Institutional Review Board - Federalwide Assurance #00002988

Cincinnati Childrens Hospital Med Ctr

Date: Friday, January 25, 2013

From: IRB Committee

To: Principal Investigator: Lawrence Dolan
Endocrinology

Re: Study ID: 2011-0407
Study Title: SEARCH for Diabetes in Youth

The above referenced protocol and all applicable additional documentation provided to the IRB were reviewed and **RE-APPROVED** using an **EXPEDITED** review procedure set forth in 45 CFR 46.110(b)(1), Category(ies)(see below) on 1/24/2013.

This study will be due for continuing review at least 30 days before 1/23/2014.

Study Documents

Atrium approval - expires 12/22/12

BCMH (OH Dept. of Health) approval - expires 1/20/13

Birthday card

Brochure - 2012

Brochure - follow-up

CES-D

CES-D - Spanish

Christ approval - expires 1/1/13

Cohort description 10-17 years

Cohort description 5-10 years

Cohort description adult

Cohort instructions

Cohort instructions - Spanish

Cohort intro letter

Cohort reminder letter

Cohort reminder letter - Spanish

Consent for 2012 visits

Consent for 2012 visits - Spanish

Consent for Single Follow-up Visit

Consent for single follow-up visit - Spanish
Consent for volunteers
Contact information
Contact information - Spanish
DVD cover
DVD disk label
Eating Problems
Eating problems - Spanish
Eye Vision
Facebook page
Family conflict
Family conflict - Spanish
Family medical history
Food Frequency
Food frequency - Spanish
Fort Hamilton Hughes waiver approval - no expiration
Health Questionnaire
Health Questionnaire - Spanish
IPS
IPS - Spanish
IPS letter
IPS letter - Spanish
IPS thank you letter
IPS thank you letter - Spanish
IPS Voucher - Spanish
Lab results description
Lab results description - Spanish
Letter - recruitment, registry visit
Letter - recruitment, registry visit - Spanish
Link to recruitment video
Link to study-wide public website
Low blood sugar
Low Blood Sugar - Spanish
McCullough-Hyde approval - expires 11/17/12

Medical record review
Medical Record Validation
Medication inventory
Medication inventory - Spanish
Mercy/Jewish approval - expires 12/20/12
MNSI
MNSI - Spanish
Newsletter - winter 2012
PDQ
PDQ - Spanish
PedsQL - diabetes-specific
PedsQL - diabetes-specific - Spanish
PedsQL - generic
PedsQL - generic - Spanish
Permission to text
Postcard - airplanes
Postcard - airplanes - Spanish
Postcard - hands
Postcard - hands - Spanish
Poster
Poster - Spanish
Protocol - version 4
Quality of Care
Quality of Care - Spanish
Referral - business size card
Referral card - depression - CCHMC pt.
Referral card - depression - non-CCHMC pt.
Refrigerator magnet
Registry description
Registry description - Spanish
Registry instructions
Registry lab result description
Registry reminder letter
Result letter - participant

Result letter - participant - Spanish

Result letter - provider

Retinal photo result letter

Script for completing forms prior to visit

Spanish translation certification - 2012 Visits Consent & recruitment documents

Spanish translation certification - consent, reminder letter, visit instructions

Spanish translation certification - Contact info.

Spanish translation certification - explanation of labs and urine instructions

Spanish translation certification - Food Freq. and QOC

Spanish translation certification - IPS

Spanish translation certification - lab results description

Spanish translation certification - Med Inventory

Spanish translation certification - MNSI

Continuing Review Documents:

Registry consent

Cohort consent

Please note the following requirements:

AMENDMENTS: The principal investigator is responsible for notifying the IRB of any changes in the protocol, participating investigators, procedures, recruitment, consent forms, FDA status, or conflicts of interest. Approval is based on the information as submitted. New procedures cannot be initiated until IRB approval has been given. If you wish to change any aspect of this study, please submit an Amendment via ePAS to the IRB, providing a justification for each requested change.

CONTINUING REVIEW: The investigator is responsible for submitting a Continuing Review via ePAS to the IRB at least 30 days prior to the expiration date listed above. Please note that study procedures may only continue into the next cycle if the IRB has reviewed and granted re-approval prior to the expiration date.

UNANTICIPATED PROBLEMS: The investigator is responsible for reporting **unanticipated problems** promptly to the IRB via ePAS according to current reporting policies.

STUDY COMPLETION: The investigator is responsible for notifying the IRB by submitting a Request to Close via ePAS when the research, including data analysis, has completed.

Research Categories

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Please note: This approval is through the IRB only. You may be responsible for reporting to other regulatory officials (e.g. VA Research and Development Office, UC Health - University Hospital). Please check with your institution and department to ensure you have met all reporting requirements.

Statement regarding International conference on Harmonization and Good Clinical Practices: The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

Thank you for your cooperation during the review process.

Greetings Dr. Dabalea, Principal Investigator,
This is official notification your NNR-01.106 Annual Report, Revised Consent Forms and your request for continuation was approved this 28th Day of January. The Continuation for period covering January 28, 2013 to January 28th with all Standard Conditions and acceptance of the Annual Report and Revised Consent Forms. .

Your Annual Report was well done and included all research related activities and information. Your protocol NNR-02.106 will be on the NNHRRB Agenda so there is an official record of action taken and you will receive your letter of notification and approval after that meeting.

I will be mailing your revised Consent Forms to the Shipock office on January 29, 2013 and you can begin utilizing the revised Consents. If you have any questions please do not hesitate to contact me.

Thank you for your cooperation and understanding these trying times regarding the research office, we will keep you updated on activities as they occur. There is no February IRV NNHRRB meeting.

Beverly Becenti-Pigman, Chairperson
Navajo Nation Human Research Review Board
The Navajo Nation
Window Rock, Arizona 86515

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Elizabeth Mayer-Davis
Nutrition

From: Non-Biomedical IRB

Approval Date: 4/01/2013
Expiration Date of Approval: 3/11/2014

RE: Notice of IRB Approval by Full Board Review
Submission Type: Renewal
Study #: 10-2341

Study Title: SEARCH for Diabetes in Youth: Carolina Site (SEARCH 3)
Sponsors: Centers for Disease Control and Prevention (CDC)
National Institute of Diabetes, Digestive and Kidney Diseases
National Institutes of Health (NIH)

This submission has been approved by the IRB for the period indicated.

Study Description:

This application includes two distinct aspects of SEARCH 3

Purpose: SEARCH for Diabetes in Youth is a multi-center study designed with a two-fold purpose of: (1) developing a uniform population based approach to finding and understanding rates and types of diabetes mellitus in youth including the development of a sustainable surveillance effort. (Registry study) and (2) Monitoring development of complications of diabetes in youth that were previously identified and participated in a SEARCH study baseline visit (Cohort Study).
Participants: Children and youth from 0-19 years of age with newly diagnosed diabetes living in South Carolina (Registry study) and individuals diagnosed with diabetes between 2002 and 2008 that previously completed a SEARCH study baseline visit and have had diabetes for at least five years(Cohort study).

Submission Description:

1. Revise introductory participant letter: Remove phone number for provider's office, replace with phone number for local SEARCH subsite.

2. Add new forms, per SEARCH Coordinating Center: Cohort Visit Employment and Economics Questionnaire; Cohort Visit Household Food Security and Food Assistance Form; Registry Visit Household Food Security Survey and Food Assistance Form (English and Spanish Versions);

3. Add revised form: Registry Visit Extended Core Form.

3. Add recruitment method: Text messaging (samples of messages included)

4. Add staff member to study: Jaime Hughes

5. Removed study team members (no longer at UNC): Megan Demaria, Jennifer Anderson, Whitney Franz, and Fran Urbina

Regulatory and other findings:

This research, which involves children, meets criteria at 45 CFR 46.404 and/or 21 CFR 50.51 (research involving no greater than minimal risk). Permission of one parent or guardian is sufficient. The surveys do not ask sensitive information and the blood draw and eye photography present minimal risk.

This research meets criteria for a waiver of written (signed) consent according to 45 CFR 46.117(c)(2) for completion of the IPS survey and for the collection of the overnight urine sample. Written consent will be collected before the urine is given to the research staff the next day.

This research meets criteria for waiver of informed consent for research [45 CFR 46.116(d)] and waiver of HIPAA authorization [45 CFR 164.512(i)(2)(ii)] for the case ascertainment and validation portion of the study.

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study (**Registry Study only**), as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA authorization will be sought. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=10-2341.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Joan Thomas, Nutrition

GREENVILLE HEALTH SYSTEM

May 22, 2013

James Amrhein, MD
Atten: Joan Thomas
Children's Hospital
200 Patewood Drive
Greenville, SC 29605

RE: IRB File # Pro00010812

Study Title: SEARCH For Diabetes in Youth-Carolina Center, Phase 3

Items Submitted for IRB Review: Study Protocol and Consent Form Reapproval

Dear Dr. Amrhein:

On May 22, 2013, the Institutional Review Board/Committee-B (IRB) of the Greenville Hospital System reviewed your research study. Full committee approval of the above-mentioned items was given for one year.

Your study will expire on *May 21, 2014. It is the investigator's responsibility to make sure the proper reapproval information is submitted to the IRB.* This information must be submitted to the IRB in ***April 2014.***

The same requirements as previously outlined for you by the IRB remain in effect as long as the study is ongoing. These requirements are as follows:

1. All participants must sign a copy of the attached IRB-stamped "approved" consent form before they can be enrolled in this study. Please use this stamped "approved" consent form to make copies for each participant.
2. Only the principal investigator or co-investigator can obtain consent from the participant.
3. The participant must sign and date the consent form in the presence of a witness.
4. A report to the IRB is required at the end of the approved time period giving the results of the participants involved in the study, the status of the study and whether or not renewed approval is desired.
5. Immediate notification must be sent to the IRB of any advertisements, modification of the Form 1572, as well as all revisions, changes, or amendments to the protocol or consent form.
6. Notification must be sent to the IRB within five (5) working days of any serious and/or unexpected adverse event that occurs locally. Notification of all non-locally occurring serious and/or unexpected adverse events must be sent to the IRB as soon as they are received from the sponsor.
7. The investigator must be sure that all consent forms are signed, dated and witnessed and placed in the participant's study record prior to study participation. The original should be retained in the participant's study record at the clinical research site. Case histories (patient charts/records) will also document that Informed Consent was obtained prior to the subject's participation in the study.
8. A signed copy of the consent form must be given to the person signing the form and a copy placed in the medical record if the study involves any type of hospital stay.
9. Please remember to use the GHS Study Drug Request Form for all participants entered in this study, when applicable. Your cooperation in this helps the pharmacy to better serve you. This form can purchased from the Supply and Distribution Center (Karen Corwin at 455-7819), Form Number A23914.

Thank you for your assistance in this matter. If you have any questions, please feel free to call the IRB Office at 455-4360.

Sincerely,

James W. Hayes, MD, Medical Director
Institutional Review Board/Committee-B
900 West Faris Road
Greenville, SC 29605

JWH:gh

MultiCare

MHS IRB Use Only

IRB Study Number
20-271

IRB Notification Approval

June 18, 2013

Catherine Pihoker, M.D.
Department of Endocrinology 7G-1
4800 Sand Point Way NE
Seattle, WA 98105

RE: Your follow-up submission of 6/17/2013 regarding study number 20-271: SEARCH for Diabetes in Youth of the Puget Sound (CDC, NIDDK)

Dear Dr. Pihoker:

Thank you for your response to requests from a prior review of your continuing review application for the study listed above. This type of response qualifies for expedited review under FDA and DHHS (OHRP) regulations.

This is to confirm that your application for continuation of your study is approved. The requested modifications have been approved. Your withdrawal of a request to conduct remote questionnaire-only cohort visits without using a consent form or a consent waiver has been accepted and approved. Thus, all interviews will be conducted onsite using your normal consenting process. The protocol is now approved through Phase 3 version dated 9/2012. The consent form(s) as submitted (6/3/2013) has been approved. You must obtain signed written consent from all subjects.

You are granted permission to continue your study as described effective immediately. Enclosed is the current "MHS IRB Approved" stamped consent form to be used when consenting patients. The study is next subject to continuing review on or before 6/2/2014, unless closed before that date.

As with the initial approval, changes to the study must be promptly reported and approved. Contact Kristina O'Brien (253-403-3877; fax 253-403-1112; email: kristina.o'brien@multicare.org) if you have any questions or require further information.

Sincerely,

H. Lester Reed, MD, FACP
Co-chair, MHS Institutional Review Board

University of Colorado
Anschutz Medical Campus

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
COMIRB Home Page [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

Certificate of Approval

05-Sep-2013

Investigator:	Dana Dabelea
Sponsor(s):	National Institutes of Health/DHHS~Juvenile Diabetes Foundation~Centers for Disease Control and Prevention/DHHS~
Subject:	COMIRB Protocol 01-934 Continuing Review
Effective Date:	05-Sep-2013
Expiration Date:	28-Jul-2014
Expedited Category:	9
Title:	SEARCH FOR DIABETES IN YOUTH

Submission ID: CRV012-2
Description:

*Response to Minor Modifications

The following changes have been made:
- The consent forms (Registry Study and Cohort Study) now reflect the CDC as the primary sponsor of the study to match the application and the Notice of Grant Award.
- Assent forms for the Registry Study and the Cohort Study remain unchanged. Clean copies of previously approved versions are uploaded.
- Attachment D – The SphygmoCor and the retinal camera devices were moved from column 1 to column 3 as it is more appropriate to consider the use of these instruments to monitor physiologic data rather than to collect safety and efficacy data. As the form instructs, page 1 only of the attachment is included.
- Attachment H – Page 3, Question 6c re: 46.406; Answer was changed from YES to NO.
- The version date was updated to 8/19/13 on the application and all attachments.

All COMIRB Approved Investigators must comply with the following:

- For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before implementation of the changes.
- Use only a copy of the COMIRB signed and dated Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form. Consent and/or assent forms must include the name and telephone number of the investigator.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- The investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted/high risk protocol, specific details will be outlined in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder 75 days prior to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1055 or UCHSC Box F-490.

Review Comments:

Documents approved/noted during this continuing review:
- PDF CR Form; version date 26-Jul-2013
- Cover letter, dated 26-Jul-2013
- Response to Minor Modifications Letter; dated 29-Aug-2013
- Application for Protocol Review with Attachments A, D, H, M, O, P, Q, R, S and Personnel Section C.
- Cohort Study Assent Form; version 2.2, dated 20-Feb-2013
- Cohort Study Consent Form; version 2.3, date 19-Aug-2013
- Registry Study Assent Form; version date 2.1, 20-Feb-2013
- Registry Study Consent Form; version 2.2, date 19-Aug-2013
- Enrollment Flow Chart
- Phase 3 Protocol; version date Dec-2010
- Publications 2012-2013

Please note that COMIRB will no longer be E-mailing approved documents. Stamped, approved documents can be retrieved in the eRA (InfoEd) system. Please click here to access instructions on finding these uploaded documents. Documents will be available within the next 48 hours.

Sincerely,

UCD Panel C

Please provide your feedback on IRB processes and support

IRB STATUS REPORT

Submit 1 copy electronically to irb@seattlechildrens.org.

IRB Number	12074	Study Title	SEARCH for Diabetes in Youth
Principal Investigator	Catherine Pihoker, MD	PI Email	catherine.pihoker@seattlechildrens.org
Study Contact	Beth Loots, MPH MSW	Contact Email	beth.loots@seattlechildrens.org

Principal Investigator Assurance

I acknowledge that the information provided in this status report is an accurate and complete description of the research study. I acknowledge that I have provided the IRB the information necessary for its complete review of this continuing research activity. I acknowledge that I am responsible for reporting any emergent problems, serious or unanticipated adverse events, or proposed changes to the research study. I acknowledge that any proposed changes described in this status report will not be put into effect until I receive IRB approval to continue this research.

I also certify that to the best of my knowledge, all current investigators have an up to date SFI disclosure on file with the Office of Research Compliance. For information on how to submit SFI disclosures, please visit the Office of Research Compliance web page on CHILD or seattlechildrens.org. For questions about SFI, contact the Office of Research Compliance.

8/7/13

Signature of Principal Investigator — Date

(Signature optional if submitted from PI's email account)

IRB Determinations

Study Status: ☑ Approved; any contingencies met on: _____ ☐ Disapproved ☐ Closed

Category of Research: 46.404

Category of Expedited Review (if applicable): 9

Parental Permission/Consent/ Assent Requirements: consent 18+; one parent permission; assent 7+; waivers for participants who turn 18 unless researcher has further interactions

IRB Chairperson/Subcommittee: _____ Date: 8-20-13

IRB Approval Valid Through: 8-19-14

IRB APPROVAL VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

1. CURRENT STATUS

A. Check the appropriate box (double-click on the box and select "checked"):

i. Continued IRB approval required because:
- ☒ Enrollment still in progress
- ☐ Enrollment closed, but participants still active in the research
- ☐ Enrolment closed, all research interventions complete, and study active for long term follow-up only - **list** remaining procedures (*e.g.*, following standard of care, completing quality of life surveys):
- ☐ Participant involvement complete; remaining activities limited to analysis of identifiable data or publication
- ☐ Enrollment not started at SCH

ii. IRB approval no longer required because:
- ☐ Study completed at SCH and no further use/analysis of identifiable data at this time (complete this form)
- ☐ Study never started

iii. IRB approval has lapsed and requesting study be re-opened:
- ☐ Indicate above the study status once re-opened and **explain** the following: (1) why the lapse occurred; (2) whether any research activities occurred after the lapse; and (3) what corrective actions will be taken to prevent future lapses:

2. RESEARCH PARTICIPANTS

A. Enrollment

i. Please complete the enrollment table for participants enrolled (consent/assent obtained) under SCH's IRB approval (include sites relying on SCH IRB) and participants enrolled at all other sites (if a multi-site study):

Label each participant group in each row (e.g. cases, controls, parents, family members, nurses, or teachers)	SCH's IRB Approval (SCH, UW, etc.)	All Sites (Multi-site trials only)
1. Total # approved for entire study	Estimated 5,500	This is a population based study, so we and other sites aim to enroll all youth with newly diagnosed diabetes in the defined geographic areas and time frames.
2. Total # enrolled to date (since study initiated)	5,025	22,911
3. Total # enrolled during the current approval period	238	820
4. Total # currently active participants	4,570	N/A

ii. Is the overall enrollment proceeding as expected?
- ☒ Yes
- ☐ No, please explain if this will affect the ability to answer study questions and what steps will be taken to improve enrollment:

iii. Have you received any complaints from participants or others during the current approval period?
- ☒ No
- ☐ Yes, please summarize:

iv. Have any participants withdrawn or been withdrawn from the study during the current approval period?
- ☒ No (N/A)
- ☐ Yes, please list the number and summarize the reasons for the withdrawals:

B. Consent/Parental Permission/Assent Process

i. Have any active participants reached 18 years of age during the current approval period? An active participant is any participant that for the purposes of this study you continue to have interactions with or whose identifiable data you continue to use, study, or analyze.

☐ No

☒ Yes, please indicate whether these participants have been or will be re-consented:

☐ All participants are re-approached after their 18th birthday

☒ IRB has previously approved a waiver for participants who turn 18 during the research

☐ If you are unable to re-approach and do not currently have waivers of consent/HIPAA, please explain why it is not practicable/feasible to re-approach these participants:

3. STUDY PROGRESS

A. Progress Report

i. Please provide a brief progress report. Your report must have sufficient detail to demonstrate the study is being conducted consistent with your IRB approval. If you have not yet enrolled research participants, please explain why:

SEARCH for Diabetes in Youth is an ongoing, multi-center, CDC/DDT and NIH/NIDDK funded observational study of childhood diabetes that provides the most comprehensive data on a large cohort of youth with diabetes ever established. SEARCH 3 includes registry and cohort components, as well as approved ancillary studies. The study is currently funded until September 29, 2015.

Study Activities

Registry

SEARCH for Diabetes in Youth is continuing to ascertain newly diagnosed incident diabetes cases in youth age <20 years across five geographically dispersed study centers, in order to assess temporal trends in diabetes by age, sex, race/ethnicity, and diabetes type. At the WA site, the geographic area for the study includes King, Kitsap, Pierce, Snohomish, and Thurston counties. The study is identifying incident cases from 2010 – 2015, and is periodically re-ascertaining cases from earlier years. We are finding that we are averaging about 270 incident cases per year, based on incident 2010 (n=256), incident 2011 (n=317), incident 2012 (n=288), and incident 2013 (n=95) cases. 2011 – 2013 case ascertainment is in process.

Participants with newly diagnosed diabetes are being asked to complete an Initial Participant Survey (IPS). We are currently averaging about a 75% response rate to the IPS. A portion of those who are diagnosed in 2012 are also being asked to complete a 'registry' visit. We have completed 80 registry visits to date at our site, out of an estimated 145 total projected visits. We are continuing to collaborate closely with our local partners on case ascertainment and IPS efforts.

Study investigators are providing consultation and support to inform the development of low-cost sustainable public health surveillance systems of childhood diabetes in the U.S. SEARCH is also assessing total and cause-specific mortality among 2002 – 2008 incident cases for the period from the date of diabetes diagnosis through December 31, 2010.

Cohort

SEARCH is conducting an in-person 'cohort' visit with SEARCH participants who were incident in 2002 or later, have a duration of diabetes about > 5 years, and have data from a baseline study visit (n=3,743 across 5 sites; n=638 in WA). Data gathered at these visits will help investigators assess the prevalence and incidence of, and risk factors for, chronic microvascular complications, selected markers of macrovascular complications, and serious acute complications of diabetes. It will help determine the degree to which barriers to care, quality of care, and the process of transition from pediatric to adult care impact disease factors, including dimensions of diabetes type and diabetes-related outcomes. This data will also be used to maintain and supplement the SEARCH repository for biological specimens, and promote access to SEARCH for conduct of scientifically and logistically appropriate ancillary studies. We have completed 278 cohort visits to date at our site, which is 44% of our target population. We are scheduling visits at times and locations that work well for participants and their families. We are also completing a medical record review on a subset of this group.

Ongoing

We are continually updating contact information for study participants via contact information mailings, newsletter mailings, LexisNexis, searching medical records, and contacting participants via phone or email.

Study-wide Activities

The WA Principal Investigator, Dr. Pihoker, is a member of the SEARCH Study Group and participates in the oversight of the national study. Other local Investigators and staff are active in the SEARCH Study Group and in a number of additional committees. Investigators and staff also participate in a number of writing groups.

Ancillary Studies

SEARCH Air

The SEARCH Air study is an ancillary study of SEARCH and is the first study to comprehensively evaluate the role of air pollution on inflammatory and subclinical CVD markers in a diverse racial/ethnic and geographic population of youth with Type 1 diabetes. Understanding the role of these environmental pollutants on this vulnerable population has the potential to have a marked impact on treatment approaches and behavioral recommendations. The study approach is utilizing rich existing SEARCH data, combined with new assays of stored plasma, to examine inflammatory markers and subclinical measures of cardiovascular function and structure in conjunction with air pollution exposures, estimated with state of the art spatio-temporal models. Participants for the study are being drawn from five SEARCH sites. Incident cases from 2002 to 2005 are being included as well as prevalent cases beginning in 2001. Existing plasma samples of 2 aliquots or more taken at baseline and follow-up visits will be analyzed for participants without existing inflammatory marker data. Recorded residential addresses are being geocoded for the baseline and follow-up visits when 1) existing inflammatory or subclinical CVD markers were assessed and 2) when blood was drawn for inflammatory markers to be analyzed by this study. Acute and chronic exposures to ambient pollution and traffic-related pollution will be modeled using spatio-temporal statistical models. These exposures will be assigned to each geocoded address for each participant. This study is in the data analysis stage.

SNAS

The SEARCH Nutrition Ancillary Study (SNAS) is an ancillary study of SEARCH funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and designed to substantially expand the nutrition component of SEARCH, using both cross-sectional and longitudinal designs. The overall goal of SNAS is to examine associations of nutritional factors with 1) the progression of insulin secretion defects, and 2) the presence of CVD risk factors in youth with T1DM. After clinical diagnosis of autoimmune mediated DM, patients can retain some capacity to secrete insulin for several weeks, months, or longer. Preservation of β-cell function has been associated with lower risk for hypoglycemic events as well as lower HbA1c values and less frequent microvascular complications. Moreover, children and adolescents with T1DM are at increased risk for cardiovascular disease in later life. The premise of the work is that preservation of β-cell function and development of CVD risk factors in youth with T1DM are impacted by nutritional factors. Identification of these nutritional determinants may provide fruitful approaches to improving the long-term health of these young people. This study is in the data analysis and manuscript writing stage.

