



UNIVERSITY OF WISCONSIN-MADISON

Wisconsin

Diabetes Registry Study

Diabetes Registry Study Consent Form Exam and Annual Questionnaires

UNIVERSITY OF WISCONSIN-MADISON**DEPARTMENT OF POPULATION HEALTH SCIENCES****Subject CONSENT to Participate in Research And
AUTHORIZATION to Use and/or Disclose Identifiable Health
Information for Research****Title of the Study:** The Wisconsin Diabetes Registry Study**Principal Investigator:**

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INVITATION / SUMMARY

You are invited to participate in the continued follow-up of the Wisconsin Diabetes Registry Study (WDRS). You are invited because you have previously participated in the WDRS since your diagnosis of type 1 diabetes. Your participation in this research study is voluntary. This follow-up involves one clinical exam visit and completing annual questionnaires (once/year) during the next 4 years. The main study procedures include photographs of the retina (back of the eye), a blood draw, a urine sample, body measurements and questionnaires on your health and diabetes care. If you decide not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

A. WHAT IS THE PURPOSE OF THIS STUDY?

The main purpose of the clinical examination and annual questionnaires is to test certain features of the eyes and kidneys and to describe and compare diabetes care and other health information that may help predict the development of complications in persons with type 1 diabetes.

B. WHAT WILL MY PARTICIPATION INVOLVE?

We will telephone you to discuss the study and invite your participation. If you decide to participate in this research you will be asked to participate in one examination which will last about 2 hours, plus your travel to the exam and eye clinic sites. (In Madison and Milwaukee, the eye clinics are a few minutes from the exam sites.) If you agree to participate, we will also ask you a few questions on your eye health during this phone call and before scheduling photographs of your eyes. (This information will be used only for scheduling the photographs and will be kept in a locked file cabinet for reference but not used for other research purposes.)

The examination will include the following:

1. General aspects (60 minutes):

- Brief discussion of your exam and your visit to the eye clinic; signing the consent form.
- Blood sugar measured by finger-stick (if your blood sugar is high or low, we will make suggestions on how you may wish to treat your blood sugar).
- Body measurements (for example: height, weight, blood pressure) and visual acuity.
- Brief electrocardiogram (ECG) for heart rate variation (take 6 breaths per minute for 1 minute while we measure your heart rate; your heart rate will be measured using 5 leads attached to your collar-bone area, your hips/thighs, and your chest).
- Complete 5-6 questionnaires/interviews. In order to save time at the exam, we will send a few questionnaires for you to complete at home before you come to the exam. These will include questions on your general health (including diabetes care, medication use, smoking and alcohol use, for example), family medical history (history of high blood pressure, heart disease and diabetes in your parents and siblings) and for women, reproductive history (including questions on your menses, birth control and pregnancies). Questionnaires completed at the exam will include questions on your medical history (including questions on high blood pressure, heart disease and diabetes-related complications, for example), on exercise habits, and on history of neurologic (nervous system) symptoms. These questionnaires are similar to those completed at previous study visits.

2. Specimens collected (15 minutes), tested and stored:

- Urine sample collected first-morning (timed from overnight), before you come to the exam.
- Blood sample collected from your arm (up to 5 tubes, which equals 2 tablespoons).
- Consent for testing of blood and urine samples (samples collected at this study visit and those already collected and stored from your previous study participation) for factors that may be related to the development of eye and/or kidney disease.
- Long-term storage of blood and urine samples for future testing of risk factors which may be related to the development of diabetes-

related complications (this does **not** include plans for genetic analysis).

