



UNIVERSITY OF WISCONSIN-MADISON

Wisconsin

# *Diabetes Registry Study*

## **Diabetes Registry Study Consent Form 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:**

Mari Palta, PhD  
phone: 608.263.4029  
email: widiabetesregistry@mailplus.wisc.edu

**Mailing Address:**

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

**INVITATION**

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. 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 DOES THIS STUDY INVOLVE?**

If you decide to participate in this portion of the study, we will ask you to complete annual questionnaires (once/year) during the next 4 years. The purpose of the questionnaires is to describe and compare diabetes care and other health information that may be related to the development of complications in people who have type 1 diabetes. The questionnaires are similar to those you answered as part of the Wisconsin Diabetes Registry Study and its ancillary studies in the past. The questionnaire 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.

Your participation in this study is completely voluntary and there is no relationship of completion of this questionnaire to the medical care you may be receiving or need. If you would like to participate in this part of the study, please sign this form and return it to us along with your completed questionnaire.

**We will also collect the following information from you for this research study:** 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)).

### **B. ARE THERE ANY BENEFITS TO ME?**

This study is not intended to directly benefit you. Your responses may be useful in helping us learn more about risk factors for diabetes complications in adolescents, young and middle-aged adults with type 1 diabetes and in guiding future research.

### **C. WILL I BE PAID FOR MY PARTICIPATION?**

You will receive \$10 for completing your annual questionnaire each year.

### **D. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?**

We do not anticipate significant risk to you for participation in this study. 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.

### **E. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?**

Information collected through this questionnaire will be linked with information already collected about you through the Wisconsin Diabetes Registry Study, its ancillary studies, and any future information collected. That way we will be able to see whether there is a way to predict later health complications. The study coordinators reviewing this information will treat the identity of all participants with complete confidentiality. Your name will never be given to anyone and the information you provide will be used only when grouped together with other study participants. Information gained from this study may be used in scientific journal articles or in presentations. However, none of this information will identify you personally.

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. Only trained personnel have access to the database and participant information, including the unique identifier used to code data. 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.

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.

**F. 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.

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.

**G. 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.

### **H. 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.

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PLEASE KEEP THIS COPY

### **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.

Name of Participant:

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*signature of Participant*

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*date*

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*signature of Personal Representative(if needed)*

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*date*

**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: **Signature of person obtaining consent and authorization:**

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*signature*

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*date*

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

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Name of Participant: 

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*signature of Participant*

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*date*

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*signature of Personal Representative(if needed)*

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*date***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: **Signature of person obtaining consent and authorization:**

*signature*

*date*

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Print This Form

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