Monogenic

The SEARCH Monogenic Ancillary Study was funded by the Juvenile Diabetes Research Foundation to extend the observations made in SEARCH. Monogenic diabetes is caused by a single mutation in genes that control either the production or release of insulin. There are two major classifications of monogenic diabetes, Maturity Onset Diabetes of the Young (MODY) and Permanent Neonatal Diabetes Mellitus (PNDM). Individuals at highest risk for MODY are those with non-autoimmune diabetes. Individuals at highest risk for PNDM are those diagnosed with diabetes at less than 12 months of age. Little is known about the frequency of either MODY or PNDM. SEARCH performed genetic analysis in the groups at high risk for monogenic diabetes. The goal of this ancillary study is to extend the observations made in the SEARCH study by performing genetic analyses for the three most common types of MODY (MODY3, MODY1, MODY2) in all SEARCH participants with non-autoimmune diabetes; performing genetic analyses for all known types of PNDM, including Kir6.2, SUR1, insulin gene, EIF2AK3 (Wolcott-Rallison syndrome), FOXP3 (IPEX syndrome), homozygous GCK, IPF1, HNF-1β, GLIS3 and PTF1A, in all SEARCH participants diagnosed with diabetes in infancy; assessing the impact of establishing a diagnosis of monogenic diabetes on clinical care; and performing genetic analysis for monogenic diabetes in selected first degree relatives of SEARCH probands to establish a link between the MODY or PNDM mutations and the presence of diabetes within these families.

IRB Status

We have continuing approval at 4 Institutional Review Boards (IRBs), including: Seattle Children's, MultiCare Health Systems, Virginia Mason, and Swedish Medical Center. Group Health Cooperative ceded review to Seattle Children's. We are continuing to submit revisions and renewals through these IRBs as appropriate.

Future Directions

Seattle Children's continues to be a key contributor to the national study. Our site benefits from an extensive local network that includes enthusiastic study participants, investigators with extensive diabetes expertise, and regular contact with youth with diabetes. Collaborating institutions include the Benaroya Research Institute, the R.H. Williams Laboratory for Diabetes Research, the Diabetes Endocrinology Research Center, the University of Washington Diabetes Care Center, Group Health Cooperative, MultiCare Health Systems (Mary Bridge Children's Hospital), and others throughout the Puget Sound region.

B. Adverse Events, Incidents, and Unanticipated Problems

i. Has the **overall** frequency and severity of **adverse events** been consistent with the research protocol, the informed consent, and the investigator brochure (as applicable)?
- ☒ Yes
- ☐ No, please **summarize** the events and what **actions** have or will be taken (*e.g.*, changes to protocol, consent form):

ii. Are there any **unexpected** adverse events (nature, severity, or frequency) that have **not** been previously reported? Please note a report is only required for participants enrolled under SCH's IRB approval.
- ☒ No
- ☐ Yes, please complete and attach the Seattle Children's Adverse Event Reporting Form.

iii. Are there any incidents, protocol deviations, or potential unanticipated problems that have **not** been previously reported? Please note a report is only required for participants enrolled under SCH's IRB approval.
- ☒ No
- ☐ Yes, please complete and attach the Seattle Children's Incident Report Form.

C. Data & Safety Monitoring

i. Does this study have a Data Safety Monitoring Board or Data Safety Monitoring Committee?
- ☒ No
- ☐ Yes, please **attach** the most recent correspondence from the Board/Committee.

ii. Has the study been reviewed by a monitor (*e.g.*, SCH compliance officer or CRO), sponsor, or agency (*e.g.*, FDA, OHRP) during the current IRB approval period?
- ☒ No
- ☐ Yes, please **attach** the report or any other available information.

D. New Information

i. Is there any new information that may be relevant to participants, whether published or unpublished? New information includes FDA warnings, off-site SAEs, suspensions in enrollment, and scientific literature/findings (including new risks).
- ☒ No
- ☐ Yes, please **summarize** the information:

ii. If there is relevant new information, will you inform previously-enrolled participants?
- ☒ No (N/A)
- ☐ Yes, please submit a modification request describing how participants will be informed of the new information (*e.g.*, letter to participants, verbal discussion at next visit, re-consenting/assenting in-person or by mail):

4. ATTACHMENT CHECKLIST

Please indicate the applicable attachments (completion of this section is mandatory). Submit 1 copy electronically to irb@seattlechildrens.org.

Adverse Event Report Form	☐ **Yes** ☒ **N/A, no new AEs to report**
Incident Report Form	☐ **Yes** ☒ **N/A, no new incidents to report**
Data & Safety Monitoring Report	☐ **Yes** ☒ **N/A, no data/safety monitor**
Monitor, Sponsor, or Agency Report	☐ **Yes** ☒ **N/A, no new monitoring reports**
Consent/Parental Permission Form(s) *(most recently approved version, unstamped)*	☒ **Yes, participants still enrolling or forms needed to re-approach at 18** ☐ **N/A or no longer enrolling**
Assent Form(s) *(most recently approved version, unstamped)*	☒ **Yes, participants still enrolling** ☐ **N/A**
Translations of Consents/Assents	☐ **Yes, translations are current** ☒ **N/A** We will translate and submit these to the IRB as the need arises.
Information Sheet(s) (*waiver of documentation of consent*)	☒ **Yes, participants still enrolling** ☐ **N/A**
HIPAA Form(s) (including other languages, if applicable)	☒ **Yes, participants still enrolling** ☐ **HIPAA does not apply**
Modification Request Form*	☒ **Yes** ☐ **N/A, no changes**

*If you wish to make changes at the time of renewal (*e.g.*, revisions to consent/assent/HIPAA forms to reflect updated template information), you must complete the Modification Request Form and submit it with the status report.

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Institutional Review Board Modification Request Form

Routing Instruction:
1 electronic copy to
irb@seattlechildrens.org

Form Information:
Form #: N/A
Form Owner: Laurie Bolton
Owning Dept: HSPP
Revision Date: 08/12

For Office Use Only ☑ ***46.404*** ☐ ***46.405*** ☐ ***46.406***

A. Study Information

IRB Study #: 12074	Date: 8/7/13
Project/Study Title: SEARCH for Diabetes in Youth	
Principal Investigator: Catherine Pihoker, MD	Phone: 206-987-5037
Department, Division: Pediatrics, Endocrinology	Center Affiliation: CCTR
IRB Contact Person: Beth Loots, MPH MSW	Phone: 206-884-4488

B. Modifications Proposed – Please check **all** categories that apply and supply requested information as applicable.

1. ☒ Change in Research Personnel

Name	Add or Remove	Role on Project & Title	Phone	**SCH Workforce?	Human Subjects Training Date & Type/Location	Will s/he obtain consent?
Richard Mauseth, MD	Remove	Co-Investigator	206-987-2540	No	n/a	n/a
Angela Badaru, MD	Remove	Co-Investigator	206-987-2540	No	n/a	n/a
Rebecca O'Connor, RN	Remove	Clinical Research Coordinator	206-987-2540	No	n/a	n/a
Emil Buscaino, BS BA	Remove	Clinical Research Associate	206-987-2540	No	n/a	n/a
Patricia D'Alessandro	Add	Clinical Research Associate	206-987-2540	Yes	8/6/13, CITI	yes

**REMINDER*: Before participating in research, all added investigators must have an up to date SFI disclosure on file with the Office of Research Compliance . For information on how to submit SFI disclosures, please visit the Office of Research Compliance web page on CHILD or seattlechildrens.org. For questions about SFI, contact the Office of Research Compliance.

* *Seattle Children's workforce: employees of Seattle Children's, Children's University Medical Group (CUMG) members, and residents and fellows working at Seattle Children's.

2. ☐ Changes in Research Design and Methods

☐ Treatment regimen
☐ Research procedures
☐ Drug used in the research (e.g. dosage change)
☐ Device/s used in the research
☐ Visit schedule
☐ Data collection methods or instruments (e.g. if adding)
☐ Randomization methods
☐ Duration of follow-up
☐ Specimen collection/use
☐ Other (describe):

* *REMINDER* (If Any Boxes in Section 2 are checked): By virtue of submitting this form, the PI attests that both the FRA and Study Manager data for this study will be updated accordingly.

3. ☐ Changes Pertaining to Research Participants

☐ Sample size change
☐ Addition of a new cohort or sample
☐ Eligibility/exclusion criteria
☐ Recruitment/approach
☐ Consent/assent process
☐ Methods for documenting consent
☐ Risks and benefits (e.g. new treatment side effects; radiation requiring safety committee review--attach relevant documents)
☐ Privacy of research participants
☐ Confidentiality of research participants' data
☐ Research Site/Location (attach relevant letters of cooperation)
☐ Other (describe):

4. ☐ Materials Revised/Amended: Check **all** documents being revised or amended at this time. Submit revised documents in electronic form with **tracked changes and clean versions** to facilitate IRB review.

☐ Protocol, **Version**:
☐ Investigator's Brochure, **Version**:
☐ Consent, **Version**:
☐ Assent, **Version**:
☐ Recruitment materials* (e.g. flyer)

Institutional Review Board Modification Request Form

☐ Data collection form
☐ HIPAA/Oath of Confidentiality
☐ Translated study documents (must include Affidavit; see IRB Policy 021)
☐ Other (describe):
☐ Questionnaire/Survey, **Please List**:

*See following link re information & templates for recruitment materials: http://research.seattlechildrens.org/rss/irb/advertising.asp

5. ☐ **Funding Information (Funded Awards Only) ****Please submit an electronic copy of the funded proposal. If this proposal applies to more than one IRB application, please submit a modification form for each study separately.

Title of Funding Proposal:	
Type of Funding Proposal: ☐ Grant ☐ Contract ☐ Subcontract ☐ Supplement ☐ Other (Please explain)	
Name of PI on Funding Proposal:	If Subcontract, name of main PI
Name of Funding Agency:	Sponsor Grant Identification Number (if known; eg. R010123456-01A1):
Funding based at? ☐ Seattle Children's ☐ UW ☐ Fred Hutchinson ☐ Other (Please explain)	
Proposed Funding Period (dates XX/YY/ZZ-XX/YY/ZZ):	
Are research activities described in this funding proposal consistent with the current IRB application? : ☐ Yes ☐ No, If No, Please explain which aims of this study apply. Please provide rationale for the differences between the grant and the IRB application.	
Are there future aims without current IRB approval? : ☐ Yes ☐ No If Yes, please explain your plans to obtain approval.	

C. Modification Summary and Rationale: Please address **ALL** of the following, use additional pages if needed:

a) Describe each change/revision in sufficient detail:

Dr. Mauseth has been removed as he has retired; Dr. Badaru has been removed as she has relocated; Rebecca O'Connor has been removed as she is no longer a Seattle Children's employee; and Emil Buscaino will be leaving employment at Seattle Children's on August 9, 2013. Patricia D'Alessandro has been added as she is a new research team member. Sharla Semana has earned a MSW degree.

b) Provide the rationale for the proposed changes:

To update the study consents and assents to reflect current research personnel.

c) Explain whether these changes add new risks or increase the current risks of study participation:

They do not.

D. Signatures and Approvals

PI Signature: ___ _____ Date: __08/07/13_____
(Optional Signature if submitted from PI's e-mail account.)

IRB Approval	☑ Approve ☐ Disapprove ☐ Noted ☑ Reviewed via expedited procedures, 45 CFR 46.110(b)(2)
IRB Chairperson/Subcommittee Signature:	8-20-13 Date Approved:

☐ Subject to the conditions/contingencies detailed in IRB correspondence dated: _____

Conditions/contingencies met on: _____

Seattle Children's
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Routing Instruction:
1 electronic copy to
irb@seattlechildrens.org

Form Information:
Form #: N/A
Form Owner: Laurie Bolton
Owning Dept: HSPP
Revision Date: 08/12

Institutional Review Board Modification Request Form

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up
ASSENT FORM: Ages 14-17

COHORT VISIT

Study Title: SEARCH for Diabetes in Youth

Principal Researcher: Catherine Pihoker, MD

The Research Team:

Name/Degree	Title	Department	Phone Number
Catherine Pihoker, MD	Principal Investigator	Endocrinology	206 987-5037
Lenna Liu, MD MPH	Co-Investigator	Pediatrics	206 987-5037
Maryam Afkarian, MD	Co-Investigator	Nephrology	206 987-5037
Irl Hirsch, MD	Co-Investigator	Medicine	206 987-5037
Carolyn Paris, MD	Co-Investigator	Emergency	206 987-5037
Joyce Yi-Frazier, PhD	Co-Investigator	Endocrinology	206 987-5037
Carla Greenbaum, MD	Co-Investigator	Benaroya Res Instit	206 987-5037
Martin Goldsmith, MD	Co-Investigator	Peds Northwest	206 987-5037
Beth Babler, ARNP	Co-Investigator	Mary Bridge	206 987-5037
Patricia Fechner, MD	Co-Investigator	Endocrinology	206 987-5037
Christian Roth, MD	Co-Investigator	Endocrinology	206 987-5037
Ildi Koves, MD	Co-Investigator	Endocrinology	206 987-5037
Craig Taplin, MD	Co-Investigator	Endocrinology	206 987-5037
Kate Ness, MD	Co-Investigator	Endocrinology	206 987-5037
Carolina DiBlasi, MD	Co-Investigator	Endocrinology	206 987-5037
Roja Motaghedi, MD	Co-Investigator	Endocrinology	206 987-5037
Erin Alving, ARNP	Co-Investigator	Endocrinology	206 987-5037
Karen Aitken, ARNP	Co-Investigator	Endocrinology	206 987-5037
Joanie Warner, ARNP	Co-Investigator	Endocrinology	206 987-5037
Sara Benitez, PA	Co-Investigator	Endocrinology	206 987-5037
Gwyn Recupero, PA	Co-Investigator	Endocrinology	206 987-5037
Beth Loots, MPH MSW	Research Manager	Endocrinology	206-987-2540
Sue Kearns, RN	Study Coordinator	Endocrinology	206 987-2540
Mary Klingsheim, RN, BSN	Study Coordinator	Endocrinology	206 987-2540

Name/Degree	Title	Department	Phone Number
Jessica Fosse, MPH, RN, BSN	Study Coordinator	Endocrinology	206 987-2540
Katherine Cochrane, BS	Clinical Research Associate	Endocrinology	206 987-2540
Sharla Semana, MSW	Clinical Research Associate	Endocrinology	206 987-2540
Patricia D'Alessandro, MA	Clinical Research Associate	Endocrinology	206 987-2540

Clinical Research Center: (206) 987-3897

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

24 hour Emergency Contact Number: 206 987-2000 Ask for the Endocrinologist on call

1. Researchers' Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants 18 years and older: This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

Potential Teen Participants: This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your parent or guardian would also need to give their permission and sign this form for you to join the study.

Parents/Guardians: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **"you"** in this form refers to your child/teen.

2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children's.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

Diabetes is the third most common chronic or ongoing disease in individuals under 20 years of age. The total number of cases of diabetes in this age group is increasing, and types of diabetes that have not been seen in young people are now being seen. These changes have resulted in gaps in our knowledge about the total number of cases and types of diabetes in the United States, the type of care young people with diabetes receive, the complications they experience, and the effect diabetes has on their lives.

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer the following questions:

- How common are long-term complications related to diabetes, including: retinopathy (damage to back of the eye), nephropathy (kidney damage), neuropathy (nerve damage), and damage to the heart and blood vessels?
- How common are short-term complications, including hypoglycemia (low blood sugar) and diabetic ketoacidosis (DKA)?
- What type of medical care are young people with diabetes receiving, and how does diabetes affect the lives of these individuals?

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you have completed a SEARCH baseline in-person visit and have had diabetes for (about) 5 years or more.

5. How many people will take part in the study?

We think that about 610 people will take part in the SEARCH cohort visit at Seattle Children's. A total of about 3,900 people will take part in the cohort visit at hospitals and clinics around the country.

6. If I agree to join this study, what would I need to do?

The cohort study visit includes:

- Blood draw
- Urine collections
- Brief physical exam
- Questionnaires
- Nerve tests
- Blood vessel test
- Eye test
- Medical record review
- Follow up contact

Blood Draw and Urine Collection

You/your child would be scheduled for an in-person study visit(s) at the Clinical Research Center at Seattle Children's or at another SEARCH outreach clinic. We would work with you to schedule 1 or 2 visits to complete the cohort study measurements at time(s) that are convenient for you. At least one of these visits would be a "fasting" visit, which means that no food or fluids, other than water, could be consumed for at least 8 hours before coming to your visit. You/your child would be asked not to take insulin or other diabetes medications the morning before the test, except for basal insulin, which should be taken as usual. If you come to the visit nonfasting, we might ask you to return another day to redraw all or part of the blood sample.

Before your scheduled appointment, you would receive a container with detailed instructions to collect one urine sample at home the morning of your visit. We will ask that you collect the urine from the first time you urinate in the morning. You would be asked to bring this urine sample with you to your visit. Your urine would be tested for microalbumin (small particles of protein) to see how well your kidneys are working.

When you arrive at your appointment, we would review the consent/assent form(s). This would take about 20 – 30 minutes. If you/your child would like a numbing agent for the blood draw, this part may take about an additional 30 minutes.

A blood sample would be drawn from your/your child's arm to measure blood sugar, hemoglobin A1c (a test measuring your/your child's average blood glucose level over the past 3 months), C-peptide (a measure of your/your child's own insulin production), different types of cholesterol (fat), islet cell antibodies (markers in the blood for type 1 diabetes), and several blood markers

associated with risk for developing heart disease or stroke. Based on age and size, the amount of blood that would be needed for this would be between 1 teaspoon and 3 tablespoons.

If possible, we would collect all blood samples at the same time that a routine blood draw would be done. If you/your child take part in more than one research study at the same visit, we would try to combine tests and results when we can.

A urine sample would also be obtained during the visit and tested for several markers associated with the risk of diabetes complications, such as heart disease and stroke. The SEARCH study would like to keep some of the blood and urine that would be collected during the study but is not used for other tests. Should we have questions about some of tests, the storage sample would allow us to repeat the tests without needing to ask for a second blood draw from you/your child. In addition, we would like to collect another sample of blood for storage for future research.

We will also ask your permission to obtain and store a sample of blood to look at DNA, the genetic material that is found in all of your cells. Researchers may look at specific genes, or they may look at all of your genes together. If researchers were to look at specific genes, you have the option of receiving the results of this testing if it would effect your clinical care. However, if they were to look at all of your genes together, you would not receive the results. The information researchers find about your DNA would be sent to a national storage center called dbGaP (part of the National Institutes of Health) to help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease. When your DNA and clinical information would be sent to the storage center, no personal information would be included, such as your name, date of birth, or address. Thus, researchers would not be able to link this information back to you. The research that would be done with your blood and urine samples would not be designed to specifically help you. It might help people who have diabetes and other diseases in the future.

The total amount of blood that would be needed for the storage sample would be 1 teaspoon for young children and up to 2 tablespoons for older children, dependent on age and weight. This part of the visit would take 10 – 20 minutes.

The total volume of blood for this visit would be up to approximately 3 tablespoons.

After the fasting blood and urine samples are collected, a snack and/or meal or meal voucher would be provided and you/your child would also take your routine medication.

Physical Exam

A trained member of the research team would perform a brief physical examination including: height, weight, waist measurements, blood pressure, and examination of the skin of the neck. The time to complete this exam would be about 20 minutes.

Nerve Tests

The purpose of these tests is to learn more about nerve damage in people with diabetes. We would ask you not to exercise heavily the day before the tests. If you get sick or get very upset

in the day or two before the tests, or you eat or drink things that may affect the tests, we may ask you to reschedule these tests.
These are the nerve tests:

1) MNSI, or Michigan Neuropathy Screening Instrument, is a 1-page survey and a brief foot exam.

You would fill out the survey yourself; it has 15 “yes or no” questions about pain, numbness, and temperature sensitivity in your legs and feet.

The foot exam is short and tests for your vibration sense, your reflexes, and your sensitivity to monofilaments. Monofilaments are just small pieces of lightweight plastic, much like fishing lines. The study coordinator would first test your vibration sense by placing a vibrating instrument on your big toe. They would then use a rubber “hammer” to test the reflexes in your ankle. These tests are not painful, and your regular doctor has probably used them with you before. Finally, the study coordinator would place a monofilament on your toe to test your sense of touch. These small pieces of plastic are not painful. The study coordinator would just ask you if you could feel them on your toe or not.

The MNSI would take about 10 minutes to complete.

2) HRV, or Heart Rate Variability, would find out the health of your heart nerves. The test uses an ECG, or electrocardiogram. This is a test that doctors regularly use to study the heart, and your doctor may have used it with you before. The study coordinator would apply three electrode stickers (special stickers that help transmit information) on your wrists and left ankle/leg. These pads would be attached to wires and would record your heartbeat. During the test, you would simply breathe normally for ten minutes while the ECG records your heartbeat. The Heart Rate Variability test would take about 20 minutes to complete.

Blood Vessel Test

We would perform a test to measure how your blood vessels function. This test is called an arterial stiffness test. You/your child would be asked to remove your outer clothing and to put on a patient gown if you are not wearing loose-fitting shorts. A trained study coordinator would check your pulse on your upper, inner thigh (groin), but would not expose private parts. A chaperone would be present during these procedures.

The following test would then be performed:

The study coordinator would measure the distance from your neck to the top of your sternum (breast bone), from your neck to your wrist, from your sternum to your belly button, from your belly button to your groin, and from your groin to your foot. The electrode pads would be left in place on your wrists and leg during this part of the test.

Your wrist would be touched with a small instrument shaped like a pen; and the stiffness of your blood vessels would be measured. This instrument detects pressure changes with a tiny,

highly-sensitive pressure sensor in the flat end of the device that is shaped like a pencil eraser. It does not use radiation (X-rays), sound waves (ultrasound), or needles. This test would be repeated 3 times.

Then the same pen-shaped instrument would be touched on the side of your neck, your groin, and your foot to measure the speed of your pulse. This test would be repeated 3 times.

The blood vessel test would take about one hour. After the test you would receive a meal or meal voucher.

Eye Test

You/your child would be asked about your eyes and your eye doctor if you have one.
We would take 2 pictures of each of your/your child's eyes. You/your child would be asked to sit in front of a special camera and place your chin in a chin rest. The study coordinator would darken the room so that your pupils would dilate (open) and we could align and focus the camera on your retina (the back of your eye). No drops would be put in your eyes, and the camera would not touch your eye. The study coordinator would sit on the other side of the camera to record information into a computer and prepare the camera. While we do this, you would see some small red bars and a multi-colored "x" in the camera lens. We would ask you to look at the "x". Just before we take the pictures, we would ask you to blink your eyes and then open them really wide. The camera would flash a light from within the camera lens as the picture is taken. This flash does not hurt the eye. Just after the picture is taken, you may see a blue or red circular spot in front of your eye. This spot would not harm you and would go away in about 5 to 7 minutes. We would wait a little while until your eyes dilate (open) again, and then we would take another picture of this eye. We would then take 2 pictures of your other eye. We might need to take extra pictures if the first ones don't come out OK.

These pictures would be sent to the Ocular Epidemiology Reading Center in Madison, Wisconsin to be read by trained eye specialists who would study the blood vessels and look for any unusual changes.

Doing the eye test would take about 30 minutes.

Questionnaires

You/your child would answer questions about the effects of diabetes on your/your child's lives, including current medications, personal and family medical history, financial information, the type of diabetes education available, health insurance, diabetes self-care habits, diet, your/your child's self-report on stage of puberty, and information about your/your child's medical care.

If you/your child is 10 years of age or older, you/your child would also be asked to answer additional questions about physical activity, smoking, alcohol, eating, and depression. Some of the questions may be sensitive, for example, there are questions about mood, how well you/your child get along in school, how you/your child gets along with family, friends, and others.

You/your child are free to not answer any questions you don't want to answer, and may stop the interview at any time. If you/your child decide not to answer any of the questions, you can still take part in the rest of the research study.

One of the questionnaires assesses risk for depression, and it would be scored while you are at your/your child's appointment. If you/your child scores in a range at risk for depression that result would be shared with your parent/you and a referral list would be shared with you if you need it.

These questionnaires would take 45 – 60 minutes to complete.

Medical Records Review

We ask your permission for the researchers involved in this study to review your/your child's medical record. Any information obtained from the medical charts is for use in this research study only. It may be necessary to review your diabetes-related inpatient and outpatient medical records. These records may include, but are not limited to visit notes, progress notes, discharge summaries, consultation notes, medication records, history and physical, emergency room records, and lab and other test reports.

Follow up

We will send you requests to update your contact information about every year. Part of this update includes a question about your/your child's social security number, which we will use to track mortality among SEARCH study participants. If this study is expanded, or if other diabetes studies are developed, we may contact you/your child in the future to ask if you/your child want to participate further. As with this study, taking part in any future study is voluntary.

7. How long would I be in the study?

The study is currently funded through September 2015.

The total time to complete the cohort visit would be about 3 ½ to 4 hours. You may complete the visit on one or two days, based on your preference and the research staff's availability. You may be able to complete some of the questionnaires at home or over the phone to shorten the length of the in-person visit.

If you join the study, you can decide to stop **at any time for any reason**. Please discuss your decision to stop with Dr. Pihoker or the research team.

