INFORMED CONSENT TO PARTICIPATE IN A DIABETES RESEARCH REGISTRY

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CO-INVESTIGATORS: WDI Health Care Providers and Research Staff
(Complete, current listing available upon request)

SOURCE OF SUPPORT: Western Diabetes Institute, Western University of Health Sciences

You are being asked to volunteer for a research registry conducted by Western Diabetes Institute (WDI). A research registry is a collection of information about patients who have a particular disease or condition, or who receive a particular treatment, that is kept for future research studies. This informed consent provides you with information that you should know and understand before agreeing to be in the registry. After reading this informed consent form, you will be able to ask any questions that you may have. You may take home an unsigned copy of this informed consent form to think about or discuss with family and friends before making your decision.

An unlimited number of subjects will participate in this registry at the WDI. Your participation in this registry will not involve any visits in addition to your routine care.

What is the purpose of a research registry?

Many advancements in medicine have resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Because the WDI is seeing you, we are asking for your permission to allow us to place your medical record information, including from the past, present, and the future, into a Diabetes Research Registry. By placing the medical record information of many patients such as yours into a research registry, researchers will be able to conduct research studies directed at increasing our knowledge about diabetes and related diseases.

Participant's Initials_____

It is anticipated that the research registry will assist our investigators in three important ways:

First, it will allow researchers to review and study the medical records of many individuals to answer questions about your disease and its treatment.

Second, it will help researchers identify and recruit patients who are eligible for participation in future research studies. For example, health care providers and other researchers associated with the WDI are also frequently involved in research studies directed at evaluating the safety and effectiveness of drugs, devices, or procedures for the treatment of diabetes and related diseases.

Third, collecting data about people with diabetes in a 'real world' setting (that is, outside of a randomized controlled trial) is extremely important to public health and disease researchers around the world. Studying helps to continue to improve our understanding of disease and how it effects different populations, and to improve the health and wellbeing of all people. As such, your data will allow other research institutions outside Western Diabetes Institute/Western University of Health Sciences to have access to your data (such age, disease, treatment) for purpose of research, after a secure approval process. Given the operating costs required to maintain the registry and perform research queries, these outside institutions, or individual investigators, will be assessed a fee as deemed appropriate. Rest assured that despite access to the registry, your identity and personal information will never be released to such investigators or outside institutions.

If you agree to participate in this Research Registry, your medical record information will be reviewed by health care providers and researchers to determine if you might qualify for various future research studies.

Who is being asked to participate in this registry?

All patients who are at least 18-years of age or older and are seeking or receiving treatment at the WDI are being asked to participate in this Research Registry.

What will my participation in this registry involve?

If you agree to participate in the WDI Research Registry, your past, present, and future medical record information will be placed into the WDI Research Registry. This will permit research studies to be conducted on the medical record information contained within the registry. You are being asked to allow us to contact you if one of our researchers determines, through review of your medical record information contained in the WDI Research Registry, that you are eligible for participation in a future research study related to diabetes and related diseases. Please note that if you qualify for any future research studies, you will be asked to sign an informed consent form that outlines in detail the nature of the research study, including its potential risks and benefits.

WDI will collect information related to all health conditions you may have, such as, but not limited to other illnesses or health conditions, laboratory and x-ray results, and all treatments, as well as patient perception surveys. However no information that identifies you such as your

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name, address, birthdate, etc., will be accessible to other investigators. Registry data available to approved investigators will be restricted to such information as your age, conditions or diseases, and the treatments you received for them.

What are the possible risks of my participation in the registry?

There are no risks of physical injury associated with your participation in the WDI Research Registry. Participation in this registry does involve the possible risk that information about your health might become known to individuals outside of the WDI.

We will attempt to preserve your medical record confidentiality by assigning a special research code number to your medical record information stored in the WDI Research Registry, and by removing personal identifiers (for example, your name, social security number, medical record number) from information stored about you in the registry. Information linking the research code number to your name and other personal identifiers will be stored in a separate secure location. Access to any identifiable information about you that is contained within the WDI Research Registry will be limited to investigators associated with the WDI and their research staffs.

What are the possible benefits of my participation in the registry?

It is unlikely that you will receive any direct benefit as a result of your participation in the WDI Research Registry.

However, medical record information contained within the Research Registry will be used for research studies directed at improving our knowledge and treatment of diabetes and this knowledge may benefit patients with diabetes and its co-occurrences in the future.

Will I, or my insurance provider, be charged for my participation in the registry?

There will be no cost to you for your participation in this registry. You will still be responsible for all of the costs related to your medical care, which will be billed to you or your insurance company. You will also be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this registry. You will also be financially responsible for any costs of your medical care not covered by your health insurance.

Will I be paid for my participation in the registry?

No. You *will not* be paid for your participation in this registry or for any future research studies conducted using the information in this registry.

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What if I decide not to give permission to use and give out my health information?

By signing this informed consent form, you are giving permission to use your health information as described above. If you refuse to give permission, your health information cannot be entered into this registry.

What else can I do if I do not want to be in the registry?

You do not have to participate in this registry to receive treatment for your condition.

Who will know about my participation in the registry?