3. The visit to the eye clinic will include the following (50-60 minutes):

- Brief travel to the eye clinic (if in Madison or Milwaukee).
- Pupils examined and dilated: A technician will briefly look in your eyes to decide whether your eyes can be dilated. Drops will be added to your eyes and you will wait approximately 15 minutes for your pupils to dilate.
- Examination of retina (back of the eye): The technician may look at your eyes to briefly study the back of your eye before taking photographs.
- Eye photographs: 7 standard photographs will be taken of each eye. These are the same photos that have been taken for previous Diabetes Registry exams.
- Photograph/Digital Image of the Retina: The following individuals will see your eye photographs/digital images: Investigators and staff of the Wisconsin Diabetes Registry Study and the University of Wisconsin Ocular Epidemiology Reading Center.

You will also be asked to complete **annual health questionnaires** once/year during the next 4 years. The questionnaires are similar to those you completed as part of the Wisconsin Diabetes Registry Study and its ancillary studies in the past, and will take approximately 10-15 minutes to complete. In addition, if any follow-up questions are necessary, we may telephone or e-mail you for clarification. Questions will include information on diabetes care, health behaviors such as use of alcohol and tobacco and exercise habits, self and family medical history, reproductive history for women and other general health information.

We will also collect the following information about you for this research study:

1. From you: information which will help us keep in contact with you (for example: your home address, phone number, email address, social security number (unless you've already provided your number to us or elect not to)).
2. From your records kept by clinics who will take photographs of your eyes for this study (UW Health, Retina and Vitreous Consultants of Wisconsin Ltd., Northeast Wisconsin Retina Associates or the Froedtert and Medical College of Wisconsin Eye Institute): we will collect results from your eye exam visit and fundus images/photographs (photographs of your retinas or backs of the eyes).
3. From medical tests or other procedures performed for this study: blood testing for blood sugar and cholesterol levels, testing of your blood for markers that could be related to the development of complications, urine testing for measures of kidney function and heart rate variation testing by ECG.

C. ARE THERE ANY BENEFITS TO ME?

This study is not intended to directly benefit you. Information collected by the glycosylated hemoglobin blood tests may help your physician adjust your diabetes management. Information provided from the blood tests (cholesterol level), blood pressure measurements, urine testing and photographs of the retina (back of the eye) may also be helpful. No direct benefit is expected from other blood testing planned at this time or from your answers on questionnaires. Your participation in this research study may benefit other people in the future by helping us learn more about the development of complications, especially eye and kidney problems, in persons with type 1 diabetes.

D. WILL I BE PAID FOR MY PARTICIPATION?

You will receive \$75 for your participation in the complete examination. If you are only able to complete parts of the examination, you will be compensated as follows: \$35 for participation in fundus photographs, \$20 for participation in the clinic examination, \$10 for participation in the blood draw and \$10 for providing a timed-overnight urine sample.

We will also provide a travel reimbursement to help with the costs of your transportation to the exam site, calculated from the number of miles you traveled. We estimate a travel reimbursement of \$ _____ from your home address in _____ to the exam site in _____.

Lastly, you will also receive \$10 for completing your annual questionnaire each year.

E. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

You may experience some momentary discomfort, possible local bruising and/or redness of the skin, and faintness when having blood drawn. At the time of the exam, you may experience some momentary discomfort from blood pressure measurement. There is a slight risk of mild local allergic reaction from drops used to dilate pupils as well as a slight risk of temporary increase in eye pressure (glaucoma) that usually requires medical or possibly surgical treatment. Persons at increased risk for this condition will be notified before dilation, and the risks will be discussed in detail. Answering sensitive questions may be uncomfortable. There is some risk that your study information could become known to someone who is not involved in performing or monitoring this study, however our research group takes steps to keep your information strictly confidential.

F. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

Our research group will take the following measures to safeguard your data from unauthorized use or disclosure: Records are stored in locked files and security measures are in place on the computer network (by passwords and authentication). Computers housing study databases where your health information is located are identified by a unique identifier. Workstation passwords secure a user's computer from unauthorized access when not in use. Urine and blood samples saved for long-term storage are placed in locked freezers in a locked room and labeled by codes and dates only. Only trained personnel have access to the database and participant information, including the unique identifier used to code data and samples. Participant information is not released unless requested by the participant or their legally authorized representative. This registry will be maintained for possible future research efforts, but participants' names will not be released to investigators outside the scope of this

study unless the Principal Investigator and the Institutional Review Board have approved a protocol modification. Future use of stored samples will also be reviewed by the Principal Investigator and the Institutional Review Board.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. It may also be shared with others at the UW-Madison and outside the UW-Madison.