If you would like your/your child's stored samples removed from storage, we would send a request to the central laboratory. They would then destroy the sample, and send us a letter certifying that the sample has been destroyed. We would send you a copy of this letter.

The research study doctor could also decide to take you out of this study. This might happen if we find out that it is not safe for you to stay in the study. Or it might happen if you cannot

complete to enough of the study elements. If we ask you to leave the study, we would always explain why.

8. What are the potential harms or risks if I join this study?

If you feel uncomfortable at any time during any of these tests, just tell the study coordinator and they would immediately stop the tests. All reasonable precautions would be taken to reduce risks.

When taking a blood sample, there may be brief discomfort, and a bruise may form where the needle poke occurs. To reduce the possibility of these risks, a local anesthetic (numbing cream or liquid) may be applied to the skin before blood is taken.

The blood tests require that you/your child not have any food or fluids overnight, other than water. In order to prevent low or high blood sugars, you/your child's blood sugar would be checked by finger-stick and your diabetes medication would be given as needed to control your/your child's blood sugar.

Some of the tests would look for the presence of health problems associated with diabetes, such as high cholesterol. If researchers find signs of these health problems, it may cause you/your child some anxiety or concern. If this happens, you/your child would be referred to the appropriate local health professionals for evaluation and treatment.

There are no majors risks associated with the MNSI foot exam. All of the devices used (a reflex hammer, a tuning fork, and a monofilament) are used daily in doctors' offices; your doctor has probably used them with you before. The tests are not painful, but some people may be slightly anxious or uncomfortable when these instruments are used.

There are no major risks associated with the Heart Rate Variability nerve test. ECGs are used daily in hospitals; you may have had one before. No electrical current is sent through the body, so there is no risk of electrical shock. Application of the patches may feel cold, and in very rare cases, a patient may develop a skin rash or irritation where the patches were applied. Some people become slightly anxious when this test is done.

You may feel some pressure for a few seconds when the arterial stiffness blood vessel device is placed on your skin.

There are no known risks associated with taking these pictures of the eye. People who are light-sensitive may see a blue or red spot after the camera flashes, but this would not hurt the eye, and it would go away within a few minutes.

If you find out that you have eye damage it could make you worried. We would share the results with your provider, and would refer you to your provider or another doctor for appropriate treatment. We would also be available to explain the results to you to help reduce your worry.

There could be harms associated with sharing your genetic information despite our safety measures to protect your genetic information. They include:

- Someone could break into the computer system. They could then find the code that links your genetic and medical information to you. This is very unlikely, but is possible.
- Find a way to link your genetic or medical information in a database back to you. Your genetic information is unique to you. But you do share some genetic information with your children, parents, brothers, sisters and other blood relatives. So it might be possible for someone to use genetic information from your relatives to help figure out who you are. That person would need to be able to access the database. They would also need genetic information from you or one of your relatives. Again, it is unlikely this would happen.
- Since some genetic information may predict health problems you or your relatives could have in the future. This information might be of interest to health providers, life insurance companies and others. There are state and federal laws that protect against genetic discrimination. There is a new federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. However, it does not completely protect you from discrimination.
- Genetic information could also be used by law enforcement agencies to identify a person or his/her blood relatives.
- There could be privacy risks we don't know about.

As with any research study, there may be additional risks that are unknown or unexpected.

9. What are the potential benefits if I join this study?

Potential Benefits for You:

You/your child may not directly benefit from participating in this research study. However, this study may more clearly tell us about your/your child's type of diabetes and whether you/your child has any of the complication of diabetes.

You would receive results of your/your child's blood and urine tests usually within 6-8 weeks of the study visit. These results would include the Hemoglobin A1C, lipid profile (cholesterol), and urine microalbumin (urine protein). These are standard tests. The report you receive would explain the results to you. Your/your child's doctor would also receive these standard test results, plus results of the research laboratory tests that are being studied to determine the type of diabetes.

You/your child and your/your child's diabetes provider may receive the results of genetic tests done for research purposes while taking part in this research study if it is determined that the results of such tests could impact clinical care.

We would give you information about any eye problems that we find. If something is found that needs urgent attention, we would phone/contact you and your health care provider as soon as we receive these results (usually within 2 – 3 days). This eye test does not take the place of a visit to your own personal doctor nor does it replace your regular dilated comprehensive eye examinations. It is not a test of your/your child's vision.

You would not receive any results or feedback on the nerve tests or blood vessel test as part of this study. These tests are for research purposes only and do not replace the normal care provided to you by your regular health care provider.

Potential Benefits for Others:

We hope that the information learned in this research study will benefit young people with diabetes in the future. This is a large research study being carried out at five major medical centers across the United States. The information we learn in this research study will improve our understanding of how education, diagnosis, and the costs of having diabetes can affect the people who live with this disease every day. The tests we do may help us better understand the short and long term effects of diabetes. This may help improve diabetes-related care in the future.

10. What other options do I have?

Taking part in research is voluntary. You/your child may choose not to take part in this study or in parts of the study.

11. How would you keep my information confidential?

All information gathered during this study would be held in strict confidence. Any publication resulting from participation in this study would not identify you/your child by name. A one of a kind number, called a research study number, would be assigned to you/your child. No other identifying information would be used. The research study number would be used to identify only the test and interview information that was collected during the research study. The research number assigned to you/your child, and not your child's name, would be sent to the study Coordinating Center at Wake Forest University in order to study the information. The list containing the research study number assigned to you/your child would be kept in a locked file in the research office of Dr. Pihoker, the research study's Principal Investigator. No one other than Dr. Pihoker and her research team would be able to connect any of research study information to you/your child.

Any stored samples would be kept in a central laboratory and stored for upcoming studies of diabetes. The central laboratory is at the University of Washington. The samples would be banked with a code, with no information at the laboratory that could link the samples to you/your child. Dr. Pihoker and the study coordinators on this project would be the only people with

access to the code. The banked samples would be stored indefinitely, although would likely be used within 7 years. When there is another researcher who wants to do a diabetes study and use the stored samples, he/she would need to talk to Dr. Pihoker. If the study seems to be important and reasonable, an Institutional Review Board (IRB) would review the study, and samples can be used only after the study is approved. The IRB is a committee responsible for protecting the rights of persons taking part in research.

The nerve test results would be sent to the University of Michigan and the SEARCH Coordinating Center. The eye test results would be sent to the Ocular Epidemiology Reading Center (OERC) at the University of Wisconsin – Madison and the SEARCH Coordinating center. Investigators would analyze these results along with other data collected in the SEARCH study.

All answers that you/your child give and other information gathered about you/your child during this study would be kept private. This is so because this study has been given a Certificate of Confidentiality. This means that anything you/your child tells us or information we learn about you/your child would not have to be given out to anyone, even if a court orders us to do so, unless you say it's OK. But under the law, we must report to the state suspected cases of child abuse or if you/your child tell us he/she is planning to cause serious harm to self or others.

If you take part, we would make every effort to keep your information confidential.

If you join this study, we may put information about this study in your medical record. We do this because the research study involves patient care.

Information collected about you during the study would be kept until all information has been studied and results have been published. Future funding may allow the study to continue for a longer period of time, however, the information about you would be destroyed as soon as it is no longer necessary for the conduct of the research study.

12. Would it cost me money to be in the study?

If you take part in this study, there would be no cost to you and no cost to your insurance company.

13. What if I were injured because I joined the study?

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.

You would NOT need to pay for this treatment and neither would your insurance company. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher Catherine Pihoker, if you think that you have been injured as a result of taking part in this study. You can call her at 206-987-5037.

14. Would I be paid if I join this study?

If needed, we may be able to offer some assistance with travel costs, dependent on availability of study funds. **Important:** You would need to give us receipts that clearly show your costs.

Once you complete all of the study procedures, we would give you/your child $120 in gift cards. You would be paid a smaller amount if you complete only part of the study procedures. In the rare circumstance that a blood redraw is necessary, you would receive an additional $20 gift card.

We will be asking a small number of study participants to repeat the Heart Rate Variability and/or Blood Vessel tests in order to assess the research team's quality control. If you are asked to participate in these repeat measurements, you would be given an additional gift card if you agreed to participate. You would receive a $10 gift card if you were asked to repeat some of these measurements, or a $20 gift card if you were asked to repeat all of them. If you are fasting for the visit, we will provide a snack after you complete the blood draw and/or a $6 meal or meal voucher after the blood vessel tests.

The IRS has certain rules about paying people who take part in research studies. If you took part in this study, we would ask you to provide your name, mailing address, and social security number so we could pay you.

You can be in this study even if you do not give us this information. If you decide not to give us this information, you could receive a gift card or no payment.

The payments you would receive for being in this study might be taxable. Seattle Children's is required to report to the IRS study payments of $600 or more made to anyone in any year.

Your samples could be used to make new products, tests or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to provide any money to you.

15. Who do I call if I have problems or questions?

If I have questions or would like to know about …	You can call …	At …
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Catherine Pihoker, MD or Endocrinologist on call	Phone: 206-987-2000
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Diabetes Research Team	Phone: 206-987-2540
• Your rights as a research participant	Institutional Review Board This is a group of scientists and community members who make sure research meet legal and ethical standards.	Phone: (206) 987-7804
• Assistance with figuring out what questions to ask the research team • Help understanding the research process	Research and Family Liaison A person who works with families to ensure they receive the information they need to make an informed decision about taking part in a research study.	Phone: (206) 884-7858 Pager: (206) 469-3983

16. If I join the study, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell the study team. You can contact this person by calling 206-987-2540.

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

17. What would my signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
  - You agree to take part in the research study.
  - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

_____

Printed Name of Research Participant

_____

Signature of Research Participant (required if 14 years or older) *Date/Time*

_____

Printed Name of Parent or Legal Guardian

_____

Signature of Parent or Legal Guardian *Date/Time*

Permissions:

Storage of Blood and Urine Samples

Do you give permission to have your/your child's blood and urine samples saved and used in current and future research??

☐ Yes, I give my permission

☐ No, I do not give permission

Storage of DNA Samples (looking at specific genes)

Do you give permission to have your/your child's DNA saved and used in current and future research?

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Genetic Test Results (looking at specific genes)

If researchers determine that genetic results could impact clinical care, would you like the results of genetic tests sent to you and your/your child's diabetes provider?

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Full Gene Analysis (looking at all of your genes) and the National Storage Center (NIH/dbGaP)

Do you give permission to have your/your child's DNA analyzed to identify a complete picture of your genetic makeup? This information would be sent to a national storage center to help researchers better understand how genes affect the risk of developing diseases. When your DNA and clinical information is sent to the storage center, no personal information would be included, such as your name, date of birth, or address. Thus, researchers would not be able to link this information back to you.

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Medical Record Review

Do you give permission to have your/your child's medical chart reviewed by research study members, as described above?

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Future contact

Do you give permission for researchers to contact you/your child in the future, to ask if you/your child are interested in participating in new research studies that are developed? As with this research study, taking part in any future studies is voluntary. Participation in this present study does not mean that you/your child are automatically volunteering to take part in any future

studies. You/your child would be asked to sign a consent form for any future research studies in which you/your child agree to participate.

☐ Yes, I give my permission

☐ No, I do not give permission

18. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

_____

Printed Name of Researcher Obtaining Parental Permission or Consent

_____

Signature of Researcher Obtaining Parental Permission or Consent *Date/Time*

19. Interpreter Information

_____

Printed Name of Interpreter during initial presentation of study *Date/Time*

_____

Printed Name of Interpreter when translated form is presented (if applicable) *Date/Time*

Original form to:
Research Team File

Copies to:
Participant
Parents/Guardians (if applicable)
Medical Records (if applicable)

PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up
ASSENT FORM: Ages 14-17

REGISTRY VISIT (2012 cohort)

Study Title: SEARCH for Diabetes in Youth

Principal Researcher: Catherine Pihoker, MD

The Research Team:

Name/Degree	Title	Department	Phone Number
Catherine Pihoker, MD	Principal Investigator	Endocrinology	206 987-5037
Lenna Liu, MD MPH	Co-Investigator	Pediatrics	206 987-5037
Maryam Afkarian, MD	Co-Investigator	Nephrology	206 987-5037
Irl Hirsch, MD	Co-Investigator	Medicine	206 987-5037
Carolyn Paris, MD	Co-Investigator	Emergency	206 987-5037
Joyce Yi-Frazier, PhD	Co-Investigator	Endocrinology	206 987-5037
Carla Greenbaum, MD	Co-Investigator	Benaroya Res Instit	206 987-5037
Martin Goldsmith, MD	Co-Investigator	Peds Northwest	206 987-5037
Beth Babler, ARNP	Co-Investigator	Mary Bridge	206 987-5037
Patricia Fechner, MD	Co-Investigator	Endocrinology	206 987-5037
Christian Roth, MD	Co-Investigator	Endocrinology	206 987-5037
Ildi Koves, MD	Co-Investigator	Endocrinology	206 987-5037
Craig Taplin, MD	Co-Investigator	Endocrinology	206 987-5037
Kate Ness, MD	Co-Investigator	Endocrinology	206 987-5037
Carolina DiBlasi, MD	Co-Investigator	Endocrinology	206 987-5037
Roja Motaghedi, MD	Co-Investigator	Endocrinology	206 987-5037
Erin Alving, ARNP	Co-Investigator	Endocrinology	206 987-5037
Karen Aitken, ARNP	Co-Investigator	Endocrinology	206 987-5037
Joanie Warner, ARNP	Co-Investigator	Endocrinology	206 987-5037
Sara Benitez, PA	Co-Investigator	Endocrinology	206 987-5037
Gwyn Recupero, PA	Co-Investigator	Endocrinology	206 987-5037
Beth Loots, MPH MSW	Research Manager	Endocrinology	206-987-2540
Sue Kearns, RN	Study Coordinator	Endocrinology	206 987-2540

Name/Degree	Title	Department	Phone Number
Mary Klingsheim, RN, BSN	Study Coordinator	Endocrinology	206 987-2540
Jessica Fosse, MPH, RN, BSN	Study Coordinator	Endocrinology	206 987-2540
Katherine Cochrane, BS	Clinical Research Associate	Endocrinology	206 987-2540
Sharla Semana, MSW	Clinical Research Associate	Endocrinology	206 987-2540
Patricia D'Alessandro, MA	Clinical Research Associate	Endocrinology	206 987-2540

Clinical Research Center: (206) 987-3897

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

24 hour Emergency Contact Number(s): 206 987-2000 Ask for the Endocrinologist on call

1. Researchers' Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants 18 years and older: This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

Potential Teen Participants: This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your parent or guardian would also need to give their permission and sign this form for you to join the study.

Parents/Guardians: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **"you"** in this form refers to your child/teen.

2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children's.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

Diabetes is the third most common chronic or ongoing disease in individuals under 20 years of age. The total number of cases of diabetes in this age group is increasing, and types of diabetes that have not been seen in young people are now being seen. These changes have resulted in gaps in our knowledge about the total number of cases and types of diabetes in the United States, the type of care young people with diabetes receive, the complications they experience, and the effect diabetes has on their lives.

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer the following questions:

- How many cases of diabetes there are in the United States among youth;
- What are the characteristics of each type of diabetes;
- What medical care is being given to young people who have different forms of diabetes;
- How is diabetes affecting the lives of young people with diabetes.

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you have any type of diabetes, were diagnosed under the age of 20 in 2012, and lived in King, Kitsap, Pierce, Snohomish, or Thurston county in 2012.

5. How many people will take part in the study?

We think that about 1,220 people will take part in the SEARCH registry study at Seattle Children's. About 225 people at this site will complete a registry visit. A total of about 6,440 people will take part in the registry study at hospitals and clinics around the country.

6. If I agree to join this study, what would I need to do?

The registry study includes:

- Written questionnaires
- Blood draw
- Urine collections
- Brief physical exam
- Medical record review
- Follow up contact

Written Questionnaires

Prior to your visit, you/your child will have been asked to answer a short series of questions – in person, via mail, online, or on the telephone – about the effects of diabetes on your/your child's lives, your family's education and income level, and general medical care. That survey will have taken about 20 minutes. During your visit, we will ask you to complete an additional brief survey about the medications that you/your child takes.

Blood Draw and Urine Collection

You/your child would be scheduled for an in-person study visit at the Clinical Research Center at Seattle Children's or at another SEARCH outreach clinic that is convenient to you. This would be a "fasting" visit, which means that no food or fluids, other than water, could be consumed for at least 8 hours before coming to your visit. You/your child would be asked not to take insulin or other diabetes medications the morning before the test, except for basal insulin, which should be taken as usual. If you come to the visit nonfasting, we might ask you to return another day to redraw all or part of the blood sample.

Before your scheduled appointment, you would receive a container with detailed instructions to collect one urine sample at home the morning of your visit. We will ask that you collect the urine from the first time you urinate in the morning. You would be asked to bring this urine sample with you to your visit. Your urine would be tested for microalbumin (small particles of protein) to see how well your kidneys are working.

When you arrive at your appointment, we would review the consent/assent form(s). This would take about 20 – 30 minutes. If you/your child would like a numbing agent for the blood draw, this part may take about an additional 30 minutes.

A blood sample would be drawn from your/your child's arm to measure blood sugar, hemoglobin A1c (a test measuring your/your child's average blood glucose level over the past 3 months), C-

peptide (a measure of your/your child's own insulin production), different types of cholesterol (fat), islet cell antibodies (markers in the blood for type 1 diabetes), and genetic markers for diabetes. Based on age and size, the total amount of blood that would be needed would be between 1 teaspoon and 3 tablespoons.

If possible, we would collect all blood samples at the same time that a routine blood draw would be done. If you/your child take part in more than one research study at the same visit, we would try to combine tests and results when we can.

A urine sample would also be obtained during the visit and tested for several markers associated with the risk of diabetes complications, such as heart disease and stroke.

The SEARCH study would like to keep some of the blood and urine that would be collected during the study but is not used for other tests. Should we have questions about some of tests, the storage sample would allow us to repeat the tests without needing to ask for a second blood draw from you/your child. In addition, we would like to collect another sample of blood for storage for future research.

We will also ask your permission to obtain and store a sample of blood to look at DNA, the genetic material that is found in all of your cells. Researchers may look at specific genes, or they may look at all of your genes together. If researchers were to look at specific genes, you have the option of receiving the results of this testing if it would effect your clinical care. However, if they were to look at all of your genes together, you would not receive the results. The information researchers find about your DNA would be sent to a national storage center called dbGaP (part of the National Institutes of Health) to help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease. When your DNA and clinical information would be sent to the storage center, no personal information would be included, such as your name, date of birth, or address. Thus, researchers would not be able to link this information back to you. The research that would be done with your blood and urine samples would not be designed to specifically help you. It might help people who have diabetes and other diseases in the future.

The total amount of blood that would be needed for the storage sample would be 1 teaspoon for young children and up to 2 tablespoons for older children, dependent on age and weight. This part of the visit would take 10 – 20 minutes.

The total volume of blood for this visit would be up to approximately 3 tablespoons.
After the fasting blood and urine samples are collected, a free breakfast or meal voucher would be provided and you/your child would take your routine medication.

Physical Exam

A trained member of the research team would perform a brief physical examination including: height, weight, waist measurements, blood pressure, and examination of the skin of the neck. The time to complete this exam would be about 20 minutes.

Follow up

We will send you requests to update your contact information about every year. Part of this update includes a question about your/your child's social security number, which we will use to track mortality among SEARCH study participants. If this study is expanded, or if other diabetes studies are developed, we may contact you/your child in the future to ask if you/your child want to participate further. As with this study, taking part in any future study is voluntary.

7. How long would I be in the study?

The study is currently funded through September 2015.

The time to complete the registry visit would be about 1 hour.

If you join the study, you can decide to stop **at anytime for any reason**. Please discuss your decision to stop with Dr. Pihoker or the research team.

If you would like your/your child's stored samples removed from storage, we would send a request to the central laboratory. They would then destroy the sample, and send us a letter certifying that the sample has been destroyed. We would send you a copy of this letter.

The research study doctor could also decide to take you out of this study. This might happen if we find out that it is not safe for you to stay in the study. Or it might happen if you cannot complete to enough of the study elements. If we ask you to leave the study, we would always explain why.

8. What are the potential harms or risks if I join this study?

If you feel uncomfortable at any time during any of these tests, just tell the study coordinator and they would immediately stop the tests. All reasonable precautions would be taken to reduce risks.

When taking a blood sample, there may be brief discomfort, and a bruise may form where the needle poke occurs. To reduce the possibility of these risks, a local anesthetic (numbing cream or liquid) may be applied to the skin before blood is taken.

The blood tests require that you/your child not have any food or fluids overnight, other than water. In order to prevent low or high blood sugars, you/your child's blood sugar would be checked by finger-stick and your diabetes medication would be given as needed to control your/your child's blood sugar.

Some of the tests would look for the presence of health problems associated with diabetes, such as high cholesterol. If researchers find signs of these health problems, it may cause

you/your child some anxiety or concern. If this happens, you/your child would be referred to the appropriate local health professionals for evaluation and treatment.

There could be harms associated with sharing your genetic information despite our safety measures to protect your genetic information. They include:

- Someone could break into the computer system. They could then find the code that links your genetic and medical information to you. This is very unlikely, but is possible.
- Find a way to link your genetic or medical information in a database back to you. Your genetic information is unique to you. But you do share some genetic information with your children, parents, brothers, sisters and other blood relatives. So it might be possible for someone to use genetic information from your relatives to help figure out who you are. That person would need to be able to access the database. They would also need genetic information from you or one of your relatives. Again, it is unlikely this would happen.
- Since some genetic information may predict health problems you or your relatives could have in the future. This information might be of interest to health providers, life insurance companies and others. There are state and federal laws that protect against genetic discrimination. There is a new federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. However, it does not completely protect you from discrimination.
- Genetic information could also be used by law enforcement agencies to identify a person or his/her blood relatives.
- There could be privacy risks we don't know about.

As with any research study, there may be additional risks that are unknown or unexpected.

9. What are the potential benefits if I join this study?

Potential Benefits for You:

You/your child may not directly benefit from participating in this research study. However, this study may more clearly tell us about your/your child's type of diabetes and whether you/your child has complication of diabetes.

You would receive results of your/your child's blood and urine tests usually within 6-8 weeks of the study visit. These results would include Hemoglobin A1C, lipid profile (cholesterol), and urine microalbumin (urine protein). These are standard tests. The report you receive would explain the results to you. Your/your child's doctor would also receive these standard test results, plus results of the research laboratory tests that are being studied to determine the type of diabetes.

You/your child and your/your child's diabetes provider may receive the results of genetic tests done for research purposes while taking part in this research study if it is determined that the results of such tests could impact clinical care.

Potential Benefits for Others:

We hope that the information learned in this research study will benefit young people with diabetes in the future. This is a large research study being carried out at five major medical centers across the United States. The information we learn in this research study will improve our understanding of how education, diagnosis, and the costs of having diabetes can affect the people who live with this disease every day.

10. What other options do I have?

Taking part in research is voluntary. You/your child may choose not to take part in this study or in parts of the study.

11. How would you keep my information confidential?

All information gathered during this study would be held in strict confidence. Any publication resulting from participation in this study would not identify you/your child by name. A one of a kind number, called a research study number, would be assigned to you/your child. No other identifying information would be used. The research study number would be used to identify only the tests and interview information that was collected during the research study. The research number assigned to you/your child, and not your child's name, would be sent to the study Coordinating Center at Wake Forest University in order to study the information. The list containing the research study number assigned to you/your child would be kept in a locked file in the research office of Dr. Pihoker, the research study's Principal Investigator. No one other than Dr. Pihoker and her research team would be able to connect any of research study information to you/your child.

Any stored samples would be kept in a central laboratory and stored for upcoming studies of diabetes. The central laboratory is at the University of Washington. The samples would be banked with a code, with no information at the laboratory that could link the samples to you/your child. Dr. Pihoker and the study coordinators on this project would be the only people with access to the code. The banked samples would be stored indefinitely, although would likely be used within 7 years. When there is another researcher who wants to do a diabetes study and use the stored samples, he/she would need to talk to Dr. Pihoker. If the study seems to be important and reasonable, an Institutional Review Board (IRB) would review the study, and samples could be used only after the study is approved. The IRB is a committee responsible for protecting the rights of persons taking part in research.

All answers that you/your child give and other information gathered about you/your child during this study would be kept private. This is so because this study has been given a Certificate of

Confidentiality. This means that anything you/your child tells us or information we learn about you/your child would not have to be given out to anyone, even if a court orders us to do so, unless you say it's OK. But under the law, we must report to the state suspected cases of child abuse or if you/your child tell us he/she is planning to cause serious harm to self or others.

If you take part, we would make every effort to keep your information confidential.

If you join this study, we may put information about this study in your medical record. We do this because the research study involves patient care.

Information collected about you during the study would be kept until all information has been studied and results have been published. Future funding may allow the study to continue for a longer period of time, however, the information about you would be destroyed as soon as it is no longer necessary for the conduct of the research study.

