in the prepaid mailing boxes provided.

CONTINUING PARTICIPATION

Accessing Your Records

During this research study, we will look into your medical records and collect information related to your general health, eye health, medical history, diabetes, medications, laboratory records, and any previous medical imaging such as eye imaging. We will collect your medical records information also after the initial visit for the duration of the study. We will also collect information about any car accidents or traffic infraction tickets you may have had in the last 3 years.

Future Participation

Some study participants will be asked to come back for an additional study visit in the future. This visit will be identical to the first visit, meaning that you will have all the same information collected again. If you are invited to participate in a future visit, we will ask for your consent before collecting any additional information from you. You do not need to decide if you want to participate in a follow-up at this time.

RISKS, STRESS, OR DISCOMFORT

Some of the study procedures may feel uncomfortable to you.

Eye Testing

One or more of the eye drops can cause mild and brief irritation to your eyes. The eye drops used for imaging will make your vision blurry and you will be sensitive to light for several hours. It is recommended that you do not drive until your vision is back to normal, or that you have someone accompany you to your visit to drive you home. We will provide you with tinted shields to reduce the effect of light on your eyes during this period. Eye imaging can occasionally take a long time, or the light source used during imaging may cause slight discomfort or a headache. To make you feel more comfortable, you can take breaks during testing.

Extremely rarely, the eye drops may cause serious reactions, including but not limited to sudden increase in eye pressure (which you may feel as eye pain, redness, sudden change in vision), increased blood pressure, fainting and allergic reactions. We do not anticipate any of these reactions will happen, but if you do experience any of these rare events during the course of the visit, we will seek out emergency medical attention for you.

Blood Samples

During collection of the blood sample, you may experience mild discomfort or pain. Some people may develop bruising at the puncture site, feel dizzy or faint. Extremely rarely the puncture site may become infected, which could lead to hospitalization or death.

Continuous Glucose Monitoring

Insertion of the CGM may cause bruising, pain, or infection at the insertion point. If the CGM is uncomfortable, you may remove it early and return it to the study by mail.

Confidentiality Breach

Although we make every effort to protect your information, a confidentiality breach is possible, but rare.

Sensitive Information Collection

In the study, we will collect information about alcohol, smoking or vaping, and marijuana use. You can refuse to provide this information if you feel uncomfortable about sharing it or if sharing would put you in legal jeopardy.

BENEFITS OF THE STUDY

Results of your blood and urine tests will be available for you to look up with your personal ID code in approximately 1 year. Please note that a doctor will not be reviewing the results of any test performed as part of this study. The results of blood and urine tests change over time, so results received after 1 year may not be reflective of your health status at that time. The results returned to you are not meant to replace any medical care you currently have planned or should receive in the future.

At the end of the study visit, you will receive a card that includes your vital signs and eyesight measurements.

The following will NOT be provided to you: genetic testing data, ECG, environmental sensor data, fitness tracker data, CGM data, retinal imaging, questionnaires and cognitive testing results, results derived from samples left in a biorepository or data obtained in future research projects.

SOURCE OF FUNDING

The study team and the University of Washington is receiving funding for this study from the National Institutes of Health, grant number NIH OT2OD032644.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Your participation in this study will be noted in your UW medical record.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish. There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct additional research if allowed by federal regulations and according to your consent for future research use as described in this form;

  local and state authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is August 31, 2027. Any data collected after expiration is <u>not</u> protected as described above. Data collected prior to expiration will continue to be protected.

USE OF INFORMATION AND SPECIMENS

Genetic Sequencing

Samples collected from you will be used to test your genetic information. We will perform whole genome sequencing on your blood sample. Whole genome sequencing is a laboratory procedure that determines a precise DNA fingerprint. The precise DNA fingerprints from all the study participants can then be used to learn how genetics impact health and type 2 diabetes. The results of the whole genome sequencing will be released in a protected data set along with other protected health information for use in future research studies.

Returning Results to You

Up to twelve months after your participation in the study, you will receive a unique identifier code. You will be able to look up your results from the blood and urine tests using this identifier code. There will be no interpretations provided for the test results, but you are able to download the results whenever you wish and discuss this with your medical provider.

Using Your Data and Specimens in Future Research

The information and specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you.

The publicly available dataset and samples collected from you will allow any company to potentially use your data and specimens for commercial gain. There is no plan to share any commercial profits with you.

It is also possible that in the future we may want to use or share study information and specimens that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you. By participating in this study, you are providing us the permission to contact you again regarding future studies.

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GENOMIC DATA SHARING

This study will involve whole genome sequencing. The National Institutes of Health (NIH) has developed data (information) banks that collect study data. The NIH will store your de-identified information in these data banks for other researchers to use in future studies on any topic. The researchers could be from government, academic, or commercial institutions. You will not receive any results related to your data to be placed in the NIH data banks.

You will not be able to withdraw your information after it has been submitted to the NIH data banks as it is not possible to guarantee retrieval of the information from all possible sources that had access to the data once it is released.

There is a small risk that others will be able to trace this information back to you or close biological relatives. The current risk of this happening is very small, but may grow in the future as new technologies are developed. If this should happen, someone might use this information to learn something about your health or genetic heritage. If linked to a medical condition and inappropriately shared with someone, it could affect your ability to get or keep some kinds of insurance. There is a possibility that this information could affect family members because certain conditions and traits run in families and are inherited through genes. This could hurt family or other relationships. There is a risk that your information could become known to the public, employers, or law enforcement agencies. The information may be used to enforce negative stereotypes. It is possible that your information could be used to identify you when combined with information from other public sources.

There may also be other risks that are not yet known.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this form. Once we receive the information, we will stop accessing any of the data or your medical records per study protocol as written in this consent but we will not be able to retrieve any data that has already been shared.

Participation in this study will not incur any charges to you or your insurance. We will cover up to $25 for your transportation or parking costs related to the study visit(s). Upon the successful completion of the In Person Study Visit, the At Home Study Participation and returning of all devices (the physical activity tracker, environmental sensor and the continuous glucose monitor) via mail, you will be paid $125 for your participation. It may take 2 weeks (or more) for you to receive your payment after you return the devices.

RESEARCH-RELATED INJURY

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call them at the 24-hour number listed at the top of this form. If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility. The cost of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Consent Presenter Statement

I have provided this participant and/or their legally authorized representative (LAR) with information about this study. The participant/LAR has been given sufficient time to consider participation and I have answered any questions they had. The participant and/or their LAR indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Signature of staff obtaining consent
Date_____

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I give permission to be contacted again for any future studies. I will receive a copy of this consent form.

Printed name of subject Signature of subject

Date _____

Electronic consent note: If you signed this consent electronically, a copy of the consent form will be emailed to you at an email address that you provide. It will be a 'PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.