

University of Oklahoma Health Sciences Center (OUHSC)
Harold Hamm Diabetes Center – Diabetes Registry Informed Consent Form
Jonea Lim, MD, Principal Investigator

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The Harold Hamm Diabetes Center (HHDC) is creating a database of volunteers who are interested in participating in diabetes research. The HHDC is actively developing clinical and basic science research programs. An important part of this work is research sponsored by pharmaceutical companies to investigate the usefulness of new treatments for diabetes and its complications. We believe that clinical practice and research work together to improve how patients are treated and increase knowledge in the areas of Diabetes and Endocrinology. To facilitate this, we wish to create a database which will include details of patients with diabetes who are willing to be enrolled in clinical and basic science studies. There are a number of different research projects going on at any time in our Center, and we would like to be able to contact you about projects for which you might be eligible.

The Registry is a computer database that can be accessed only by the designated staff who have passed the necessary Human Participant Protection in Research training. The information will be used to identify subjects who might be eligible for specific clinical and basic science studies.

Periodically, you will be contacted to update your information. The information you supply will be entered into a secure, confidential database. The information collected is not detailed. It will include some details of your medical status and treatment (if any) with regard to diabetes and its complications, and the necessary information for us to contact you. Data entered into the Registry will remain there forever, or until you ask us to remove it. You will also be asked to complete a separate privacy authorization form.

While there will be no direct benefit to you for participating in the Registry, there are no costs or risks either. It is possible that you may never be contacted to participate in a study.

Efforts will be made to keep your personal information confidential, but absolute confidentiality cannot be guaranteed. You will not be identifiable by name or description in any reports or publications about this registry. There are organizations that may inspect and/or copy your records for quality assurance and data analysis, including the OUHSC Institutional Review Board.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food and Drug Administration and other regulatory agencies. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes.

Taking part in this registry is voluntary. You may choose not to participate or may withdraw your permission to be contacted. If you agree to participate then decide to withdraw permission later, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or wish to be removed from the Registry, contact Dr. Jonea Lim’s staff at 405-271-3604. If you cannot reach the investigator’s staff or wish to speak to someone other than the investigator’s staff, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045. For questions about your rights as a research subject, contact the OUHSC Director, Office of Human Research Participant Protection Program at 405-271-2045.

By signing this form, you are agreeing to participate in this Registry under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this Registry:

PARTICIPANT SIGNATURE (age ≥18)

Printed Name

Date

SIGNATURE OF PERSON
OBTAINING CONSENT

Printed Name

Date



IRB NUMBER: 1945
IRB APPROVAL DATE: 04/18/2017
IRB EXPIRATION DATE: 01/31/2018