12. Would it cost me money to be in the study?

If you take part in this study, there would be no cost to you and no cost to your insurance company.

13. What if I were injured because I joined the study?

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.

You would NOT need to pay for this treatment and neither would your insurance company. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher Catherine Pihoker, if you think that you have been injured as a result of taking part in this study. You can call her at 206-987-5037.

14. Would I be paid if I join this study?

If needed, we may be able to offer some assistance with travel costs, dependent on availability of study funds. **Important:** You would need to give us receipts that clearly show your costs. To thank you for taking part in the study we would give you/your child a $10 gift card for completion of the Initial Participant Survey, and an $80 gift card for completion of the visit. In the rare circumstance that a blood redraw is necessary, you would receive an additional $20 gift card. If you are fasting for the visit, we will provide a $6 breakfast voucher, or breakfast, after you complete the blood draw.

The IRS has certain rules about paying people who take part in research studies. If you took part in this study, we would ask you to provide your name, mailing address, and social security number so we could pay you.

You can be in this study even if you do not give us this information. If you decide not to give us this information, you could receive a gift card or no payment.

The payments you would receive for being in this study might be taxable. Seattle Children's is required to report to the IRS study payments of $600 or more made to anyone in any year.

Your samples could be used to make new products, tests or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to provide any money to you.

15. Who do I call if I have problems or questions?

If I have questions or would like to know about …	You can call …	At …
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Catherine Pihoker, MD or Endocrinologist on call	Phone: 206-987-2000
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Diabetes Research Team	Phone: 206-987-2540
• Your rights as a research participant	Institutional Review Board This is a group of scientists and community members who make sure research meet legal and ethical standards.	Phone: (206) 987-7804

If I have questions or would like to know about …	You can call …	At …
• Assistance with figuring out what questions to ask the research team • Help understanding the research process	Research and Family Liaison A person who works with families to ensure they receive the information they need to make an informed decision about taking part in a research study.	Phone: (206) 884-7858 Pager: (206) 469-3983

16. If I join the study, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell the study team at 206-987-2540.

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

17. What would my signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
  - You agree to take part in the research study.
  - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

Printed Name of Research Participant

Signature of Research Participant (required if 14 years or older) *Date/Time*

Printed Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian *Date/Time*

Permissions:

Storage of Blood and Urine Samples

Do you give permission to have your/your child's blood and urine samples saved and used in current and future research?

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Storage of DNA Samples (looking at specific genes)

Do you give permission to have your/your child's DNA saved and used in current and future research?

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Genetic Test Results (looking at specific genes)

If researchers determine that genetic results could impact clinical care, could you like the results of genetic tests sent to you and your/your child's diabetes provider?

- ☐ Yes, I give my permission
- ☐ No, I do not give permission

Full Gene Analysis (looking at all of your genes) and the National Storage Center

Do you give permission to have your/your child's DNA analyzed to identify a complete picture of your genetic makeup? This information would be sent to a national storage center to help researchers better understand how genes affect the risk of developing diseases. When your DNA and clinical information is sent to the storage center, no personal information would be included, such as your name, date of birth, or address. Thus, researchers would not be able to link this information back to you.

☐ Yes, I give my permission

☐ No, I do not give permission

Future contact

Do you give permission for researchers to contact you/your child in the future, to ask if you/your child are interested in participating in new research studies that are developed? As with this research study, taking part in any future studies is voluntary. Participation in this present study does not mean that you/your child are automatically volunteering to take part in any future studies. You/your child would be asked to sign a consent form for any future research studies in which you/your child agree to participate.

☐ Yes, I give my permission

☐ No, I do not give permission

18. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

_____

Printed Name of Researcher Obtaining Parental Permission or Consent

_____

Signature of Researcher Obtaining Parental Permission or Consent *Date/Time*

19. Interpreter Information

Printed Name of Interpreter during initial presentation of study *Date/Time*

Printed Name of Interpreter when translated form is presented (if applicable) *Date/Time*

Original form to:
Research Team File

Copies to:
Participant
Parents/Guardians (if applicable)
Medical Records (if applicable)

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Monogenic Ancillary Study

Consent Form: Initial Genetic Testing

To be signed by participants age 18 and older, cosigned by participants ages 14 to 17, and signed by parent/guardian of participants under age 18

Principal investigator: Catherine Pihoker, MD, Department of Endocrinology, 206/987-5037
Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037
Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, MD, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987-5037
Erin Alving, ARNP, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, PA, Department of Endocrinology, 206/987-5037

Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number:
Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

Researcher's Statement
You/your child are being asked to give permission for you/your child to take part in a research study. Taking part in research is voluntary. Please take time to make your decision, and discuss it with family and friends. If you/your child decide to participate, but then later want to drop out of the research study, you are free to do so without loss of any benefits, treatment, or services to which you are otherwise entitled.

This form provides a summary of the information the researchers will discuss with you. If you/your child takes part in this research study, you will keep a copy of this form. Be sure to ask any questions you have about the research study.

You/your child are being asked to take part in a research study because you/your child were diagnosed with diabetes at <1 year of age. Because of this, you/your child may have a genetic form of diabetes called **Permanent Neonatal Diabetes Mellitus (PNDM)**. As part of the SEARCH study, we are currently testing people diagnosed with diabetes at <1 year of age for mutations in the genes that cause these inherited forms of diabetes.

Purpose
We have learned from recent research that many infants who are diagnosed with diabetes at **less that one year of age** have an inherited form of diabetes. The reason that it is very important to test for these mutations in people who develop diabetes as infants is because, in some cases, it can dramatically affect the treatment. It is possible that some people may receive treatment for diabetes that does not include the use of insulin.

The purpose of this research study is to:

a. Learn how many patients with PNDM there are in the United States

b. Learn more about patients with PNDM

c. Offer genetic testing for PNDM at no charge

Benefits
If you/your child agree to take part in this study, there may or may not be direct medical benefits to you/your child. If we find an abnormal test result for PNDM, this could affect your/your child's treatment. It is possible that some people with PNDM may receive treatment for diabetes that does not include the use of insulin, and it is also possible that the diabetes control will improve with a different form of treatment. However, it is also possible, even if your/your child's results are abnormal, that the diabetes treatment will not change. In addition, the information we learn in this research study may benefit other children by improving our understanding of who needs to be tested for PNDM, and whether testing for PNDM improves the lives of patients in whom mutations are found.

Procedures
This study consists of 2 parts:
1) We will obtain a blood or saliva sample in order to perform the genetic testing
2) You will fill out questionnaires about diabetes in your family and the effects that diabetes has on your/your child's life

Sample Collection for Genetic Testing

You/your child will be scheduled for an in-person study visit in the Clinical Research Center at Seattle Children's Hospital and Regional Medical Center or another SEARCH outreach clinic. This may be scheduled at the same time as a SEARCH study visit. A blood sample will be drawn from your/your child's arm. DNA will be removed from the blood and used to test for mutations in one of several genes that may cause PNDM. The total amount of blood needed for this sample is 2 teaspoons. If your child weighs less than 11 pounds at the time of the blood draw, a smaller amount of blood will be drawn; we will follow guidelines that tell us what is a safe amount of blood to take. This part of the visit will take 10 – 20 minutes. If you/your child needs a numbing cream for the blood draw, this part will take at least 30 minutes.

If you/your child are not able to come for an in-person visit, you can have blood drawn by your local doctor and then send the blood sample to us in the mail.

If we can not get a blood sample, we can instead collect a saliva (spit) sample. We are not able to get as much DNA from saliva as we can from blood, so we may not be able to test for all the genes that may cause PNDM. For the saliva collection, you/your child will spit about 2 teaspoons (10 milliliters) of saliva into a container. If we are collecting this sample from your baby, we will rub some soft sponges in your baby's mouth to collect the saliva. If you are not able to come to the study center, you may be able to collect the saliva sample at home and send the container to us in the mail.

Written Questionnaires

After completing the blood draw or saliva collection, you/your child will answer some questions about diabetes in your family, the effects of diabetes on your/your child's life, and other aspects of your/your child's medical history. You/your child are free to not answer any questions you don't want to answer, and you may stop the interview at any time. If you/your child decide not to answer any of the questions, you can still take part in the rest of the research study. This part of the study visit will take about 20-30 minutes.

Research Data and Specimens

Blood and saliva samples will be sent to a central laboratory located at the University of Washington and some DNA from these samples will be sent to a laboratory that specializes in these genetic studies (Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K.). The remaining DNA will be stored for upcoming studies of diabetes. The samples are banked with a code, with no information at either laboratory that could link the samples to you/your child. Some information about your/your child's health and about diabetes in your family may be sent to the U.K. laboratory to guide further testing in case the initial tests are negative. This information will also be sent with a code, so that it cannot be linked to you/your child. Dr. Pihoker and the study coordinators on this project will be the only people with access to the code. The banked samples will be stored indefinitely, although will likely be used within 7 years. When there is another researcher who wants to do a diabetes study and use the stored samples, he/she will need to talk to Dr. Pihoker. If the study seems to be important and reasonable, an Institutional Review Board (IRB) will review the study, and samples can be used only after the study is approved. The IRB is a committee responsible for protecting the rights of persons taking part in research.

You may choose to withdraw from the study at any time. If you would like your/your child's stored samples removed from storage, we will send a request to the central laboratory. They will then

destroy the sample, and send us a letter certifying that the sample has been destroyed. We will send you a copy of this letter.

Risks, Stress or Discomfort
When taking a blood sample, there may be brief discomfort, and a bruise may form where the needle poke occurs. To reduce the pain associated with the blood draw, a local anesthetic (numbing cream) may be applied to the skin before blood is taken.

Knowing that you/your child have a genetic form of diabetes may cause you to have more questions. We will answer any questions you may have to the best of our abilities. If needed, you/your child will be referred to an appropriate local health professional for further evaluation and treatment.

You might worry about whether results of this genetic test will lead to discrimination, for example denial of health insurance or employment. Laws exist to protect against genetic discrimination, and these vary from state to state. While it is theoretically possible that genetic information about you/your child could lead to this sort of discrimination, this is very unlikely. Information about you/your child will not be given to insurance companies, employers, or other parties without your permission. Results of this genetic testing *will* be reported to your health care provider with your permission (as indicated at the end of this form), and will therefore go into your medical record.

Test results
Test results will be mailed to you approximately 6 months after the blood is collected. If you have a positive test result, someone from the study will also call you to explain the results to you before you receive the letter in the mail. Your/your child's diabetes provider will also receive the results, if you have given your permission.

Privacy and Confidentiality
All information gathered during this study will be held in strict confidence. Any publication resulting from participation in this study will not identify you/your child by name.

Once you/your child decide to join the research study, a one of a kind number, called a research study number, will be assigned to you/your child. No other identifying information will be used. The research study number will be used to identify only the test and interview information that was collected during the research study. The research number assigned to you/your child will be kept in a locked file in the research office of Dr. Pihoker, the research study's Principal Investigator. No one other than Dr. Pihoker and her research team will be able to connect any of research study information to you/your child.

All answers that you/your child give and other information gathered about you/your child during this study will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means that anything you/your child tells us or information we learn about you/your child will not have to be given out to anyone, even if a court orders us to do so, unless you say it's ok. But, under the law we must report to the state suspected cases of child abuse or if you/your child tell us he/she is planning to cause serious harm to self or others'.

Taking Part in Research is Voluntary
Taking part in research is voluntary. You/your child may choose not to take part. If you/your child do take part, you/your child may withdraw from this study at any time. If you/your child drop out of the research study you can request that all blood or DNA samples that have been collected be

destroyed. Withdrawal from this research study will have no effect on access to medical care nor will it have any effect on the standard of care your/your child's health care professionals are providing.

Compensation
For the in-person visit, you/your child will receive a $20 gift card.

If you or your child is injured as the direct result of this research study, we (Seattle Children's) will treat you or your child. If appropriate, we will refer you or your child for treatment. You or your insurance company will be billed for the cost of this treatment. Please call Catherine Pihoker at 206-987-2540 if you believe you or your child have been injured as a result of this study.

Questions
For questions about the research, please call Dr. Catherine Pihoker at 206/987-2540. For questions about your/your child's rights as a research participant, contact Seattle Children's Institutional Review Board (IRB) at 206-987-7804. The IRB is a committee that reviews the research and is responsible for protecting the rights and welfare of children and families taking part in research.

_____ _____

Signature of Researcher *Date/Time*

Permissions:

Storage of DNA Samples
Do you give permission to have your/your child's DNA stored and used in future research studies, to find better ways to diagnose the different types of diabetes, and to study the health risks associated with this disease, such as insulin not working and obesity?

☐ Yes, I give my permission

☐ No, I do not give permission

Communication of Genetic Test Results
Do you give permission to have the results of these genetic tests communicated to your/your child's diabetes provider?

☐ Yes, I give my permission

☐ No, I do not give permission

Participant's Statement:

The study described above has been explained to me, and I voluntarily consent to participate (or have my child participate) in this study. I have had the opportunity to ask questions and understand future questions I may have about the research study or about research participants' rights will be answered by the investigators listed above.

_____ _____

Signature of Participant *Date/Time*

_____ _____

*Signature of Parent/Legal Guardian** *Date/Time*

*If the child to be involved in this research study is a foster child or a ward of the state, please notify the researcher or their staff who is obtaining your consent.

Copies to: Participant/parent, Medical Record (when appropriate), Investigator's file

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Monogenic Ancillary Study

Consent Form: Confirmation of Positive Result

To be signed by participants age 18 and older, cosigned by participants ages 14 to 17, and signed by parent/guardian of participants under age 18

Principal investigator: Catherine Pihoker, MD, Department of Endocrinology, 206/987-5037
Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037
Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, MD, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987-5037
Erin Alving, ARNP, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, PA, Department of Endocrinology, 206/987-5037

Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number:
Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

Researcher's Statement
You/your child are being asked to give permission for you/your child to take part in a research study. Taking part in research is voluntary. Please take time to make your decision, and discuss it with family and friends. If you/your child decide to participate, but then later want to drop out of the research study, you are free to do so without loss of any benefits, treatment, or services to which you are otherwise entitled.

This form provides a summary of the information the researchers will discuss with you. If you/your child takes part in this research study, you will keep a copy of this form. Be sure to ask any questions you have about the research study.

You/your child are being asked to take part in a research study because through your/your child's participation in the SEARCH Study for Diabetes in Youth, we have found that **you/your child had a positive test for an inherited form of diabetes**.

Purpose
There are a few rare inherited forms of diabetes. You/your child had a positive test in the SEARCH study for either **Permanent Neonatal Diabetes Mellitus (PNDM) or Maturity Onset Diabetes of the Young (MODY).** The study coordinator will tell you which one you have.

In infants who are diagnosed with diabetes at <6 months of age, very recent research studies have shown that an inherited cause of diabetes (**PNDM**) is extremely common (about half of cases). Diabetes may also be caused by inherited forms of diabetes in infants diagnosed between 6 months and 1 year of age, although not as frequently as in the younger age group. The reason that it is very important to test for these mutations in people who develop diabetes as infants is because, in some cases, it can dramatically affect the treatment. It is possible that some people may receive treatment for diabetes that does not include the use of insulin.

MODY are a set of diabetes types that affect about 1-2% of people with diabetes. MODY usually runs in families because of a change in a single gene that is passed on by parents to their children. The usual course of MODY is different than the usual course of type 1 diabetes. Generally the progression to needing treatment is more gradual. Some patients do not require insulin but rather can be effectively treated with a certain oral medication (sulfonylurea). However, it is often not possible to tell MODY from Type 1 or Type 2 diabetes when the diabetes is first diagnosed without special testing. By finding out which type of diabetes a person has, the most appropriate treatment for them can be determined.

The purpose of this research study is to:

a. Learn how many patients with PNDM and MODY there are in the United States

b. Learn more about patients with PNDM and MODY

c. Offer genetic testing for PNDM or MODY at no charge

Benefits
Although much care is taken when handling the research samples and performing the research tests, it is still important to make sure the result is verified following the usual procedures for medical tests. If we confirm an abnormal test result for PNDM or MODY, this could affect your/your

child's treatment. It is possible that some people may receive treatment for diabetes that does not include the use of insulin, and it is also possible that the diabetes control will improve with a different form of treatment. However, it is also possible, even if your/your child's results are abnormal, that your/your child's treatment will not change.

In addition, while this research study may not benefit you directly, the information we learn may benefit other people by improving our understanding of who needs to be tested for these genetic forms of diabetes, and whether testing improves the lives of patients in whom mutations are found.

Procedures

This study consists of 3 parts:

1) We will obtain a blood or saliva sample in order to perform the confirmatory genetic testing
2) If you have not already done this, you will fill out questionnaires about diabetes in your family, the effects that diabetes has on your/your child's life, and the effects that participating in this research study has had on your/your child's life
3) We will review your/your child's medical records to get complete information for the research study

Sample Collection for Genetic Testing

You/your child will be scheduled for an in-person study visit in the Clinical Research Center at Seattle Children's Hospital and Regional Medical Center or another SEARCH outreach clinic. This may be scheduled at the same time as a SEARCH study visit. A blood sample will be drawn from your/your child's arm. DNA will be removed from the blood and used to confirm the abnormal test result, by rechecking to be sure that you have a mutation in a gene that causes PNDM or MODY. The total amount of blood needed for this sample is 2 teaspoons. If your child weighs less than 11 pounds at the time of the blood draw, a smaller amount of blood will be drawn; we will follow guidelines that tell us what is a safe amount of blood to take. This part of the visit will take 10 – 20 minutes. If you/your child needs a numbing cream for the blood draw, this part will take at least 30 minutes.

If you/your child are not able to come to the study center for an in-person visit, you can have blood drawn by your local doctor and then send the blood sample to us in the mail.

If we can not get a blood sample, we will instead collect a saliva (spit) sample. For the saliva collection, you/your child will spit about 2 teaspoons (10 milliliters) of saliva into a container. If we are collecting this sample from your baby, we will rub some soft sponges in your baby's mouth to collect the saliva. If you are not able to come to the study center, you may be able to collect the saliva sample at home and send the container to us in the mail.

Written Questionnaires

After completing the blood draw or saliva collection, you/your child will answer some questions about diabetes in your family, the effects of diabetes on your/your child's life, other aspects of you/your child's medical history, and the effects that participating in this research study has had on you/your child's life. You/your child are free to not answer any questions you don't want to answer, and may stop the interview at any time. If you/your child decide not to answer any of the questions, you can still take part in the rest of the research study. This part of the study visit will take about 20 – 30 minutes.

Medical Records Review

We will ask your permission for the researchers involved in this study to review your/your child's medical record. Any information obtained from the medical charts is for use in this research study only. Researchers will gather information on the current status and treatment of your/your child's diabetes. This information will include medications used to treat your diabetes and recent results of laboratory tests. The medical records review will take place approximately one year after the confirmatory test results are reported to you and your healthcare provider and will go back to the period of time beginning 6 months before you received this test result.

Research Data and Specimens

Blood and/or saliva samples will be labeled with your/your child's name and date of birth and sent directly to the laboratory where the testing will be performed (Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K.). Some health information and information about diabetes in your family will also be sent to the lab in the U.K. in order to aid in the interpretation of the genetic test result. This information will be linked with your name and date of birth. After the blood/saliva sample has been tested, the rest of the sample will be destroyed. All other study data obtained at this study visit (written questionnaires, documentation from medical records review) will be labeled with a code, with no information that could link the data to you/your child. Dr. Pihoker and the study coordinators on this project will be the only people with access to the code.

You may choose to withdraw from the study at any time.

Risks, Stress or Discomfort

When taking a blood sample, there may be brief discomfort, and a bruise may form where the needle poke occurs. To reduce the pain associated with the blood draw, a local anesthetic (numbing cream) may be applied to the skin before blood is taken.

Knowing that you/your child have a genetic form of diabetes may cause you to have more questions. We will answer any questions you may have to the best of our abilities. If needed, you/your child will be referred to an appropriate local health professional for further evaluation and treatment.

You might worry about whether results of this genetic test will lead to discrimination, for example denial of health insurance or employment. Laws exist to protect against genetic discrimination, and these vary from state to state. While it is theoretically possible that genetic information about you/your child could lead to this sort of discrimination, this is very unlikely. Information about you/your child will not be given to insurance companies, employers, or other parties without your permission. Results of this genetic testing *will* be reported to your health care provider with your permission (as indicated at the end of this form), and will therefore go into your medical record.

Test results

As the test results from this research study become available, you/your child will receive the results. Results will be mailed to you approximately 1 month after the blood is collected. Someone from the study will also call you to explain the results to you before you receive the letter in the mail. Your/your child's diabetes provider will also receive the results, if you have given your permission.

Privacy and Confidentiality
All information gathered during this study will be held in strict confidence. Any publication resulting from participation in this study will not identify you/your child by name.

A one of a kind number, called a research study number, will be used to label all data obtained as a part of this study visit. No other identifying information will be used. The research number assigned to you/your child will be kept in a locked file in the research office of Dr. Pihoker, the research study's Principal Investigator. No one other than Dr. Pihoker and her research team will be able to connect any of the research study information to you/your child.

Because results of the genetic tests may be used to change the type of treatment you/your child are receiving for your diabetes, the blood or saliva sample needs to be sent with your name and birth date so we can be sure that the sample belongs to you. The sample will be destroyed after the testing has been completed, to protect your privacy.

All answers that you/your child give and other information gathered about you/your child during this study will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means that anything you/your child tells us or information we learn about you/your child will not have to be given out to anyone, even if a court orders us to do so, unless you say it's ok. But, under the law we must report to the state suspected cases of child abuse or if you/your child tell us he/she is planning to cause serious harm to self or others.

Taking Part in Research is Voluntary
Taking part in research is voluntary. You/your child may choose not to take part. If you/your child do take part, you/your child may withdraw from this study at any time. If you/your child drop out of the research study you can request that all blood or DNA samples that have been collected be destroyed. Withdrawal from this research study will have no effect on access to medical care nor will it have any effect on the standard of care your/your child's health care professionals are providing.

Compensation
For the in-person visit, you/your child will receive a $20 gift card.

If you or your child is injured as the direct result of this research study, we (Seattle Childrens) will treat you or your child. If appropriate, we will refer you or your child for treatment. You or your insurance company will be billed for the cost of this treatment. Please call Catherine Pihoker at 206-987-2540 if you believe you or your child have been injured as a result of this study.

Questions
For questions about the research, please call Dr. Catherine Pihoker at 206/987-2540. For questions about your/your child's rights as a research participant, contact the Seattle Children's Institutional Review Board (IRB) at 206-987-7804. The IRB is a committee that reviews the research and is responsible for protecting the rights and welfare of children and families taking part in research.

_____ _____

Signature of Researcher *Date/Time*

Permissions:

Medical Record Review
Do you give permission to have your/your child's medical chart(s), reviewed by research study members, as described above?

☐ Yes, I give my permission

☐ No, I do not give permission

Communication of Genetic Test Results
Do you give permission to have the results of these genetic tests communicated to your/your child's diabetes provider?

☐ Yes, I give my permission

☐ No, I do not give permission

Participant's Statement:
The study described above has been explained to me, and I voluntarily consent to participate (or have my child participate) in this study. I have had the opportunity to ask questions and understand future questions I may have about the research study or about research participants' rights will be answered by the investigators listed above.

_____ _____
Signature of Participant *Date/Time*

_____ _____
*Signature of Parent/Legal Guardian** *Date/Time*

*If the child to be involved in this research study is a foster child or a ward of the state, please notify the researcher or their staff who is obtaining your consent.

Copies to: Participant/parent, Medical Record (when appropriate), Investigator's file

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Monogenic Ancillary Study

Consent Form: Family Members

To be signed by participants age 18 and older, cosigned by participants ages 14 to 17, and signed by parent/guardian of participants under age 18

Principal investigator: Catherine Pihoker, MD, Department of Endocrinology, 206/987-5037
Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, MD, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987-5037
Erin Alving, ARNP, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, PA, Department of Endocrinology, 206/987-5037
Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number:
Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

Researcher's Statement
You/your child are being asked to give permission for you/your child to take part in a research study. Taking part in research is voluntary. Please take time to make your decision, and discuss it with family and friends. If you/your child decide to participate, but then later want to drop out of the research study, you are free to do so without loss of any benefits, treatment, or services to which you are otherwise entitled.

This form provides a summary of the information the researchers will discuss with you. If you/your child takes part in this research study, you will keep a copy of this form. Be sure to ask any questions you have about the research study.

You/your child are being asked to take part in a research study because as part of the SEARCH study, we have found that **one of your/your child's family members (your child, sister, or brother) had a positive test for an inherited form of diabetes.**

Purpose
There are a few rare inherited forms of diabetes. Your family member had a positive test in the SEARCH study for either **Permanent Neonatal Diabetes Mellitus (PNDM) or Maturity Onset Diabetes of the Young (MODY)**. The study coordinator will tell you which one your family member has.