Any information from your medical records that is placed into the WDI Research Registry will be kept as confidential (private) as possible. In addition, you will not be identified by name in any publication of the results of research studies involving the use of your medical record information unless you sign a separate informed consent form (release) giving your permission.

What is the nature of my medical record information that will be placed into the registry?

All of your past, present, and future medical record information related to your diabetes will be recorded into the WDI Research Registry. Since medical conditions and treatments, not related directly to your diabetes may affect diabetes, its related diseases, and/or its treatment, it is likely that all of your existing and future medical record information will be placed in the Research Registry. This information will be collected from your WDI Clinic records, hospital records and, if applicable, private physician records.

Who will have access to my identifiable medical record information contained in the registry?

Access to your identifiable medical record information contained within this Research Registry will be limited to investigators associated with the WDI and their research staffs. A current, complete listing of these individuals will be provided to you upon your written request. In addition, the following individuals may have access to your identifiable medical record information contained within this Research Registry: authorized representatives of the Western University of Health Sciences Research Conduct and Compliance Office may review information contained within the WDI Research Registry to ensure that the Research Registry adequately protects your privacy.

In unusual cases, the researchers may be required to release your identifiable medical record information from the Research Registry in response to an order from a court of law.

Assurance of Confidentiality

No information obtained in connection with this registry can identify you, except for this informed consent. Participants are assigned a number that is only known to the research team.

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However, your records may be inspected by state or federal regulatory agencies. Data will be presented as a summary of all subjects enrolled in this registry.

Data and records created by this registry are the property of the university. You may have access to information collected on or about you by making a written request to the principal investigator, Dr. Andrew Pumerantz.

We do not anticipate using the protected health information (PHI) you will be providing. Should the PHI be used, we will comply with the rules and regulations concerning the privacy and security of PHI under the federal health insurance portability and accountability act (HIPAA) of 1996.

How long will my information be part of the registry and be used for research purposes?

We will continue to place your medical record information into the WDI Research Registry until 1) you are no longer living; or 2) you withdraw your permission for participation in the Research Registry.

May I withdraw, at a future date, my consent for participation in this registry?

You may withdraw, at any time, your consent for participation in the WDI Research Registry, to include the additional collection of your medical record information and its further use for the research purposes described above. However, any research use of your medical record information prior to the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation in the WDI Research Registry you should provide a written and dated notice of this decision to the principal investigator of the Research Registry at the address listed on the first page of this informed consent.

Is my participation in the registry voluntary?

Yes. Your participation in the WDI Research Registry, to include the use of your medical record information for the research purposes described above, is completely voluntary. Whether or not you provide your permission for participation in this Research Registry will have no effect on your current or future medical care at the WDI, Western University of Health Sciences, its affiliated health care providers, or your present or future relationship with health care insurance providers.

Offer to answer questions

You should feel free to ask questions now or at any time. If you have any questions about this registry, you can contact the WDI Health Care Providers and Research Staff or the Principal Investigator, Dr. Andrew Pumerantz at 909-706-3779 or 795 E. Second Street, Suite 4, Pomona, CA 91766-2007. If you have questions about the rights and research subjects, contact the WesternU IRB (Institutional Review Board) Office at (909) 469-5636 or 309 E. Second Street, Pomona, CA 91766-1854 (or email at irbadmin@westernu.edu).

Participant's Initials_____

Agreement to Participate: Witnessing and Signature

To be in this Diabetes Research Registry, you must sign this page. By signing this page, you are voluntarily agreeing to be in this registry at the Western Diabetes Institute.

Before signing, you should be sure of the following:

You have read all of the information in this "Informed Consent to Participate in Diabetes Research Registry" form.

You have discussed the implications of your being in the registry with your Western Diabetes Institute health care provider.

You have had the chance to ask questions about the registry, and your questions were answered to your satisfaction.

If you did not understand any of the answers to your questions, you asked your Western Diabetes health care provider or a staff member to explain them to you.

You have had time to think about the information and decide whether or not to be in the registry.

If you decide to be in this registry:

You are expected to provide the information needed by the health care providers or other WDI staff members for the registry.

You may freely choose to stop being in the registry at any time.

I have read and understand the information contained in this informed consent which has been provided in English (a language I can read and understand). By signing this consent form, I am voluntarily agreeing to be in this Diabetes Research Registry.

You must be given a signed copy of this informed consent form to keep for yourself.

_____

Printed Name of Participant

Participant's Initials_____

_____ _____
Signature of Participant Date

Certification of Informed Consent

By signing above I confirm that:

(i) I have discussed the registry with the participant named above (and/or his/her Parent/Legal Guardian, if applicable), including explaining the registry to, and reviewing this informed consent form with, the participant;
(ii) this informed consent form was left with the participant and he/she was given time to consider whether or not to be in the registry;
(iii) the participant was provided with an opportunity to ask questions about the registry and have them answered; and
(iv) the participant agreed to take part in the registry and signed this informed consent form prior to his/her participation in the registry.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

As a WDI representative, my signature indicates that I have given a signed copy of this informed consent form to the participant.

Note to investigators:
- The original of this informed consent form must be placed in the participant's study file.
- A signed copy of this informed consent form must be given to the participant.

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