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices.
- Accounting and billing personnel at the UW-Madison.
- Research support services staff at the UW-Madison and its affiliates.

Others outside of UW-Madison and its affiliates who may receive your health information in the course of this research:

- The study sponsor, the National Institute of Diabetes & Digestive & Kidney Diseases

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates, it is not shared in a way that can identify an individual.

Urine and blood samples will be tested by laboratories outside of UW-Madison, however samples will be labeled by a unique identifier and sample date only and otherwise not identifiable to these laboratories.

G. WILL I RECEIVE RESULTS OF THIS RESEARCH?

Any information obtained from this study which can identify you will remain strictly confidential or will be disclosed only with your written permission unless otherwise stated above. If you wish, we will provide you and your physician with glycosylated hemoglobin (HbA1c), blood cholesterol and urine test results, blood pressure measurements and results from the photographs of your retinas (backs of your eyes): Please indicate your preference by checking the appropriate boxes:

- Please **do not** inform me or my doctor
- OR
- Please inform me
- AND/OR
- Please inform my doctor

If any of the results described above are of potential concern, we will notify you and describe what values are considered normal. In this case, you should contact your physician for further information and interpretation of the potentially concerning results.

Name of physician(s) to contact

If you do wish that results be sent to your physician(s), please provide his/her/their contact information (including phone number, if known) below:

| | |
|-------|-------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

H. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely withdraw from the study at any time. You also may choose to cease participation or skip any questions that you do not feel comfortable answering. You may withdraw from the sample banking/storage section of this study by contacting the investigator. In this case your samples will be de-identified.

If you decide not to participate in this study or if you stop while the study is underway, the health care you receive from the UW-Madison and its affiliates will not be affected in any way.

I. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed below:

Mari Palta, PhD
 Dept. of Population Health Sciences
 610 Walnut St
 WARF Office Bldg
 Madison, WI 53726

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

J. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator, Mari Palta, at 608.263.4029 or the Study Director, Tammy LeCaire, at 608.263.5305.

For information on the rights of research subjects, you may contact the UW Hospital and Clinics Patient Relations Representative at 608.263.8009.

**AGREEMENT TO PARTICIPATE IN THIS STUDY AND
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH
INFORMATION**

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

Surrogate decisions should be based upon that which the surrogate believes is, or would be, desired by the subject. If a subject's wishes cannot be determined, surrogate decisions should be based upon that which the surrogate believes to be in the subject's best interest.

I agree to complete the research questionnaires:

Yes No

I agree to collect and provide the urine sample:

Yes No

I agree to have my current/stored samples saved for long-term storage and testing:

Yes No

I agree to come for the exam visit:

Yes No

If you checked "Yes" to the exam visit, please bring one signed copy of this document to the exam site (keep a second copy for your record).

If you checked "No" to the exam visit, please return one signed copy of this document using the provided self-addressed envelope (keep a second copy for your record) and complete the following information:

My current phone number is:

Best time to call me:

Name of Participant:

signature of Participant

date

*signature of Personal Representative(if needed)**date***You will receive a copy of this form with your signature.****If this form is signed by a personal representative, please enter his or her name and relationship to the individual:**Name of Personal Representative: Relationship: **Person obtaining Consent/Assent and Authorization:**

I have discussed this research study with the participant (and personal representative, if appropriate) using language that is understandable and appropriate. I believe I have fully informed the participant of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and consented/assented to participate in this study.

Name of Person Obtaining
Consent/Assent:

signature

date

File last updated: November 3rd, 2020