In infants who are diagnosed with diabetes at <6 months of age, very recent research studies have shown that an inherited cause of diabetes (**PNDM**) is extremely common (about half of cases). Diabetes may also be caused by inherited forms of diabetes in infants diagnosed between 6 months and 1 year of age, although not as frequently as in the younger age group. The reason that it is very important to test for these mutations in children who develop diabetes as infants is because, in some cases, it can dramatically affect the treatment. It is possible that some children may receive treatment for diabetes that does not include the use of insulin.

MODY are a set of diabetes types that affect about 1-2% of people with diabetes. MODY usually runs in families because of a change in a single gene that is passed on by affected parents to their children. The usual course of MODY is different than the usual course of type 1 diabetes. Generally the progression to needing treatment is more gradual. Some patients do not require insulin but rather can be effectively treated with a certain oral medication (sulfonylurea). However, it is often not possible to tell MODY from Type 1 or Type 2 diabetes when the diabetes is first diagnosed without special testing. By finding out which type of diabetes a person has, the most appropriate treatment for them can be determined.

The purpose of this research study is to:

a. Learn whether the genetic mutation found in your/your child's family member is likely to be causing his/her diabetes

b. Offer genetic testing and testing for diabetes at no charge

c. Determine whether you are likely to pass this condition on to any future children.

Benefits
If you/your child have diabetes and are found to have the same abnormal test result, it could affect your/your child's treatment. It is possible that some people may receive treatment for diabetes that

does not include the use of insulin, and it is also possible that the diabetes control will improve with a different form of treatment. However, it is also possible, even if you/your child's results are abnormal, that you/your child's treatment will not change.

If you/your child do not have diabetes, we may find by testing that you do have diabetes. You may benefit from this because treating diabetes early can prevent complications from developing.

In addition, while this research study may not benefit you directly, the information we learn may benefit other people by improving our understanding of who needs to be tested for these genetic forms of diabetes, and whether testing improves the lives of patients in whom mutations are found.

Procedures

This study consists of 4 parts:

1) We will obtain a blood or saliva sample in order to look for the same abnormal test result that was found in your/your child's family member
2) If you do not have diabetes, we will test to see whether you have diabetes
3) We will ask you to fill out questionnaires about diabetes in your family, the effects that diabetes has on your/your child's life, and the effects that participating in this research study has had on your/your child's life
4) If you/your child have diabetes or are found to have diabetes, we will review your/your child's medical records to get complete information for the research study

Sample Collection for Genetic Testing

You/your child will be scheduled for an in-person study visit in the Clinical Research Center at Seattle Children's Hospital and Regional Medical Center or another SEARCH outreach clinic. A blood sample will be drawn from your/your child's arm. DNA will be removed from the blood and used to repeat the test for the gene(s) for which your family member had an abnormal test result. The total amount of blood needed for this sample is 2 teaspoons. If your child weighs less than 11 pounds at the time of the blood draw, a smaller amount of blood will be drawn; we will follow guidelines that tell us what is a safe amount of blood to take. This part of the visit will take 10 – 20 minutes. If you/your child needs a numbing cream for the blood draw, this part will take at least 30 minutes.

If you/your child are not able to come to the study center for an in-person visit, you can have blood drawn by your local doctor and then send the blood sample to us in the mail.

If we can not get a blood sample, we will instead collect a saliva (spit) sample. For the saliva collection, you/your child will spit about 2 teaspoons (10 milliliters) of saliva into a container. If we are collecting this sample from your baby, we will rub some soft sponges in your baby's mouth to collect the saliva. If you are not able to come to the study center, you may be able to collect the saliva sample at home and send the container to us in the mail.

Testing for Diabetes

If you/your child do *NOT* have diagnosed diabetes, we will also perform a test to determine whether you have diabetes that has not been diagnosed. A member of the research team will set up an early morning appointment. You/your child will come for a "fasting" visit, which means that you will eat no food or fluids, other than water, for 8–10 hours prior to the visit.

A small plastic needle will be placed in your/your child's forearm. You/your child will rest for 10 minutes and then 2-3 teaspoons of blood will be drawn through the plastic needle. You/your child

will then drink a liquid meal. A final ½ teaspoon of blood will be drawn 2 hours after the first blood draw. The needle will be removed after the last blood sample is obtained. Upon completion of the test, you/your child will be given a free breakfast or meal voucher.

Written Questionnaires

After completing the blood draw or saliva collection, you/your child will answer some questions about diabetes in your family, the effects of diabetes on your/your child's life, other aspects of you/your child's medical history, and the effects that participating in this research study has had on you/your child's life. You/your child are free to not answer any questions you don't want to answer, and may stop the interview at any time. If you/your child decide not to answer any of the questions, you can still take part in the rest of the research study. This part of the study visit will take about 20 – 30 minutes.

Medical Records Review

If you have diabetes or are found to have diabetes, we will ask your permission for the researchers involved in this study to review your/your child's medical record. Any information obtained from the medical charts is for use in this research study only. Researchers will gather information on the current status and treatment of your/your child's diabetes. This information will include medications used to treat your diabetes and recent results of laboratory tests. The medical records review will take place approximately one year after the confirmatory test results are reported to you and your healthcare provider and will go back to the period of time beginning 6 months before you received this test result.

Research Data and Specimens

Blood and/or saliva samples will be labeled with your/your child's name and date of birth and sent directly to the laboratory where the testing will be performed (Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K.). After the blood/saliva sample has been tested, the rest of the sample will be destroyed. Some health information and information about diabetes in your family will also be sent to the lab in the U.K. in order to aid in the interpretation of the genetic test result. This information will be linked with your name and date of birth. All other study data obtained at this study visit (written questionnaires, documentation from medical records review) will be labeled with a code, with no information that could link the data to you/your child. Dr. Pihoker and the study coordinators on this project will be the only people with access to the code.

You may choose to withdraw from the study at any time. If you would like your/your child's stored samples removed from storage, we will send a request to the central laboratory. They will then destroy the sample, and send us a letter certifying that the sample has been destroyed. We will send you a copy of this letter.

Risks, Stress or Discomfort

When taking a blood sample, there may be brief discomfort, and a bruise may form where the needle poke occurs. To reduce the pain associated with the blood draw, a local anesthetic (numbing cream) may be applied to the skin before blood is taken.

Knowing that you/your child have a genetic form of diabetes may cause you to have more questions. We will answer any questions you may have to the best of our abilities. If needed, you/your child will be referred to an appropriate local health professional for further evaluation and treatment.

You might worry about whether results of this genetic test will lead to discrimination, for example denial of health insurance or employment. Laws exist to protect against genetic discrimination, and these vary from state to state. While it is theoretically possible that genetic information about you/your child could lead to this sort of discrimination, this is very unlikely. Information about you/your child will not be given to insurance companies, employers, or other parties without your permission. Results of this genetic testing *will* be reported to your health care provider with your permission, and will therefore go into your medical record.

If you do not have diabetes and agree to participate, it is possible that we will diagnose you with diabetes as a part of this study. Again, you might worry about whether results of this testing will lead to discrimination, for example denial of health insurance or employment. It is possible that a new diagnosis of diabetes could lead to this sort of discrimination. If you do not want to potentially discover that you have diabetes, you should not participate in this research study.

Test results

As the test results from this research study become available, you/your child will receive results of the tests. Genetic test results will be mailed to you approximately 1 month after the blood is collected. Someone from the study will also call you to explain the results to you before you receive the letter in the mail. Your/your child's diabetes provider will also receive the results, if you have given your permission. If you/your child do not have diabetes, you will also receive results of the diabetes testing. These results will be available approximately 2 weeks after the blood is collected. If we discover that you do have diabetes, you will be referred to a health care provider who can help you to treat your diabetes.

Privacy and Confidentiality

All information gathered during this study will be held in strict confidence. Any publication resulting from participation in this study will not identify you/your child by name.

Once you/your child decide to join the research study, a one of a kind number, called a research study number, will be assigned to you/your child. No other identifying information will be used. The research study number will be used to identify study data (written questionnaires, documentation from medical records review) that was collected during the research study. The research number assigned to you/your child will be kept in a locked file in the research office of Dr. Pihoker, the research study's Principal Investigator. No one other than Dr. Pihoker and her research team will be able to connect any of the research study information to you/your child.

Because results of the genetic tests may be used to change the type of treatment you/your child are receiving for your diabetes, the blood or saliva sample needs to be sent with your name and birth date so we can be sure that the sample belongs to you. In addition, because results of the diabetes testing may be important for your medical care, these blood samples will also be sent with your name and birth date. The samples will be destroyed after the testing has been completed, to protect your privacy.

All answers that you/your child give and other information gathered about you/your child during this study will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means that anything you/your child tells us or information we learn about you/your child will not have to be given out to anyone, even if a court orders us to do so, unless you say it's ok. But, under the law we must report to the state suspected cases of child abuse or if you/your child tell us he/she is planning to cause serious harm to self or others.

Taking Part in Research is Voluntary
Taking part in research is voluntary. You/your child may choose not to take part. If you/your child do take part, you/your child may withdraw from this study at any time. If you/your child drop out of the research study you can request that all blood or DNA samples that have been collected be destroyed. Withdrawal from this research study will have no effect on access to medical care nor will it have any effect on the standard of care your/your child's health care professionals are providing.

Compensation
For the in-person visit, you/your child will receive a $20 gift card.

If you or your child is injured as the direct result of this research study, we (Seattle Children's) will treat you or your child. If appropriate, we will refer you or your child for treatment. You or your insurance company will be billed for the cost of this treatment. Please call Catherine Pihoker at 206-987-2540 if you believe you or your child have been injured as a result of this study.

Questions
For questions about the research, please call Dr. Catherine Pihoker at 206-987-2540. For questions about your/your child's rights as a research participant, contact the Seattle Children's Institutional Review Board (IRB) at 206-987-7804. The IRB is a committee that reviews the research and is responsible for protecting the rights and welfare of children and families taking part in research.

_____ _____

Signature of Researcher *Date/Time*

Permissions:

Medical Record Review
Do you give permission to have your/your child's medical chart, reviewed by research study members, as described above?

☐ Yes, I give my permission

☐ No, I do not give permission

Communication of Genetic Test Results
Do you give permission to have the results of these diabetes and genetic tests communicated to your/your child's healthcare and/or diabetes provider?

☐ Yes, I give my permission

☐ No, I do not give permission

Participant's Statement:

The study described above has been explained to me, and I voluntarily consent to participate (or have my child participate) in this study. I have had the opportunity to ask questions and understand future questions I may have about the research study or about research participants' rights will be answered by the investigators listed above.

_____ _____

Signature of Participant *Date/Time*

_____ _____

*Signature of Parent/Legal Guardian** *Date/Time*

*If the child to be involved in this research study is a foster child or a ward of the state, please notify the researcher or their staff who is obtaining your consent.

Copies to: Participant/parent, Medical Record (when appropriate), Investigator's file

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Consent Form: Genetic Testing for Group Health Cooperative (GHC) participants
Complete at Registry Visit for 2012 Incident Cases

To be signed by participants age 18 and older, cosigned by participants ages 14 to 17, and signed by parent/guardian of participants under age 18

Principal investigator: Catherine Pihoker, MD, 206/987-2540
Department of Endocrinology A-5902
Seattle Children's
4800 Sand Point Way NE
Seattle, WA 98105

Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037
Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987-5037
Erin Alving, ARNP, CDE, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, ARNP, Department of Endocrinology, 206/987-5037

Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number: Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

Researcher's Statement
You/your child are taking part in a research study because you/your child have diabetes. Taking part in research is voluntary. This form provides a summary of information on genetic tests performed as part of this study. Please read this consent form carefully, and ask questions about anything that is not clear to you. Take enough time to make your decision, and discuss it with family and friends. If you/your child decide to consent to genetic testing, but then later want to withdraw this consent, you are free to do so without loss of any benefits, treatment or services to which you are otherwise entitled.

Purpose
One of the goals of this research study is to examine the different types of diabetes that occur in children and adolescents. Genetic testing tells us about traits that run in families, such as brown eyes. A very small fraction of children with diabetes may have one of several rare, inherited forms of diabetes. In the past few years, new research discoveries have been made related to these rare forms of diabetes.

Benefits
Researchers hope to gather more information on these different types of diabetes by conducting tests on stored samples in this research study.

Procedures
Genetic testing will be done on samples stored as part of this research study. No additional procedures are needed. Prior to the visit, we will talk with you/your child about when genetic test results might be shared and the pros and cons of receiving these genetic test results. You/your child and your/your child's diabetes provider may receive the results of genetic tests done for research purposes while taking part in this research study if there is a consensus among doctors that the results of such tests could affect your medical care.

Research Data and Specimens
The blood samples are kept in a central laboratory at the University of Washington. The samples are banked with a code, with no information at the laboratory that could link the samples to you/your child. Dr. Pihoker and her research staff are the only people with access to the code.

Risks, Stress or Discomfort
If, in the future, it is determined that the results of genetic tests could affect your/your child's medical care, your/your child's medical insurance may not pay for the costs of tests to confirm the research results or for the costs of genetic counseling. If the results indicate that you/your child might have one of these rare types of diabetes, it might cause you/your child anxiety or concern. If this happens, Dr. Pihoker will be available to answer questions, and if appropriate, you/your child will be referred to the appropriate local health professionals for evaluation and treatment. Genetic testing has risks, including the potential for inaccurate results, unknown meaning of results, or misuse of results by others. If genetic test results are sent to your/your child's physician, they would become part of your medical record, which could affect future employment or insurance availability.

Test results
If it is determined that the results of these tests could impact your medical care, researchers would give you/your child and your/your child's provider any positive results along with information on follow-up testing to confirm the research results. As a result of follow-up testing, treatment changes might be recommended. It is possible some children may receive treatment for diabetes

that does not include the use of insulin. It would be very important that you not make any changes in your/your child's therapy without confirmation testing and consulting with your/your child's provider. Confirmation testing would need to be done in a CLIA-certified lab. You may need to pay for confirmation testing

Privacy and Confidentiality
All information gathered during this study will be held in strict confidence. Any publication resulting from participation in this study will not identify you/your child by name. Once you/your child decide to join the research study, a one of a kind number, called a research study number, will be assigned to you/your child. No other identifying information will be used. The research study number will be used to identify only the test and interview information that was collected during the research study. The research number assigned to you/your child, and not your child's name, will be sent to the study Coordinating Center at Wake Forest University in order to study the information. The list containing the research study number assigned to you/your child will be kept in a locked file in the research office of Dr. Pihoker, the research study's Principal Investigator. No one other than Dr. Pihoker and her research team will be able to connect any of research study information to you/your child.

All answers that you/your child give and other information gathered about you/your child during this study will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means that anything you/your child tells us or information we learn about you/your child will not have to be given out to anyone, even if a court orders us to do so, unless you say it's OK. But under the law, we must report to the state suspected cases of child abuse or if you/your child tell us he/she is planning to cause serious harm to self or others.

There is a risk that if people other than the researchers obtain genetic information, they could misuse it. Because the genetic test results are kept with a code number, not your name, we think the chance of this happening is very small.

Taking Part in Research is Voluntary
Taking part in research is voluntary. You/your child may choose not to take part. If you/your child do take part, you/your child may withdraw from this study at any time. If you/your child drop out of the research study you can request that all blood or DNA samples that have been stored be destroyed. Withdrawal from this research study will have no effect on access to medical care nor will it have any effect on the standard of care your/your child's health care professionals are providing.

Compensation
You/your child will not receive any additional compensation for this part of the study.

Questions
For questions about the research or feel you have been harmed, please call Dr. Catherine Pihoker at 206/987-2540. For questions about your/your child's rights as a research participant, contact the Seattle Children's Institutional Review Board (IRB) at 206-987-7804. This committee reviews the research and is responsible for protecting the rights and welfare of children and families taking part in research.

_____ _____

Signature of Researcher *Date/Time*

Permissions:

Genetic Test Results
Do you give permission to have the results of genetic tests done for research purposes communicated to you and your/your child's diabetes provider, if it is determined that the results of such tests could impact clinical care?

☐ Yes, I give my permission

☐ No, I do not give permission

Results to Participant/Parent or Guardian of Participant
Do you give permission to researchers to send these results to you/your child?

☐ Yes, I give my permission

☐ No, I do not give permission

Results to Your/Your Child's Provider
Do you give permission to researchers to send these results to your/your child's provider?

☐ Yes, I give my permission

☐ No, I do not give permission

Participant's Statement
The study described above has been explained to me, and I voluntarily consent to genetic testing of my/my child's samples stored in this study. I have had the opportunity to ask questions and understand future questions I may have about the research study or about research participants' rights will be answered by the investigators listed above.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

_____ _____
Signature of Participant *Date/Time*

_____ _____
Signature of Parent/Legal Guardian *Date/Time*

Copies to: Participant/parent, Medical Record (when appropriate), Investigator's file

ASSENT FORM
For Participants 7 - 13 Years of Age

COHORT VISIT

Study Title: SEARCH for Diabetes in Youth

Principal Researcher: Catherine Pihoker, MD

The Research Team:

Name/Degree	Title	Department	Phone Number
Catherine Pihoker, MD	Principal Investigator	Endocrinology	206 987-5037
Lenna Liu, MD MPH	Co-Investigator	Pediatrics	206 987-5037
Maryam Afkarian, MD	Co-Investigator	Nephrology	206 987-5037
Irl Hirsch, MD	Co-Investigator	Medicine	206 987-5037
Carolyn Paris, MD	Co-Investigator	Emergency	206 987-5037
Joyce Yi-Frazier, PhD	Co-Investigator	Endocrinology	206 987-5037
Carla Greenbaum, MD	Co-Investigator	Benaroya Res Instit	206 987-5037
Martin Goldsmith, MD	Co-Investigator	Peds Northwest	206 987-5037
Beth Babler, ARNP	Co-Investigator	Mary Bridge	206 987-5037
Patricia Fechner, MD	Co-Investigator	Endocrinology	206 987-5037
Christian Roth, MD	Co-Investigator	Endocrinology	206 987-5037
Ildi Koves, MD	Co-Investigator	Endocrinology	206 987-5037
Craig Taplin, MD	Co-Investigator	Endocrinology	206 987-5037
Kate Ness, MD	Co-Investigator	Endocrinology	206 987-5037
Carolina DiBlasi, MD	Co-Investigator	Endocrinology	206 987-5037
Roja Motaghedi, MD	Co-Investigator	Endocrinology	206 987-5037
Erin Alving, ARNP	Co-Investigator	Endocrinology	206 987-5037
Karen Aitken, ARNP	Co-Investigator	Endocrinology	206 987-5037
Joanie Warner, ARNP	Co-Investigator	Endocrinology	206 987-5037
Sara Benitez, PA	Co-Investigator	Endocrinology	206 987-5037
Gwyn Recupero, PA	Co-Investigator	Endocrinology	206 987-5037
Beth Loots, MPH MSW	Research Manager	Endocrinology	206-987-2540
Sue Kearns, RN	Study Coordinator	Endocrinology	206 987-2540
Mary Klingsheim, RN, BSN	Study Coordinator	Endocrinology	206 987-2540
Jessica Fosse, MPH, RN, BSN	Study Coordinator	Endocrinology	206 987-2540

Name/Degree	Title	Department	Phone Number
Katherine Cochrane, BS	Clinical Research Associate	Endocrinology	206 987-2540
Sharla Semana, MSW	Clinical Research Associate	Endocrinology	206 987-2540
Patricia D'Alessandro, MA	Clinical Research Associate	Endocrinology	206 987-2540

Clinical Research Center: (206) 987-3897

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

24 hour Emergency Contact Number: 206 987-2000 Ask for the Endocrinologist on call

What is research?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about our research study. We want you to ask us any questions that you have. You can ask questions anytime.

There are a few things you should know about the study:

- You get to decide if you want to be in the study.
- You can say 'No' or you can say 'Yes'.
- Whatever you decide is OK.
- If you say 'Yes', you can always say 'No' later.
- No one will be upset if you say 'No'.
- We will still take good care of you no matter what you decide.

Why are we doing this research study?

We want to talk to you about this study because you have diabetes.

In this study we want to find out more about your health, and how diabetes affects you and your family. We are trying to understand how children, teenagers, and young adults with diabetes might develop nerve, heart, or eye damage.

What would happen if I join this study?

If you decide to be in the study:

- We want to take some blood from your arm with a needle so we can do some tests on the blood that tell us about your diabetes. This would take 10 – 20 minutes.
- We want to look at some of the genes that we know have something to do with diabetes. A sample from this blood will be kept in a freezer until we do tests on it.
- We want to take some samples of your urine. This collection would take a few minutes.
- We would give you a snack and/or a meal or meal voucher after the blood and urine are collected.
- We want to measure your height, weight, blood pressure, and waist. This will be a lot like the measurements you get at your doctor's office. This would take about 20 minutes.
- We want to ask you some questions about feelings in your legs and feet. We want to also test how well your feet can feel things using tools a lot like your doctor uses. This would take about 10 minutes.
- We want to place stickers on your wrists and left leg so that we can measure your heartbeat. We would ask you to breathe normally for ten minutes. We would then check your pulse on your thigh, and take your blood pressure again. We would touch your wrist, neck, leg, and foot with a pen-shaped device. These tests will not hurt. They will take about an hour and a half.
- We want to ask you questions about your eyes and your eye doctor if you have one. We would take pictures of the backs of your eyes using a special camera. This would take about 30 minutes.

- We want to ask you questions about how you take care of your diabetes. You and your parents/caretakers will answer the questions. If you are over 8 years old, you will be asked to fill out a self-report on your stage of puberty. If you are over 10 years old, you will have some extra questions to answer about exercise, the foods you eat, smoking, alcohol, and your sleeping habits. This would take about one hour.
- We want to look in your medical record for information that is needed for the study.
- We want to keep in contact with you in the future.

Could bad things happen if I join this research?

The researcher would need to test some of your blood. These pokes can hurt. Sometimes the needle can leave a bruise on the skin. We can put a cream on your skin before we take blood. This cream would help so it won't hurt as much.

The researcher would need to ask you some questions. They might be hard to answer.

If I join the study would it help me?

We think being in this study would possibly help you because we will let you know what we learn about your diabetes after the tests are done.

We hope to learn something from this study. And someday we hope it will help other kids who have diabetes like you do.

What else should I know about this research?

Being in the study is your choice. You can say 'Yes' or 'No'. Either way is OK.

It is also OK to say yes and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors.

Your information:

We don't plan to share your information. Or tell anyone if you join this study. But, there are a few reasons we would tell someone:

- If we found out you were in serious danger.
- If we found out someone else was in serious danger.

Here are some examples of when we would tell someone:

- If you told us you were being abused.
- If you told us you were going to hurt yourself or someone else.

We would tell to protect you or someone else from being hurt.

Can I do something else instead?

If you don't want to be in the study, you don't have to be.

Would I be paid if I do research?

Once you finish the study, we would give you $120 in gift cards. You would get less if you did only some of the study. We will ask some children to repeat some of the tests, and if we ask you to do this we will give you an extra $10 gift card. You should talk with your parents about how you would like to use these gift cards.

If I have questions who do I ask?

You can talk to Dr. Pihoker or the study team at 206-987-2540. Ask us any questions you have. You can ask questions any time. Take the time you need to make your choice.

Child's/Adolescent's Statement

The researchers have told me about the research. I had a chance to ask questions. I know I can ask questions any time. I want to be in the research.

Remember - being in the research is up to you. No one will be upset if you don't sign this paper or if you change your mind later.

Name of Child/Adolescent _____

Signature of Child/Adolescent _____

Date _____

Name of Researcher _____

Signature of Researcher _____

Date/Time _____

Interpreter Information Section:

Note: The researcher only writes the interpreter's name if the assent is documented via a corresponding translated assent form.

_____

Printed Name of Interpreter (if interpreter is used) *Date/Time*

_____

Printed Name of Interpreter (if interpreter is used) *Date/Time*

Original form to:
Research Team File

Copies to:
Participant
Parents/Guardians
Medical Records (if appropriate)

ASSENT FORM
For Participants 7 - 13 Years of Age

REGISTRY VISIT (2012 Cohort)

Study Title: SEARCH for Diabetes in Youth

Principal Researcher: Catherine Pihoker, MD

The Research Team:

Name/Degree	Title	Department	Phone Number
Catherine Pihoker, MD	Principal Investigator	Endocrinology	206 987-5037
Lenna Liu, MD MPH	Co-Investigator	Pediatrics	206 987-5037
Maryam Afkarian, MD	Co-Investigator	Nephrology	206 987-5037
Irl Hirsch, MD	Co-Investigator	Medicine	206 987-5037
Carolyn Paris, MD	Co-Investigator	Emergency	206 987-5037
Joyce Yi-Frazier, PhD	Co-Investigator	Endocrinology	206 987-5037
Carla Greenbaum, MD	Co-Investigator	Benaroya Res Instit	206 987-5037
Martin Goldsmith, MD	Co-Investigator	Peds Northwest	206 987-5037
Beth Babler, ARNP	Co-Investigator	Mary Bridge	206 987-5037
Patricia Fechner, MD	Co-Investigator	Endocrinology	206 987-5037
Christian Roth, MD	Co-Investigator	Endocrinology	206 987-5037
Ildi Koves, MD	Co-Investigator	Endocrinology	206 987-5037
Craig Taplin, MD	Co-Investigator	Endocrinology	206 987-5037
Kate Ness, MD	Co-Investigator	Endocrinology	206 987-5037
Carolina DiBlasi, MD	Co-Investigator	Endocrinology	206 987-5037
Roja Motaghedi, MD	Co-Investigator	Endocrinology	206 987-5037
Erin Alving, ARNP	Co-Investigator	Endocrinology	206 987-5037
Karen Aitken, ARNP	Co-Investigator	Endocrinology	206 987-5037
Joanie Warner, ARNP	Co-Investigator	Endocrinology	206 987-5037
Sara Benitez, PA	Co-Investigator	Endocrinology	206 987-5037
Gwyn Recupero, PA	Co-Investigator	Endocrinology	206 987-5037
Beth Loots, MPH MSW	Research Manager	Endocrinology	206-987-2540
Sue Kearns, RN	Study Coordinator	Endocrinology	206 987-2540

Name/Degree	Title	Department	Phone Number
Mary Klingsheim, RN, BSN	Study Coordinator	Endocrinology	206 987-2540
Jessica Fosse, MPH, RN, BSN	Study Coordinator	Endocrinology	206 987-2540
Katherine Cochrane, BS	Clinical Research Associate	Endocrinology	206 987-2540
Sharla Semana, MSW	Clinical Research Associate	Endocrinology	206 987-2540
Patricia D'Alessandro, MA	Clinical Research Associate	Endocrinology	206 987-2540
Clinical Research Center: (206) 987-3897			

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

24 hour Emergency Contact Number: 206 987-2000 Ask for the Endocrinologist on call

What is research?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about our research study. We want you to ask us any questions that you have. You can ask questions anytime.

There are a few things you should know about the study:

- You get to decide if you want to be in the study.
- You can say 'No' or you can say 'Yes'.
- Whatever you decide is OK.
- If you say 'Yes', you can always say 'No' later.
- No one will be upset if you say 'No'.
- We will still take good care of you no matter what you decide.

Why are we doing this research study?

We want to talk to you about this study because you have diabetes.

In this study we want to find out about the types of diabetes children and teenagers have. We also want to find out how many children and teenagers who live around your area have diabetes. We also want to learn more about your health, and how diabetes affects you and your family.

What would happen if I join this study?

If you decide to be in the study:

- We want to take some blood from your arm with a needle so we can do some tests on the blood that tell us about your diabetes. This would take 10 – 20 minutes.
- We want to look at some of the genes that we know have something to do with diabetes. A sample from this blood will be kept in a freezer until we do tests on it.
- We want to take some samples of your urine. This collection would take a few minutes.
- We would give you a free breakfast or meal voucher after the blood and urine are collected.
- We want to measure your height, weight, blood pressure, and waist. This will be a lot like the measurements you get at your doctor's office. This would take about 20 minutes.
- We want to ask you questions about the medications you take. You and your parents/caretakers will answer the questions. This would take about 20 minutes.
- We want to keep in contact with you in the future.

Could bad things happen if I join this research?

The researcher would need to test some of your blood. These pokes can hurt. Sometimes the needle can leave a bruise on the skin. We can put a cream on your skin before we take blood. This cream would help so it won't hurt as much.

The researcher would need to ask you some questions. They might be hard to answer.

If I join the study would it help me?

We think being in this study would possibly help you because we will let you know what we learn about your diabetes after the tests are done.

We hope to learn something from this study. And someday we hope it will help other kids who have diabetes like you do.

What else should I know about this research?

Being in the study is your choice. You can say 'Yes' or 'No'. Either way is OK.

It is also OK to say yes and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors.

Your information:

We don't plan to share your information. Or tell anyone if you join this study. But, there are a few reasons we would tell someone:

- If we found out you were in serious danger.
- If we found out someone else was in serious danger.

Here are some examples of when we would tell someone:

- If you told us you were being abused.
- If you told us you were going to hurt yourself or someone else.
- If you or your parent told us you did not have enough to eat.

We would tell to protect you or someone else from being hurt.

Can I do something else instead?

If you don't want to be in the study, you don't have to be.

Would I be paid if I do research?

To thank you for completing the visit, we would give you $80 in gift cards. You should talk with your parents about how you would like to use these gift cards.

If I have questions who do I ask?

You can talk to Dr. Pihoker or the study team at 206-987-2540. Ask us any questions you have. You can ask questions any time. Take the time you need to make your choice.

Child's/Adolescent's Statement

The researchers have told me about the research. I had a chance to ask questions. I know I can ask questions any time. I want to be in the research.

Remember - being in the research is up to you. No one will be upset if you don't sign this paper or if you change your mind later.

Name of Child/Adolescent _____

Signature of Child/Adolescent _____

Date _____

Name of Researcher _____

Signature of Researcher _____

Date/Time _____

Interpreter Information Section:

Note: The researcher only writes the interpreter's name if the assent is documented via a corresponding translated assent form.

_____

Printed Name of Interpreter (if interpreter is used) *Date/Time*

_____

Printed Name of Interpreter (if interpreter is used) *Date/Time*

Original form to:
Research Team File

Copies to:
Participant
Parents/Guardians
Medical Records (if appropriate)

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Monogenic Ancillary Study

Assent Form: <u>Initial Genetic Testing</u>
To be read to children younger than age 7, and read and signed by children ages 7 to 13

Principal investigator: Catherine Pihoker, MD, Department of Endocrinology, 206/987-5037
Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037
Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, MD, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987-5037
Erin Alving, ARNP, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, PA, Department of Endocrinology, 206/987-5037

Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number:
Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

There are different kinds of diabetes. Children who get diabetes when they are very little may have a special kind of diabetes caused by one of the genes in the body. These special kinds of diabetes may run in the family. The treatment for these special kinds of diabetes may be different. We want to find out if you have one of these special kinds of diabetes. We also want to learn more about your health, and how diabetes affects you and your family.

We will ask you to do the things that have a check √ in the box:

- ❑ We will take some blood from your arm with a needle. The needle poke may hurt a little, but the nurse can apply a numbing cream to the area so it will not hurt as much. You may have a bruise on your arm but this should not last long. A sample from this blood will be kept in a freezer until we do tests on it. We will then test for some of the changed genes that we see in children who get diabetes when they are very little. This will help us to find out if you have a special kind of diabetes.

- ❑ We will take a saliva (spit) sample. You will spit about 2 teaspoons of saliva into a container. This will take between 10 and 20 minutes. We will then test for some of the changed genes that we see in children who develop diabetes when they are very little. This will help us to find out if you have a special kind of diabetes.

- ❑ We want to ask you questions about your health and how you take care of your diabetes. We also want to ask you questions about who else in your family has diabetes. You and your parents/caretakers will answer the questions. This will take about 20 minutes.

We will give you a $20 gift card for doing these blood tests, giving these spit samples, or answering these questions.

If you don't want to do something, tell us and we will stop.

You don't have to be in this study if you don't want to. It is OK to say No. If you do say yes, you can stop any time. We'll answer all of your questions any time.

_____ _____
Researcher's signature Date/Time

Child's Statement
The doctor has told me about this study. I want to be in it.

_____ _____
Child's signature Date

_____ _____
Parent or Legal Guardian's signature Date/Time

Copies to: Child/Parent, Medical Record (when appropriate), Investigators file

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Monogenic Ancillary Study

Assent Form: <u>Confirmation of Positive Result</u>
To be read to children younger than age 7, and read and signed by children ages 7 to 13

Principal investigator: Catherine Pihoker, MD, Department of Endocrinology, 206/987-5037
Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037
Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, MD, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987-5037
Erin Alving, ARNP, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, PA, Department of Endocrinology, 206/987-5037

Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number:
Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

There are different kinds of diabetes. Some kinds of diabetes are caused by a change in one of the genes in the body. These special kinds of diabetes may run in the family. The treatment for these special kinds of diabetes may be different. A while ago, you gave a blood and/or spit sample as part of the SEARCH study. This sample was tested for changes in genes that cause diabetes. Your test came back positive. We want to make sure that this positive test is right. This might help your doctor in taking care of you. We also want to find out how many children have this special kind of diabetes that you probably have. We want to learn more about this special kind of diabetes so that we can help other children.

We will ask you to do the things that have a check √ in the box:

- ❑ We will take some blood from your arm with a needle. The needle poke may hurt a little, but the nurse can apply a numbing cream to the area so it will not hurt as much. You may have a bruise on your arm but this should not last long. A sample from this blood will be kept in a freezer until we do tests on it. We will then test for some of the changed genes that we see in children who develop diabetes when they are very little. This will help us to find out if you have a special kind of diabetes.

- ❑ We will take a saliva (spit) sample. You will spit about 2 teaspoons of saliva into a container. We will then test for some of the changed genes that we see in children who develop diabetes when they are very little. This will help us to find out if you have a special kind of diabetes. This will take between 10 and 20 minutes.

- ❑ We want to ask you questions about your health and how you take care of your diabetes. We also want to ask you questions about who else in your family has diabetes. You and your parents/caretakers will answer the questions. This will take about 20 minutes.

We will give you a $20 gift card for doing these blood tests, giving these spit samples, or answering these questions.

If you don't want to do something, tell us and we will stop.

You don't have to be in this study if you don't want to. It is OK to say No. If you do say yes, you can stop any time. We'll answer all of your questions any time.

_____ _____
Researcher's signature Date/Time

Child's Statement
The doctor has told me about this study. I want to be in it.

_____ _____
Child's signature Date

_____ _____
Parent or Legal Guardian's signature Date/Time

Copies to: Child/Parent, Medical Record (when appropriate), Investigators file

SEATTLE CHILDREN'S
UNIVERSITY OF WASHINGTON
SEARCH for Diabetes in Youth
Monogenic Ancillary Study

Assent Form: <u>Family Members</u>
To be read to children younger than age 7, and read and signed by children ages 7 to 13

Principal investigator: Catherine Pihoker, MD, Department of Endocrinology, 206/987-5037
Co-investigators: Lenna L. Liu, MD, MPH, Department of Pediatrics, 206/987-5037
Maryam Afkarian, MD, Department of Nephrology, 206/987-5037
Irl Hirsch, MD, Department of Medicine, 206/987-5037
Carolyn Paris, MD, Department of Emergency Medicine, 206/987-5037
Joyce Yi-Frazier, PhD, Department of Endocrinology, 206/987-5037
Carla Greenbaum, MD, Clinical Research Center, 206/987-5037
Martin Goldsmith, MD, Pediatrics Northwest, 206/987-5037
Beth Babler, ARNP, Mary Bridge, 206/987-5037
Patricia Fechner, MD, Department of Endocrinology, 206/987-5037
Christian Roth, MD, Department of Endocrinology, 206/987-5037
Ildi Koves, MD, Department of Endocrinology, 206/987-5037
Craig Taplin, MD, Department of Endocrinology, 206/987-5037
Kate Ness, MD, Department of Endocrinology, 206/987-5037
Carolina DiBlasi, MD, Department of Endocrinology, 206/987-5037
Roja Motaghedi, MD, Department of Endocrinology, 206/987 5037
Erin Alving, ARNP, Department of Endocrinology, 206/987-5037
Karen Aitken, ARNP, Department of Endocrinology, 206/987-5037
Joanie Warner, ARNP, Department of Endocrinology, 206/987-5037
Sara Benitez, PA, Department of Endocrinology, 206/987-5037
Gwyn Recupero, PA, Department of Endocrinology, 206/987-5037

Study Coordinators: Beth Loots, MPH, MSW, Department of Endocrinology, 206/987-2540
Sue Kearns, RN, Department of Endocrinology, 206/987-2540
Mary Klingsheim RN BSN, Department of Endocrinology, 206/987-2540
Jessica Fosse, MPH RN BSN, Department of Endocrinology, 206/987-2540
Katherine Cochrane, BS, Department of Endocrinology, 206/987-2540
Sharla Semana, MSW, Department of Endocrinology, 206/987-2540
Patricia D'Alessandro, MA, Department of Endocrinology, 206/987-2540

24-hour emergency telephone number:
Catherine Pihoker, MD, or Pediatric Endocrinologist on call: 206/987-2000

There are different kinds of diabetes. Some kinds of diabetes are caused by a change in one of the genes in the body. These special kinds of diabetes may run in the family. The treatment for these special kinds of diabetes may be different. A while ago, your sister or brother was tested for changes in genes that can cause diabetes. The test was positive. We want to find out if you also have a change in the same gene. This will help us to understand if the changed gene is causing your sister or brother's diabetes. If you do not have diabetes and you are 10 years old or older, we may test you for diabetes by measuring how much insulin is made after you eat.

We will ask you to do the things that have a check √ in the box:

- ❑ We will take some blood from your arm with a needle. The needle poke may hurt a little, but the nurse can apply a numbing cream to the area so it will not hurt as much. You may have a bruise on your arm but this should not last long. A sample from this blood will be kept in a freezer until we do tests on it. We will then test for the same changed gene(s) that we found in your sister or brother.

- ❑ We will take a saliva (spit) sample. You will spit about 2 teaspoons of saliva into a container. We will then test for the same changed gene that we found in your sister or brother. This will take between 10 and 20 minutes.

- ❑ We will test to see if you have diabetes. You cannot eat any food, or drink anything except water, the morning of the test. You might feel hungry before the test is done. We will put a small tube called a catheter in a vein in your arm. The nurse will apply a numbing cream to the area so it will not hurt as much. The needle-poke when we put the tube in your arm may still hurt a little. Once the needle is in your arm, drawing the blood should not hurt you at all. First we will take some blood from your arm. Then you will drink a milkshake-like drink over a short period of time. After 2 hours, we will take some more blood from the catheter that is in your arm. You may have a small bruise from where the needle was in your arm, but this should not last a long time. After the test is done, you can eat breakfast. A total of 2 blood samples will be drawn and the whole test should take about 2 to 2 ½ hours. We will let you know what we learn after the tests are done.

- ❑ We want to ask you questions about your health and, if you have diabetes, how you take care of your diabetes. We also want to ask you questions about who else in your family has diabetes. You and your parents/caretakers will answer the questions. This will take about 20 minutes.

We will give you a $20 gift card for doing these blood tests, giving these spit samples, taking the diabetes milkshake test, or answering these questions.

If you don't want to do something, tell us and we will stop.

You don't have to be in this study if you don't want to. It is OK to say No. If you do say yes, you can stop any time. We'll answer all of your questions any time.

_____ _____

Researcher's signature Date/Time

Child's Statement

The doctor has told me about this study. I want to be in it.

_____ _____

Child's signature Date

_____ _____

Parent or Legal Guardian's signature Date/Time

Copies to: Child/Parent, Medical Record (when appropriate), Investigators file

Permission to Use, Create and Share Health Information for Research
Research Study Title: SEARCH for Diabetes in Youth
IRB Study #: 12074

The federal Privacy Rule protects your/your child's health information. The Privacy Rule is part of the Health Insurance Portability and Accountability Act (HIPAA).

If you/your child agree to take part in this research study (named above), the researchers may use, create or share your/your child's health information as part of the research. The researchers will do so **only** if you give permission to use, create or share your/your child's health information as part of the research. This form gives you information to help you decide if you will give such permission. **Please read this form carefully**. After reading this form, you can refuse to sign this form.

What does "health information" include? It includes:

☒ Name ☒ Address ☒ Social Security Number ☒ Medical and/or birth history ☒ Demographic information

☒ Results of physical exams ☒ Results of laboratory and/or radiology tests

☒ Interview and/or focus group data ☒ Survey and/or questionnaire data

☒ Results of behavioral tests ☒ Information related to your health condition

☒ Information in your medical record relevant to this study ☐ Other (please specify) * _____

* If using a translated HIPAA Form, this information must also be translated

What the researchers may do with health information

Researchers may create new health information about you/your child during the study. Researchers may use health information in your/your child's records.

Researchers may also share health information about you/your child collected during the study with the following:

1. The sponsor of this study and its representatives. Sponsor Name: **Centers for Disease Control/National Institute of Digestive & Kidney Diseases/JDRF**
2. Researchers at other centers taking part in this research study.
   Name(s) of other center(s): **Cincinnati Children's Hospital Medical Center, University of Colorado, Pacific Health Research Institute (HI), University of North Carolina, University of South Carolina, Southern California Kaiser Permanente, Wake Forest University, Northwest Lipid Research Labs, University of Washington; and the Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K., Ocular Epidemiology Reading Center at the University of Wisconsin – Madison, and the University of Michigan**

3. Government agencies, ethics review boards, data and safety monitoring boards, and others responsible for watching over the safety, effectiveness, and conduct of the research.
4. Your health care insurance company if it is paying for care provided as part of the research study.
5. Other health care providers involved in your/your child's care.
6. National Institutes of Health and its grantholders for the purpose of research administrative activities (e.g., tracking overall research activity).
7. Others, as provided by law.

The Privacy Rule applies to doctors, hospitals and other health care providers. Some of the groups listed above are not required to follow the Privacy Rule and may share your/your child's information with others, if other laws allow. However, other privacy protections may still apply.

Research Records

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research records may not be available to you/your child while the study is going on. This does not affect your right to see what is in your/your child's medical (hospital) records.

The researchers may publish or present the research findings. You/your child will not be identified in any findings that are published or presented.

The federal Privacy Rule does not apply to health information that is not identified in any way. The researchers may decide to remove any information that could identify you/your child. If they do this, the information may be used and shared by the researchers and the sponsor as the law allows. This may include use in other research studies.

Permissions to Take Part in Research

If you agree to take part or allow your child to take part in the research, you will be asked to sign a **research consent form**. The research consent form gives you details about the research. The consent form describes the risks and benefits of the research. It explains the purpose of the study, what will happen and other important information for you to know.

To be in this research study, you must also sign this permission form (Permission to Use, Create and Share Health Information for Research). If you do not want to sign this permission form, this will not affect the care and treatment you or your child receive.

How Long does the Permission Last? What if You Change Your Mind?

This permission will not expire, but you may cancel it at any time.

If you change your mind and want to cancel your permission, please let us know in writing. Write to Principal Investigator (PI)/Researcher:

[Name and Address of PI]. **Catherine Pihoker, MD, Seattle Children's, 4800 Sand Point Way NE/OC.7.820, Seattle, WA 98105-0371**

If you cancel your permission and you/your child are a patient at Children's, please send a copy of your letter to:

Director of Health Information and Privacy, Health Information Management, M/S OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

If you cancel your permission, no other health information about you/your child will be collected for this research. However, the health information that was received with your permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons;
- to verify the research data;
- if required by law.

If you agree to take part or allow your child to take part, you will be given a copy of this permission form after you have signed it.

Permission

I agree to the use, creation, and sharing of my or my child's health information for purposes of this research study (named on page 1). For Children's patients, your medical record # will be recorded on this form and used to place a copy of this form in your medical record.

_____ Printed Name of Participant	_____ Signature of Participant (if 18 years or Older)
_____ Date	_____ Time
_____ Printed Name of Participant's Parent or Legal Representative	_____ Signature of Research Participant's Parent or Legal Representative (if younger than18 years)
_____ Date	_____ Time

Researcher Obtaining Authorization

_____ Printed Name of Research Team Member*	_____ Signature of Research Team Member
_____ Date	_____ Time

***INSTRUCTIONS TO RESEARCHER**

1. File signed original of this form in Research File ☐
2. Provide copy of signed form to Research Participant/Parent ☐

For Children's Patients

3. Complete or attach patient label: ☐

Participant's Medical Record # _____

Participant's Date of Birth _____/_____/_____

4. Send copy of the signed form to Health Information Filing: Mailstop OC.6.820 ☐

Permiso para utilizar, crear y compartir información para fines de investigación
Título del estudio de investigación: SEARCH for Diabetes in Youth
N.º de estudio del IRB: 12074

La Regla de privacidad federal protege su información/la información de salud de su hijo. La Regla de privacidad es parte de la Ley de Responsabilidad y Portabilidad del Seguro de Salud (*Health Insurance Portability and Accountability Act*, "HIPAA").

Si usted/su hijo acepta participar en este estudio de investigación (nombrado arriba), los investigadores podrán usar, crear o compartir su información de salud/la información de salud de su hijo como parte de la investigación. Los investigadores lo harán **únicamente** si usted da permiso para utilizar, crear o divulgar su información de salud/la información de salud de su hijo como parte de la investigación. En este formulario se le proporciona información para ayudarle a decidir si dará ese permiso. **Lea este formulario con atención.** Después de leer el formulario, puede rehusarse a firmarlo.

¿Qué incluye la "información de salud"? Incluye:

☒ Nombre
Name

☒ Dirección
Address

☒ Núm. Seguro Social
Social Security Number

☒ Antecedentes médicos y/o de nacimiento
Medical and/or birth history

☒ Información demográfica
Demographic information

☒ Resultados de los exámenes médicos
Results of physical exams

☒ Resultados de análisis y/o estudios radiográficos
Results of laboratory and/or radiology tests

☒ Datos de entrevistas y/o grupos de enfoque
Interview and/or focus group data

☒ Datos de encuestas y/o cuestionarios
Survey and/or questionnaire data

☒ Resultados de pruebas conductuales
Results of behavioral tests

☒ Información relacionada con su problema médico
Information related to your health condition

☒ Información de su expediente médico pertinente a este estudio
Information in your medical record relevant to this study

☐ Otra (explique)* _____
Other (please specify)*

* Si está usando un formulario HIPAA traducido, esta información también tiene que estar traducida.
* If using a translated HIPAA Form, this information must also be translated

Lo que los investigadores pueden hacer con información de salud

Los investigadores pueden crear nueva información de salud acerca de usted/su hijo durante el estudio. Los investigadores pueden utilizar la información de salud que se encuentra en su expediente clínico/en el expediente clínico de su hijo.

También puede ser necesario que los investigadores compartan información de salud sobre usted/su hijo obtenida durante el estudio con las siguientes personas o entidades:

1. El patrocinador de este estudio y sus representantes. Nombre del patrocinador: **Centers for Disease Control/National Institute of Digestive & Kidney Diseases/JDRF**
2. Investigadores en otros centros que están participando en este estudio de investigación. Nombres de los otros centros: **Cincinnati Children's Hospital Medical Center, University of Colorado, Pacific Health Research Institute (HI), University of North Carolina, University of South Carolina, Southern California Kaiser Permanente, Wake Forest University, Northwest Lipid Research Labs, University of Washington; and the Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K., Ocular Epidemiology Reading Center at the University of Wisconsin – Madison, and the University of Michigan**
3. Dependencias del gobierno, comités de ética, consejos que supervisan los datos y la seguridad, y otros responsables por velar por la seguridad, la eficacia y la conducta de la investigación.
4. Su compañía de seguro médico, si ellos están pagando por la atención facilitada como parte del estudio de investigación.
5. Otros proveedores de atención de la salud que participan en la atención de usted/de su hijo.
6. National Institutes of Health y los cesionarios de sus subvenciones para fines de actividades administrativas de la investigación (p. ej. para llevar seguimiento de toda actividad de la investigación).
7. Otras entidades o personas según lo disponga la ley.

La Regla de privacidad corresponde a médicos, hospitales y otros proveedores atención de la salud. Algunos de los grupos enumerados más arriba no tienen obligación de observar la Regla de privacidad y podrán divulgar su información de salud/la información de salud de su hijo a otras personas o entidades, si otras leyes lo permiten. No obstante, podrían corresponder aún otras protecciones de la privacidad.

Expedientes de la investigación

Usted puede ver o copiar la información que podría usarse o divulgarse. Sin embargo, en ciertos tipos de estudios de investigación es posible que parte de los expedientes de la investigación no estén a su disposición en el transcurso del estudio. Eso no afecta su derecho de ver lo que se encuentra en su expediente clínico/el expediente clínico de su hijo.

Los investigadores podrían publicar o presentar los resultados de sus investigaciones. Usted/su hijo no serán identificados en ningunos resultados que sean publicados o presentados.

La Regla de privacidad federal no corresponde a información de salud que no está identificada de manera alguna. Es posible que los investigadores decidan retirar cualquier información que pudiera identificar a usted/su hijo. Si lo hacen, la información podrá ser utilizada y compartida entre los investigadores y el patrocinador según lo permita la ley. Eso podría incluir el uso en otros estudios investigación.

Permiso para participar en la investigación

Si usted acepta participar o permite que su hijo participe en la investigación, se le pedirá que firme un **formulario de consentimiento**. El formulario de consentimiento para investigación proporciona los detalles sobre la investigación. En el formulario de consentimiento se describen los riesgos y beneficios de la investigación. En él se explica el propósito del estudio, lo que ocurrirá y otra información importante que usted necesita saber.

Para poder participar en este estudio de investigación, usted también deberá firmar este formulario de permiso (Permiso para utilizar, crear y compartir información para fines de investigación). Si usted no desea firmar este formulario de autorización, eso no tendrá ningún efecto sobre la atención y el tratamiento que usted o su hijo reciba.

¿Cuánto tiempo dura el permiso? ¿Qué ocurrirá si cambia de parecer?

Este permiso no tiene vencimiento, pero lo puede cancelar en cualquier momento.

Si cambia de parecer y desea cancelar su permiso, por favor avísenos por escrito. Envíe su correspondencia al investigador principal:

[Nombre y dirección del IP] **Catherine Pihoker, MD, Seattle Children's, 4800 Sand Point Way NE/OC.7.820, Seattle, WA 98105-0371**
[Name and Address of PI]

Si cancela su permiso y usted/su hijo es un paciente de Children's, sírvase enviar una copia de su correspondencia a:

Director of Health Information and Privacy, Health Information Management, OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

Si cancela su permiso, no se recolectará ninguna otra información de salud sobre usted/su hijo para esta investigación. Sin embargo, la información de salud que haya sido obtenida con su permiso podrá ser divulgada o utilizada. Por ejemplo, podría ser necesario que los investigadores utilicen o divulguen esta información:

- por motivos de seguridad;
- para verificar los datos de la investigación;
- si la ley lo dispone.

Si usted acepta participar o permitir que su hijo participe, le entregarán una copia de este formulario de permiso después de que lo firme.

Permiso

Yo convengo al uso, creación y divulgación de mi información de salud/la información de salud de mi hijo para los fines de este estudio de investigación (nombrado en la página 1). Para los pacientes de Children's, su número de expediente clínico se anotará en este formulario y se utilizará para incluir una copia de este formulario en su expediente clínico.

Nombre del participante (en letra de imprenta) Printed Name of Participant	Firma del participante (si es mayor de 18 años) Signature of Participant (if 18 years or Older)
Fecha Date	Hora Time
Nombre impreso del padre, madre o tutor legal del participante Printed Name of Participant's Parent or Legal Representative	Firma del padre, madre o tutor legal del participante de la investigación (si es menor de 18 años) Signature of Research Participant's Parent or Legal Representative (if younger than18 years)
Fecha Date	Hora Time

Investigador que obtuvo la autorización

Nombre del miembro del equipo de la investigación (en letra de imprenta)* Printed Name of Research Team Member*	Firma del miembro del equipo de la investigación Signature of Research Team Member
Fecha Date	Hora Time

***INSTRUCCIONES PARA EL INVESTIGADOR**
***INSTRUCTIONS TO RESEARCHER**

1. Archive el original firmado de este formulario en el archivo de la investigación ☐
   File signed original of this form in Research File
2. Proporcione una copia del formulario firmado al participante/padre/madre ☐
   Provide copy of signed form to Research Participant/Parent

Para pacientes del Children's (For Children's Patients)

3. Complete o adjunte la etiqueta del paciente: ☐
   Complete or attach patient label:

No. de expediente médico del participante _____
Participant's Medical Record #
Fecha de nacimiento del participante _____/_____/_____
Participant's Date of Birth

4. **Envíe una copia del formulario firmado a Health Information Filing: Mailstop OC.6.820** ☐
   Send copy of the signed form to Health Information Filing: Mailstop OC.6.820

Tso Cai los Siv, Tsim thiab Qhia Lus Txog Kev Mob rau Kev Tshawb Xyuas
Lub Npe Rau Kev Tshawb Xyuas:
Kev Kawm IRB #:

Txoj cai ntawm tebchaw hu ua Privacy Rule (tsab cai tsis pub qhia) tiv thaiv koj/koj tus menyuam cov lus qhia txog kev mob. Txoj cai Privacy Rule yog ib qho ntawm qhov Health Insurance Portability and Accountability Act (HIPAA; txoj cai saib xyuas cov kev pov hwm kho mob).

Yog koj/koj tus menyuam pom zoo los koom nrog qhov kev kawm tshawb xyuas no (lub npe nyob rau saum toj sauv), cov neeg tshawb xyuas yuav siv, tsim lossis qhia tau koj/koj tus menyuam cov lus qhia txog kev mob thaum ua txoj kev tshawb xyuas. Cov neeg tshawb xyuas **tsuas** ua li no thaum koj tso cai tag kom los siv, tsim lossis qhia koj/koj tus menyuam cov lus qhia txog kev mob rau txoj kev tshawb xyuas. Daim ntawv sau no yuav muab lus qhia los pab koj txiav txim siab seb koj puas tso cai. **Thov ua zoo nyeem daim ntawv sau no**. Thaum koj nyeem daim ntawv sau no tag, koj tsis kam xees daim ntawv no los tau.

Cov "lus qhia txog kev mob" yog muaj dabtsi hauv? Nws muaj:

☐ Npe
Name

☐ Chaw nyob
Address

☐ Lej Xaus Saus
Social Security Number

☐ Keebkwm mob thiab/lossis kev yug
Medical and/or birth history

☐ Lus qhia seb yog neeg dabtsi
Demographic information

☐ Qhov tshwm sim ntawm kev kuaj ib ce
Results of physical exams

☐ Qhov tshwm sim ntawm chaw kuaj sim thiab/lossis cov kev xoos faisfab
Results of laboratory and/or radiology tests

☐ Lus khaws los ntawm kev sib tham thiab/lossis sib tham ua ib pab
Interview and/or focus group data

☐ Lus khaws ntawm kev ntsuam xyuas thiab/lossis lus nug
Survey and/or questionnaire data

☐ Qhov tshwm sim ntawm kev sim cwj pwm
Results of behavioral tests

☐ Lus qhia txog koj qhov kev mob
Information related to your health condition

☐ Lus qhia txog koj cov ntawv sau txog kev mob uas phim rau txoj kev tshawb xyuas no
Information in your medical record relevant to this study

☐ Lwm yam (thov qhia) * _____
Other (please specify)*

* Yog koj siv daim ntawv HIPAA uas tau muab txhais, cov lus ntawm no yuav tsum muab txhais thiab
* If using a translated HIPAA Form, this information must also be translated

Tej yam cov neeg tshawb xyuas yuav ua nrog cov lus qhia txog cov kev mob

Tejzaum cov neeg tshawb xyuas yuav tsim cov lus qhia tshiab txog cov kev mob rau koj/koj tus menyuam thaum ua kev kawm no. Tejzaum cov neeg tshawb xyuas yuav siv cov lus qhia txog mob hauv koj/koj tus menyuam cov ntawv sau tseg txog cov kev mob.

Cov neeg tshawb xyuas tejzaum yuav qhia lwm tus txog kev mob ntawm koj/koj tus menyuam uas tau khaws thaum ua qhov kev kawm no nrog rau cov nram qab no:

1. Tus txhawb nqa qhov kev kawm no thiab tus sawv cev rau nws. Tus Txhawb Nqa Lub Npe:

2. Lwm cov neeg tshawb xyuas ntawm lwm qhov chaw uas koom kawm tshawb xyuas nrog qhov no.
   Lwm qhov (cov) chaw kawm lub npe (cov npe):
3. Kooshaum nom tswv, pab pawg neeg saib kom ncaj, pab pawg neeg saib lus khaws tseg thiab kev nyab xeeb, thiab lwm cov uas muaj lub haujlwm los saib kev nyab xeeb, kev ua kom raug, thiab kev coj rau qhov tshawb xyuas.
4. Koj lub khw pov hwm kev mob yog lawv them rau kev tu xyuas uas yog ib qho ntawm qhov kev kawm tshawb xyuas no.
5. Lwm cov muab kev tu mob ua nrog koj/koj tus menyuam.
6. Lub National Institutes of Health (kooshaum tebchaws txog kev mob) thiab nws cov neeg muab nyiaj txhawb rau yam ua los tswj kev tshawb xyuas (xws li, taug raws kev tshawb xyuas tag nrho).
7. Lwm cov, raws txoj cai.

Txoj cai Privacy Rule yuav raug rau cov kws kho mob, tsev kho mob thiab lwm cov muab kev tu xyuas mob. Ib txhia ntawm cov saum toj no yuav tsis raug ua kom raws li txoj cai Privacy Rule thiab yuav qhia tau koj/koj tus menyuam cov lus rau lwm tus, yog lwm cov cai pub ua. Txawm li cas los, tejzaum nws yeej muaj lwm cov cai tswj kom tsis pub qhia uas yuav tiv thaiv tau thiab.

Ntawv Tshawb Xyuas Sau Tseg

Koj saib tau lossis luam tseg cov lus uas tejzaum yuav muab siv lossis qhia tawm. Txawm li cas los, rau tej hom kev kawm tshawb xyuas, tej cov ntawv tshawb xyuas sau tseg yuav tsis muaj rau koj/koj tus menyuam thaum qhov kev kawm tseem tab tom khiav. Qhov no yuav tsis raug koj txoj cai los pom seb muaj dabtsi nyob hauv koj/koj tus menyuam cov ntawv sau tseg txog kev mob (tsev kho mob loj).

Cov neeg tshawb xyuas yuav luam tawm lossis muab qhia qhov tshwm sim ntawv kev tshawb xyuas tau. Peb yuav tsis qhia tias koj/koj tus menyuam yog leej twg ntawm qhov tshwm sim ntawd thaum tau muab luam tawm lossis muab nthuav qhia.

Txoj cai Privacy Rule ntawm tebchaw yuav tsis raug txog cov lus qhia txog mob uas tsis qhia tseeb tias yog dabtsi kiag. Tejzaum cov neeg tshawb xyuas yuav txiav txim siab los tshem cov lus uas qhia tau tias yog koj/koj tus menyuam. Yog lawv ua li no lawm, cov lus qhia no yuav muab siv thiab pub qhia tau rau cov neeg tshawb xyuas thiab lawv cov txhawb nqa lawv raws li txoj cai pub. Qhov no tejzaum yuav pub siv rau lwm txoj kev kawm tshawb xyuas.

Tso Cai los Koom Nrog Kev Tshawb Xyuas

Yog koj pom zoo los koom lossis pub koj tus menyuam los koom nrog qhov kev tshawb xyuas, lawv yuav nug koj los xees npe rau daim **ntawv tso cai rau kev tshawb xyuas**. Daim ntawv tso cai rau kev tshawb xyuas yuav qhia txog qhov kev tshawb xyuas. Daim ntawv tso cai yuav piav txog tej yam uas yuav muaj feem raug rau koj thiab qhov yuav pab los ntawm qhov kev tshawb xyuas. Nws yuav qhia lub hom phiaj ntawm qhov kev kawm, seb yuav muaj licas thiab lwm yam lus tseem ceeb kom koj paub.

Yuav kom koj koom tau nrog qhov kev tshawb xyuas no, koj yuav tsum xees daim ntawv tso cai no thiab (Tso Cai los Siv, Tsim thiab Qhia Lus Txog Kev Mob rau Kev Tshawb Xyuas). Yog koj tsis xav xees daim ntawv tso cai no, qhov no yuav tsis hloov txoj kev tu xyuas thiab kev kho mob uas koj lossis koj tus menyuam txais.

Qhov Kev Tso Cai No Kav Hov Ntev? Yuav Ua Li Cas Yog Koj Ho Pauv Siab?

Qhov kev tso cai no tsis txawj tag sijhawm, tiamsis koj yuav muab ncua tseg thaum twg los tau.

Yog tias koj loov tswv yim thiab tsis kam tso cai lawm, thov sau ntawv tuaj qhia rau peb. Sau ntawv rau tus Principal Investigator (PI)/Researcher:

[Npe thiab Chaw Nyob ntawm Tus PI].
[Name and Address of PI].

Yog koj tsis kam tso cai thiab koj/koj tus menyuam yog ib tug neeg mob tom Children's, thov xa ib tsab ntawv luam ntawm koj daim ntawv mus rau:

Director of Health Information and Privacy, Health Information Management, M/S OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

Yog koj tsis kam tso cai lawm, peb yuav tsis nrhiav lwm cov lus qhia kev mob txog koj/koj tus menyuam rau qhov kev tshawb xyuas no ntxiv lawm. Txawm li cas los, cov lus qhia txog mob uas twb tau txais nrog koj lo lus tso cai tejzaum tseem yuav muab pub qhia lossis siv. Piv txwv, cov neeg tshawb xyuas tejzaum yuav xav siv lossis pub qhia cov lus no vim:

- kev nyab xeeb;
- los saib seb cov ntawv khaws tseg txog qhov kev tshawb xyuas puas muaj tseeb;
- yog txoj cai hais tias yuav tsum ua.

Yog koj pom zoo los koom lossis pub koj tus menyuam los koom, peb mam muab ib tsab ntawv luam ntawm daim ntawv tso cai no rau koj thaum koj xees tag.

Tso Cai

Kuv pom zoo rau txoj kev siv, tsim, thiab pub qhia kuv cov lossis kuv tus menyuam cov lus qhia txog kev mob rau txoj kev kawm tshawb xyuas no (muaj npe rau nplooj 1). Rau Children's cov neeg mob, koj cov ntawv khaws tseg txog mob tus # yuav muab sau rau daim ntawv no thiab siv los tso ib tsab luam ntawm daim no rau koj cov ntawv khaws tseg txog mob.

_____ Sau Tus Mob Lub Npe Kom Nyeem Tau Printed Name of Participant	_____ Tes Xees Ntawm Tus Tuaj Koom (yog tias18 xyoo lossis Luas Tshaj) Signature of Participant (if 18 years or Older)
_____ Hnub Tim Date	_____ Sijhawm Time
_____ Sau Tus Tuaj Koom Niam Txiv Lub Npe lossis Tus Sawv Cev Raws Cai Kom Nyeem Tau Printed Name of Participant's Parent or Legal Representative	_____ Tes Xees Ntawm Tus Tuaj Koom Kev Tshawb Xyuas Tus Niam Txiv lossis Tus Sawv Cev Raws Cai (yog hluas dua 18 xyoo) Signature of Research Participant's Parent or Legal Representative (if younger than18 years)
_____ Hnub Tim Date	_____ Sijhawm Time

Tus Neeg Tshawb Xyuas Muab Kev Tso Cai

_____ Sau Lub Npe Ntawm Tus Neeg Ua Nrog Pab Neeg Tshawb Xyuas Kom Nyeem Tau* Printed Name of Research Team Member*	_____ Tes Xees Ntawm tus Neeg Ua Nrog Pab Neeg Tshawb Xyuas Signature of Research Team Member
_____ Hnub Tim Date	_____ Sijhawm Time

***KEV QHIA RAU TUS NEEG TSHAWB XYUAS**
***INSTRUCTIONS TO RESEARCHER**

1. Muab daim tseem ntawm daim no uas tau xees tag tso hauv phau Research File ☐
   File signed original of this form in Research File
2. Muab ib daim luam ntawm daim ntawv tau xees rau tus
   Tuaj Koom Kev Tshawb Xyuas/Niam Txiv ☐
   Provide copy of signed form to Research Participant/Parent

Rau Cov Neeg Mob Uas Yog Menyuam Yaus (For Children's Patients)

3. Sau kom tiav lossis lo daim ntawv rau tus mob: ☐
   Complete or attach patient label:

   Tus Tuaj Koom Tus Lej Ntawm Cov Ntawv Mob
   Khaws Tseg # _____
   Participant's Medical Record #
   Tus Tuaj Koom Lub Hnub Yug _____/_____/_____
   Participant's Date of Birth

4. **Xa ib tsab luam ntawm daim tau xees mus rau**
   Health Information Filing: Mailstop OC.6.820 ☐
   Send copy of the signed form to Health Information Filing: Mailstop OC.6.820

Разрешение на использование, создание и передачу сведений медицинского характера для исследовательских целей
Название исследовательского проекта: SEARCH for Diabetes in Youth
IRB-номер проекта: 12074

Федеральное Правило неприкосновенности личной жизни охраняет доступ к медицинской информации, как Вашей, так и Вашего ребенка. Правило неприкосновенности личной жизни содержится в Законе о соблюдении принципов преемственности и ответственности при страховании здоровья (HIPAA).

Если Вы или Ваш ребенок дадите согласие на участие в вышеназванном научном исследовании, это даст право научным работникам в рамках данного исследования использовать, создавать или передавать третьим лицам сведения медицинского характера о Вас или Вашем ребенке. При этом научные работники вправе делать это **только** при наличии Вашего согласия на использование, создание или передачу сведений медицинского характера о Вас или Вашем ребенке в рамках указанной научной работы. Этот формуляр содержит информацию, которая поможет Вам принять решение о предоставлении такого разрешения. **Просим внимательно ознакомиться с ним.** Прочитав этот формуляр, вы можете отказаться подписывать его.

Что входит в состав «информации медицинского характера»? Она включает:

☒ Имя и фамилия
Name

☒ Адрес ☒ Номер соц. обесп. ☒ История болезни и/или рождения ☒ Демографич. информация
Address Social Security Number Medical and/or birth history Demographic information

☒ Результаты медицинских осмотров
Results of physical exams

☒ Результаты лабораторных и/или рентгеновских обследований
Results of laboratory and/or radiology tests

☒ Данные из бесед и/или целевых групп
Interview and/or focus group data

☒ Данные из анкет и/или опросов
Survey and/or questionnaire data

☒ Результаты поведенческих тестов
Results of behavioral tests

☒ Сведения, касающиеся состояния вашего здоровья
Information related to your health condition

☒ Сведения из вашей мед. карточки, касающиеся данного исследования
Information in your medical record relevant to this study

☐ Прочее (укажите)* _____
Other (please specify)*

* Если используется переведенный формуляр HIPAA, эта информация тоже должна быть переведена.
* If using a translated HIPAA Form, this information must also be translated

Как исследователи могут поступать с медицинской информацией

Исследователи могут создавать новую информацию медицинского характера о Вас или Вашем ребенке в процессе научной работы. Научные работники могут использовать информацию медицинского характера, содержащуюся в Вашей медкарте или медкарте Вашего ребенка.

В ходе работы исследователям, возможно, потребуется передать информацию медицинского характера о Вас или Вашем ребенке, собранную в процессе исследований, третьим лицам, таким как:

1. Спонсору данного исследования и его представителям. Фамилия/наименование спонсора: **Centers for Disease Control/National Institute of Digestive & Kidney Diseases/JDRF**
2. Исследователям из других организаций, принимающим участие в данном проекте. Наименование организаций: **Cincinnati Children's Hospital Medical Center, University of Colorado, Pacific Health Research Institute (HI), University of North Carolina, University of South Carolina, Southern California Kaiser Permanente, Wake Forest University, Northwest Lipid Research Labs, University of Washington; and the Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K., Ocular Epidemiology Reading Center at the University of Wisconsin – Madison, and the University of Michigan**
3. Государственным учреждениям, комиссиям по этике, контрольным органам по вопросам информации и безопасности и другим структурам, отвечающим за соблюдение безопасности, эффективности и организации научно-исследовательских работ.
4. Вашей медицинской страховой компании, если она оплачивает Ваше лечение или лечение Вашего ребенка в рамках проводящегося исследования.
5. Другим лечебным учреждениям, предоставляющим медицинские услуги Вам или Вашему ребенку.
6. Национальному институту здравоохранения и получателям его субсидий для целей администрирования исследований (например, отслеживания исследовательской деятельности в целом).
7. Другим организациям в соответствии с законом.

Правило неприкосновенности личной жизни является обязательным для врачей, больниц и других лечебных учреждений. Некоторые из вышеприведенных структур не обязаны соблюдать Правило неприкосновенности личной жизни и вправе передавать третьим лицам информацию медицинского характера о Вас или Вашем ребенке в соответствии с другими законами. При этом, однако, могут применяться и иные средства правовой защиты неприкосновенности личной жизни.

Научно-исследовательская документация

Вы имеете право читать или копировать сведения, которые разрешается использовать или разглашать. Однако во время проведения некоторых видов исследований некоторые из исследовательских документов могут быть недоступны Вам/Вашему ребенку. Это не относится к Вашему праву на ознакомление с Вашей медкартой или медкартой Вашего ребенка.

Исследователи вправе публиковать или представлять на конференциях результаты своих исследований. В публикуемых или представляемых результатах не указываются Ваши личные данные.

Федеральное Правило неприкосновенности личной жизни не распространяется на обезличенные сведения медицинского характера. Исследователи могут исключить из документации любую информацию, которая может помочь идентифицировать Вас или Вашего ребенка. В этом случае такая информация может использоваться и передаваться другим исследователям и заказчику проекта в установленном порядке. Это положение может распространяться и на использование ее в других исследованиях.

Согласие на участие в научных исследованиях

Если Вы не возражаете против Вашего личного участия или участия Вашего ребенка в данном научном исследовании, Вам предложат подписать **согласие на участие в исследовательском проекте** по установленной форме. В этом документе изложены необходимые сведения о данной исследовательской работе. В нем также описаны все риски и польза от указанного исследования. Разъясняется также цель исследования, предполагаемые результаты и дается другая важная информация для Вашего сведения.

Для того, чтобы принять участие в этом научном исследовании, Вам необходимо также подписать настоящее разрешение (на использование, создание и передачу третьим лицам сведений медицинского характера для научных целей). Если Вы не желаете подписывать настоящее согласие, то это не отразится на лечении и медицинском обслуживании, предоставляемом Вам или Вашему ребенку.

Каков срок действия данного разрешения? Что произойдет, если Вы передумаете?
Срок действия разрешения не истекает, но вы имеете право отменить его в любое время.

Если вы передумаете и пожелаете отменить свое разрешение, просим сообщить нам об этом письменно. Направьте письмо на имя руководителя темы (PT)/научного работника:

[Имя, фамилия и адрес PT] **Catherine Pihoker, MD, Seattle Children's, 4800 Sand Point Way NE/OC.7.820, Seattle, WA 98105-0371**
[Name and Address of PI].

Если Вы решили отменить разрешение, а Вы или Ваш ребенок являетесь пациентами клиники Children's, просим направить копию письма начальнику отдела медицинской информации и неприкосновенности личной жизни клиники Children's:

Director of Health Information and Privacy, Health Information Management, OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

Если Вы аннулировали свое разрешение, то сбор медицинских данных о Вас или Вашем ребенке для данного исследования прекращается. Однако информация, полученная в период действия Вашего разрешения, может использоваться или передаваться третьим лицам.

Например, исследователям, возможно, потребуется использовать или передать эту информацию по следующим причинам:

- в целях обеспечения безопасности;
- для проверки данных, полученных в ходе исследования;
- на основании закона.

Если Вы дадите согласие на Ваше участие или участие Вашего ребенка в данном научном исследовании, Вам будет выдан второй экземпляр настоящего разрешения с Вашей подписью.

Разрешение

Я даю согласие на использование, создание и передачу третьим лицам информации медицинского характера обо мне или о моем ребенке для целей данного научного исследования (название которого указано на стр. 1). Вниманию пациентов Children's: № вашей медицинской карточки будет написан на этом формуляре и использован для включения копии этого формуляра в вашу медицинскую карточку.

Печатными буквами имя и фамилия участника исследования Printed Name of Participant	Подпись участника исследования (если возраст участника 18 лет или старше) Signature of Participant (if 18 years or Older)
Дата Date	Время Time
Печатными буквами имя и фамилия родителя или законного представителя участника исследования Printed Name of Participant's Parent or Legal Representative	Подпись родителя или законного представителя участника исследования (если участник младше 18 лет) Signature of Research Participant's Parent or Legal Representative (if younger than18 years)
Дата Date	Время Time

Исследователь, получающий разрешение

Печатными буквами имя и фамилия члена исследовательского коллектива* Printed Name of Research Team Member*	Подпись члена исследовательского коллектива Signature of Research Team Member
Дата Date	Время Time

***УКАЗАНИЯ ДЛЯ ИССЛЕДОВАТЕЛЯ**
***INSTRUCTIONS TO RESEARCHER**

1. Внести подписанный оригинал данного формуляра в Исследовательское дело ☐
   File signed original of this form in Research File
2. Передать копию подписанного формуляра участнику исследования/его родителю ☐
   Provide copy of signed form to Research Participant/Parent

Для пациентов больницы Children's (For Children's Patients)

3. Заполнить или прикрепить ярлык пациента: ☐
   Complete or attach patient label:

   Номер медкарты участника: _____
   Participant's Medical Record #

   Дата рождения участника: _____/_____/_____
   Participant's Date of Birth

4. Отправить копию подписанного формуляра в отдел регистрации медицинской информации (Health Information Filing): Mailstop OC.6.820 ☐
   Send copy of the signed form to Health Information Filing: Mailstop OC.6.820

Ogolaansho U Helid Isticmaalka, Samaynta, Iyo La Qaybsiga Warka Caafimaadka ee Cilmi Baadhida
Cinwaanka Cilmi Baadhida: SEARCH for Diabetes in Youth
Tirsiga Daraasada IRB#: 12074

Dawlada sharcigeeda qarsoodiga ama khaaska ah ayaa ilaalineysa warka caafimaadkaaga/ka canugaaga. Sharcigan khaaska ah wuxuu ka mid yahay caymiska caafimaadka qaadasho karida Iyo masuul noqosho karida sharciga (HIPAA).

Hadii adiga/canugaaga ogolaataan inaad ka qayb qaadataan cilmi baadhistan barashada (kor ku magacaaban), cilmi baadhayaasha waxaa laga yaabaa iney isticmaalaan, sameeyaan ama la qaybsadaan warka caafimaadkaaga/ka canugaaga oo ka mid ah cilmi baadhistan. Cilmi baadhayaashu waxay samayn doonaan sidaas oo kale **keliya** hadii aad ogolaansho u siisid isticmaalka, samaynta ama la qaybsashada adiga/canugaaga warkiina caafimaad oo ka mid ah cilmi baashista. Foomkani wuxuu ku siinayaa war kaa caawinaaya inaad go'aan ka gaadhid hadii aad siin doontid ogolaanshahan oo kale. **Fadlan, u akhri foomkan si taxadir ah.** Kadib, marka aad aakhridid foomkan, waxaad karaysa in aad diidid in saxeexdid foomkan.

Maxaa "maclumaadka cafimaadka" ka mid ah? waxaa ka mid ah:

☒ Magac
Name
☒ Cinwaan
Address
☒ Tirsiga Badbaadada Bulshada
Social Security Number
☒ Taariikh Cafimaad iyo/ama dhalasho
Medical and/or birth history
☒ Maclumaadka guud ee geedi socodka isbadadalada qofka
Demographic information
☒ Natiijada baadhista Jidhka
Results of physical exams
☒ Natiijada Sheybaadhka iyo/ama baadhista raajada
Results of laboratory and/or radiology tests
☒ Wareysiga iyo/ama maclumaadka kooxda ahmiyada u leh
Interview and/or focus group data
☒ Daraasad iyo/ama maclumaadka suaalaha laga Jawaabayo
Survey and/or questionnaire data
☒ Natiijada imitixaanada hab dhaqanka
Results of behavioral tests
☒ Maclumaad la xidhiidha cafimaadkaaga
Information related to your health condition
☒ Maclumaad la xidhiidha xaaladaada xaaladaada cafimaad ee waafaqsan cilmibaadhistan
Information in your medical record relevant to this study
☐Waxyaabo kale (tilmaam gaar ah ka bixi)* _____
Other (please specify)*

*Haddii aad isticmaaleysid foom turjuuman oo ah HIPAA, waa in sido kale maclumaadkan turjumaada lagu sameeyo
* If using a translated HIPAA Form, this information must also be translated

Maxay cilmi baadhayaashu ku samayn karayaan maclumaadka caafimaadka

Cilmi baadhayaashu waxaa surtagal ah in ay soo saaraan maclumaad cusub oo la xidhiidha cafimaadkaaga adiga/ ilmahaaga inta lagu gudo jiro daraasada. Cilmi baadhayaashu waxaa isticmaali karaan maclumaadka dhinaca cafimaadka ee ku xusan diwaankaaga adiga /ilmahaaga.

Cilmi baadhayaashu waxaa sido kale laga yaaba in ay ku wadaagaan macluumaadka la xidhiidha cafimaadkaaga/ka ilmahaaga ee lasoo ururiyay inti lagu gudo jiray daraasada iyada oo loo marayo marxaladahan hoosta ku qeexan:

1. kafaalasho qaataha daraasaddan iyo wakiilkiisa. Magaca kafaalasho qaataha: **Centers for Disease Control/National Institute of Digestive & Kidney Diseases/JDRF**
2. Cilmi baadhayaasha xarumaha kale ee cilmi baadhistan ka qayb qaadanaya. Magaca /Magacyada xarumaha kale/Magaca xarumaha kale: **Cincinnati Children's Hospital Medical Center, University of Colorado, Pacific Health Research Institute (HI), University of North Carolina, University of South Carolina, Southern California Kaiser Permanente, Wake Forest University, Northwest Lipid Research Labs, University of Washington; and the Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K., Ocular Epidemiology Reading Center at the University of Wisconsin – Madison, and the University of Michigan**
3. Hayadaha dowlada, gudiyada dibu eegista anshaxa, gudiyada dabagalka diwaanada qoraalada iyo amniiga, iyo kuwo kale oo ka masuul ah ilaalinta amniga, wax tarida, iyo nidaamka cilmi baadhista.
4. Kambanigaaga caymiska ee caafimaadka hadii ay dhiibayaan xanaaneynta lagu siiyey ay qeyb ka tahay barashada cilmi baadhistu.
5. Caafimaad bixiyayaasha kale ee ku jira adiga/canugaaga xanaanadiina.
6. Xarumaha Cafimaadka Qaranka iyo deeq hayayaashiisa ku shaqada leh arrimaha cilmi baadhiista hawlaha maamulka (tusaale; lasocodka dhamaan hawlaha cilmi baadhiista)
7. Kuwo kale, oo sida uu sharcigu dhigayo ah.

Sharciga khaaska ah wuxuu khusaynayaa dhakhtarada, cisbitaalada iyo kuwo kale oo caafimaadka bixiya. Mida ururada kor ku xusan lagama rabo inay raacaan sharcigii khaaska ahaa iyo laga yaabee adiga/canugaaga iney idin la qabsadaan warar kuwo kale, Hadii sharciyo kale ogol yihiin. Si kasta, kuwo kale oo ilaalin khaas ah waa laga yaabaa iney weli khuseeyaan.

Diwaanada Cilmi baadhista

Waxaa surtagal ah in aad daawatid ama aad nuqulka ka sameeysatid maclumaadka la isticmaali doono ama la shaaciin doono, Haseyeeshe, cilmi baadhiisyo khaas ah oo cayiman, ayaa waxaa laga yaaba in aydaan qaar ka mid ah qoraalada cilmi baadhiste helin adigu iyo lmahaaguba inta ay socto cilmi baadhiistu Amuurtani wax uma dhimeyso xuquuqdaada gaarka ah adigu lmahaaguba aad ku eegi laheydeen diwaanadiina dhinaca cafimaadka (isbitaalka). Tani waxba uma dhimeyso xaqaaqa inaad aragtid waxa ku jira canugaaga diiwaanada caafimaadkiisa (isbitaalka).

Cilmi baadhayaashu waxa laga yaabaa iney daabacaan ama soo bandhigaan cilmi baadhida wixii laga helay. Adiga/canugaaga laydiin ma sheegayo ama laydin ma muujinaayo aqoonsigiina wixii la helay midnaba oo la daabacay ama la soo bandhigey.

Dowladii sharcigeeda qarsoodiga ama khaaska ahaa ee aan khusaynin warka caafimaadka si kastaba kaas oo muujineyn aqoonsasho. Cilmi baadhayaashu wax laga yaabaa iney go'aansadaan in war kasta laga saaro adiga ku muujinaayo aqoonsigaaga/canugaaga. Hadii ay sameeyaan sidan, warkaa waxaa laga yaabaa in loo

adeegsado iyo in lala wadaago cilmi baadhayaashu iyo kafaalo qaadida sida sharcigu ogolyahay. Tan waxaa laga yaabaa oo ku jira in loo isticmaalo dersid cilmi baadhisyo kale.

Ogolaanshaha Ka Qayb Qaadashada Cilmi Baadhista

Hadii aad ogolaatid inaad ka qayb qaadato ama u ogolaato canugaaga ka qayb galka cilmi baadhista, waxaa lagu weydiin doonaa inaad saxiixdid **foomka ogolaanshaha cilmi baadhista.** Cilmi baadhista wuxuu ku siinayaa faahfaahinta ku saabsan cilmi baadhista. Foomkii cilmi baadhistu wuxuu sharaxayaa khatarta iyo faa'iidada cilmi baadhista. Waxay kuu sharaxeysaa ula jeedada barashada, wixii dhici doona iyo warka muhiimka kuu ah inaad ogaatid.

Si aad ugu jirtid barashada cilmi baadhistan, waa inaad saxiixdid foomkan ogolaanshahan (Ogolaansho aad ku isticmaasho, ku samaysid iyo kula qaybsatid warka caafimaadka ee cilmi baadhista). Hadii aadan rabin inaad saxiixdid foomka ogolaanshaha, tani ma joojinayso xanaaneynta iyo daaweynta adiga ama cunugaaga aad helaysaan.

Muddo inte leeg ayaa uu ku eeg yahay ogolaanshahan? Maxaase dhacaya haddii aad goaankaaga badashid?
Ogolaanshahan waqtigiisa ma dhamaanayo,laakiin mar waliba waad iska joojin kartaa.

Haddii is bedeshid aadna rabto ogolaanshahan, fadlan inoogu soo sheeg Isagoo qoraal ah.
U soo qor warqada Principal Investigator (PI)/Researcher:

[Magaca iyo Cinwaanka Baadhaha sare] **Catherine Pihoker, MD, Seattle Children's, 4800 Sand Point Way NE/OC.7.820, Seattle, WA 98105-0371**
[Name and Address of PI].

Hadii aad joojisid ogolaanshahaagii hore/kii canugaaga aadna tihiin bukaan socodtada Xarunta Children's, fadlan usoo dir nuquulka warqadaada:

Director of Health Information and Privacy, Health Information Management, OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

Hadii aad joojisid ogolaanshaha, war ku saabsan caafimaadkaga/ka canugaaga looma ururin doono cilmi baadhistan. Si kastaba, warka caafimaadkan ee lagu helay ogolaanshahaaga waxaa laga yaabaa in la qeybsado ama la isticmaalo. Tusaale ahaan, cilmi baadhayaashu waxaa laga yaabaa iney u baahdaan iney isticmaalaan ama la qeybsadaan wararkan:

- Amaanka sababihiisa;
- Hubinta macluumaadka cilmi baadhista;
- Hadii sharcigu u baahan yahay.

Hadii aad ogolaato inaad ka qeyb qaadato ama u ogolaato canugaaga inuu ka qeyb qaato, waxaa lagu siin doonaa koobi foomka ogolaanshaha markaad sixiixdid ka dib.

Ogolaansho

Waan ogolahay inaan isticmaalo, abuurida, iyo la qaybsiga canugayga maclumaadka caafimaadka oo ah ula jeedada cilmi baadhista waxbarasho (lagu magacaabey boga 1). Carrurta bukaanka ah, diwaankaaga cafimaadka waxaa lagu diwaangalinaya foomkan kaas oo loo adeegsan doono in lagu dhigo nuquulka foomkan diwaankaaga cafimaadka.

Magaca Kaqeybgalaha Cilmi baadhista oo Daabacan Printed Name of Participant	Saxeexa kaqeybgalaha Cilmi baadhisla (haddii 18 Jir u yahay ama ka weyn yahay) Signature of Participant (if 18 years or Older)
Taariikhda Date	Wakhtiga Time
Magaca Waalidka ama Wakiilka Cilmi baadhista oo Daabacan Sharciyeesan ee Kaqeybgalaha Printed Name of Participant's Parent or Legal Representative	Saxeexa waalidka ama wakiilka (haddii uu ka yar yahay 18 Jirka) Cilmi baadhista Sharciyeesan ee Kaqeybgalaha Signature of Research Participant's Parent or Legal Representative (if younger than18 years)
Taariikhda Date	Wakhtiga Time

Ogolaanshaha helida Cilmi baadhaha

Magaca Xubinka Kooxda Cilmi baadhista oo Daabacan Printed Name of Research Team Member*	Cilmi baadhista Saxeexa Xubinka Kooxda Signature of Research Team Member
Taariikhda Date	Wakhtiga Time

***TILMAAMAHA LOOGU TALO GALAY CILMI BAADHAHA**
***INSTRUCTIONS TO RESEARCHER**

1. **Sii nuqulka foomkan oo saxeexan Waalidka/Kaqeybgadaha cilmi baadhista** ☐
   File signed original of this form in Research File
2. **Ku xaree nuqulka asalka ee foomkan oo saxeexan fagyilka cilmi baadhista** ☐
   Provide copy of signed form to Research Participant/Parent

Carrurta Bukaanka Ah (For Children's Patients)

3. **Dhameystir ama ku lifaaq heerka bukaanka:** ☐
   Complete or attach patient label:

   Diwaanka Cafimaadka Kaqeybgalaha # _____
   Participant's Medical Record #

   Taariikhda Dhalashada Kaqeybgalaha _____/_____/_____
   Participant's Date of Birth

4. **Dir nuqulka foomkan oo saxeexan Faayilka Maclumaadka Cafimaadka: Mailstop OC.6.820** ☐
   Send copy of the signed form to Health Information Filing: Mailstop OC.6.820

同意在研究專案中使用、建立和共享健康資料

專題研究題目：SEARCH for Diabetes in Youth

IRB 研究號碼： 12074

聯邦「隱私條例」保護您本人/您的子女的健康資料。「隱私條例」是「健康保險便利及責任法案」（HIPAA）的一部份。

如果您本人/您的子女同意參加此項專題研究（上述名稱），研究人員可將您本人/您的子女的健康資料作為研究的一部份而使用、建立或共享。研究人員**僅**在您同意將您本人/您的子女的健康資料作為研究的一部份使用、建立或共享時才會這樣做。本表格提供必要的資訊以幫助您決定是否給予此種同意。**請仔細閱讀本表格。**讀完後您可以拒絕在本表格簽名。

「健康資料」包括什麼？「健康資料」包括：

☒ 姓名 Name
☒ 地址 Address
☒ 社會安全號碼 Social Security Number
☒ 醫療及/或出生史 Medical and/or birth history
☒ 統計資訊 Demographic information

☒ 體檢結果 Results of physical exams
☒ 化驗及/或放射線測試結果 Results of laboratory and/or radiology tests

☒ 面談及/或專題小組資料 Interview and/or focus group data
☒ 調查問卷資料 Survey and/or questionnaire data

☒ 行為測試結果 Results of behavioral tests
☒ 與您的健康狀況相關的資訊 Information related to your health condition

☒ 您的醫療記錄中與本項研究相關的資訊 Information in your medical record relevant to this study
☐ 其他（請說明）*_____ Other (please specify)*

* 如果使用翻譯的 HIPAA 表格，此處的資訊也必須翻譯。
* If using a translated HIPAA Form, this information must also be translated

研究人員如何使用健康資料

研究人員在研究中可以建立有關您本人/您的子女新的健康資料。研究人員可以使用您本人/您的子女醫療記錄中的健康資料。

研究人員也可能需要與下列各方共享在研究中收集的有關您本人/您的子女的健康資料：

1. 此項研究的贊助方及其代表。贊助方名稱： **Centers for Disease Control/National Institute of Digestive & Kidney Diseases/JDRF**
2. 參加此項專題研究的其他中心的研究人員。

   其他中心名稱：**Cincinnati Children's Hospital Medical Center, University of Colorado, Pacific Health Research Institute (HI), University of North Carolina, University of South Carolina, Southern California Kaiser Permanente, Wake Forest University, Northwest Lipid Research Labs, University of Washington; and the Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K., Ocular Epidemiology Reading Center at the University of Wisconsin – Madison, and the University of Michigan**
3. 政府機構、倫理審查委員會、資料及安全監督委員會，以及其他負責監督研究之安全性、有效性及行為的部門。
4. 您的醫療保險公司——如果他們支付專題研究中部份醫療的費用。
5. 其他參與您本人/您的子女保健的醫療提供者。
6. 美國衛生院及其撥款持有人從事研究管理活動（例如，追蹤總體研究活動）。
7. 法律規定的其他方。

「隱私條例」適用於醫生、醫院和其他醫療提供者。在上述團體中，有一些未被要求遵守《隱私條例》，而且若有其他法律允許，可與其他人共享您本人/您的子女的資料。但其他隱私保護規定仍可適用。

研究記錄

您可以查閱或複印可能使用或披露的信息。但是，對於某些類型的研究，您/您的子女可能無法在研究進行時獲得研究記錄。但這不會影響您查看您/您的子女的醫療（醫院）記錄的權利。

研究人員可以發表或展示研究結果。在任何發表或展示的研究結果中都不會辨識您本人/您的子女的身份。

聯邦「隱私條例」不適用於無法以任何方式辨識身份的健康資料。研究人員可決定去除任何可能辨識出您本人/您的子女身份的資訊。在這種情況下，研究人員和贊助方可依法使用和共享資料，包括用於其他專題研究。

參加研究的同意書

如果您同意參加或允許子女參加研究，您會被要求簽署一份**研究同意書**。這份**研究同意書**提供有關此研究的詳細情況，描述研究的風險和利益，說明這項研究的目的、將發生什麼以及其他您需要知道的重要資訊。

要參加這項專題研究，您還必須在這份同意書上簽字（「同意在研究專案中使用」、「建立和共享健康資料」）。如果您不想簽署這份同意書，並不會影響您本人/您的子女接受的護理和治療。

這份同意書的時效有多久？您如果改變主意該怎麼辦？

本同意書不會失效，但是您可以在任何時候取消。

如果您改變主意，想撤消您的同意書，請書面通知我們。請致函首席研究員(PI)/研究人員：

[首席研究員的姓名及地址] **Catherine Pihoker, MD, Seattle Children's, 4800 Sand Point Way NE/OC.7.820, Seattle, WA 98105-0371**
[Name and Address of PI]

如果您撤消同意書，而且您本人/您的子女是 Children's 醫院的患者，請將一份信函的副本寄至：

Director of Health Information and Privacy, Health Information Management, OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

如果您撤消同意書，我們將不再為此項研究收集有關您本人/您的子女的健康資料，但仍可共享或使用以前在您同意下收到的健康資料。例如，研究人員可能因以下原因需要使用或共享這些資料：

- 安全原因；
- 證實研究資料；
- 遵照法律要求。

如果您同意參加或允許子女參加，您會在簽署同意書後收到一份同意書副本。

同意書

我同意為此項專題研究（姓名列於第一頁）之目的而使用、建立及共享我或子女的健康資料。對於子女的父母，您的醫療記錄號碼將在本表中記錄，並被用於將本表的一份副本存入您的醫療記錄。

_____	_____
參加研究者姓名（正楷）	參加研究者簽名（如果年滿 18 歲或以上）

Printed Name of Participant

Signature of Participant (if 18 years or Older)

日期
Date

時間
Time

參加研究者的父母或法定代表姓名（正楷）
Printed Name of Participant's Parent or Legal Representative

參加研究者的父母或法定代表簽名（如果參加研究者的年齡未滿 18 歲）
Signature of Research Participant's Parent or Legal Representative (if younger than18 years)

日期
Date

時間
Time

徵求授權的研究人員

研究團隊成員姓名（正楷）*
Printed Name of Research Team Member*

研究團隊成員簽名
Signature of Research Team Member

日期
Date

時間
Time

*** 供研究人員使用的說明**

***INSTRUCTIONS TO RESEARCHER**

1. **將本表的簽名原件在研究文件中存檔** ☐
   File signed original of this form in Research File

2. **將簽名表格的副本交給參加研究者/父母** ☐
   Provide copy of signed form to Research Participant/Parent

供 Children's 病人使用 (For Children's Patients)

3. **填寫或隨附病人標籤：**
   Complete or attach patient label: ☐

   參加者的醫療記錄號碼 _____
   Participant's Medical Record #
   參加者的出生日期 _____/_____/_____
   Participant's Date of Birth

4. **將簽名表格的副本送交至健康資訊檔案部：Mailstop OC.6.820** ☐
   Send copy of the signed form to Health Information Filing: Mailstop OC.6.820

Giaáy Cho Pheùp Söû Duïng, Taïo Laäp, Vaø Chia Seû Thoâng Tin Y Teá Cho Muïc Ñích Nghieân Cöùu

Ñeà Taøi Nghieân Cöùu: SEARCH for Diabetes in Youth

Soá Nghieân Cöùu IRB: 12074

Quy Ñònh veà Quyeàn Rieâng Tö cuûa Chính Quyeàn Lieân Bang baûo veä caùc thoâng tin y teá cuûa quyù vò/con quyù vò. Quy Ñònh veà Quyeàn Rieâng Tö naèm trong Ñaïo Luaät veà Traùch Nhieäm vaø Quyeàn Chuyeån Ñoåi Chöông Trình Baûo Hieåm Söùc Khoûe (tieáng Anh goïi taét laø HIPAA).

Neáu quyù vò/con quyù vò ñoàng yù tham gia vaøo cuoäc nghieân cöùu naøy (xem teân ñeà taøi ñöôïc ghi treân ñaây), nhöõng ngöôøi nghieân cöùu coù theå söû duïng, taïo laäp, hay chia seû caùc thoâng tin y teá cuûa quyù vò/con quyù vò trong quaù trình nghieân cöùu. Nhöõng ngöôøi nghieân cöùu **chæ** ñöôïc pheùp laøm nhöõng ñieàu naøy neáu quyù vò cho pheùp hoï söû duïng, taïo laäp, hay chia seû caùc thoâng tin y teá cuûa quyù vò/con quyù vò trong quaù trình nghieân cöùu. Maãu ñôn naøy cung caáp thoâng tin ñeå giuùp quyù vò suy nghó xem coù neân kyù vaøo giaáy pheùp naøy hay khoâng. **Xin ñoïc kyõ maãu naøy.** Sau khi ñoïc xong, quyù vò coù theå töø choái kyù maãu naøy.

Töø "thoâng tin y teá" bao haøm nhöõng gì? Töø naøy bao haøm:

☒ Teân Hoï (Name) ☒ Ñòa Chæ (Address) ☒ Soá An Sinh Xaõ Hoäi (Social Security Number)

☒ Beänh söû vaø/hoaëc quaù trình sinh haï (Medical and/or birth history)

☒ Thoâng tin nhaân khaåu hoïc (Demographic information) ☒ Keát quaû cuûa caùc cuoäc khaùm söùc khoûe toång quaùt (Results of physical exams)

☒ Keát quaû xeùt nghieäm trong phoøng thí nghieäm va/hoaëc quang tuyeán (Results of laboratory and/or radiology tests)

☒ Döõ lieäu töø caùc cuoäc phoûng vaán vaø/hoaëc nhoùm taäp trung (Interview and/or focus group data)

☒ Döõ lieäu töø caùc cuoäc khaûo saùt vaø/hoaëc baûng hoûi (Survey and/or questionnaire data) ☒ Keát quaû xeùt nghieäm veà haønh vi (Results of behavioral tests)

☒ Thoâng tin lieân quan ñeán tình traïng söùc khoûe cuûa quyù vò (Information related to your health condition)

☒ Thoâng tin trong hoà sô y teá coù lieân quan ñeán cuoäc nghieân cöùu naøy (Information in your medical record relevant to this study)

☐ Khaùc (cho bieát cuï theå) * _____ (Other (please specify)*)

* Neáu söû duïng maãu HIPAA ñöôïc dòch saün, thoâng tin naøy cuõng phaûi ñöôïc chuyeån ngöõ
* If using a translated HIPAA Form, this information must also be translated

Nhöõng ngöôøi nghieân cöùu coù theå söû duïng thoâng tin y teá nhö theá naøo?

Nhöõng ngöôøi nghieân cöùu coù theå taïo laäp thoâng tin y teá môùi veà quyù vò/con quyù vò trong quaù trình nghieân cöùu. Hoï cuõng coù theå söû duïng caùc thoâng tin y teá saün coù trong hoà sô y teá cuûa quyù vò/con quyù vò.

Nhöõng ngöôøi nghieân cöùu cuõng coù theå caàn chia seû thoâng tin y teá veà quyù vò/con quyù vò ñöôïc thu thaäp trong quaù trình nghieân cöùu vôùi nhöõng ngöôøi/toå chöùc sau ñaây:

1. Nhaø taøi trôï cuoäc nghieân cöùu naøy vaø caùc ñaïi dieän. Teân cuûa Nhaø Taøi Trôï laø: **Centers for Disease Control/National Institute of Digestive & Kidney Diseases/JDRF**
2. Nhöõng ngöôøi nghieân cöùu taïi nhöõng trung taâm khaùc cuõng tham gia vaøo cuoäc nghieân cöùu naøy.
   Teân cuûa caùc trung taâm khaùc laø: **Cincinnati Children's Hospital Medical Center, University of Colorado, Pacific Health Research Institute (HI), University of North Carolina, University of South Carolina, Southern California Kaiser Permanente, Wake Forest University, Northwest Lipid Research Labs, University of Washington; and the Molecular Genetics Laboratory, Royal Devon and Exeter NHS Healthcare Trust, Exeter, U.K., Ocular Epidemiology Reading Center at the University of Wisconsin – Madison, and the University of Michigan**
3. Caùc cô quan nhaø nöôùc, uûy ban xem xeùt veà tính hôïp ñaïo ñöùc, hoäi ñoøng quan saùt söï an toaøn vaø döõ lieäu, vaø caùc toå chöùc khaùc coù traùch nhieäm theo doõi söï an toaøn, hieäu quaû vaø quaù trình thöïc hieän caùc cuoäc nghieân cöùu.
4. Coâng ty baûo hieåm söùc khoûe cuûa quyù vò, neáu coâng ty bao traû cho caùc dòch vuï chaêm soùc ñöôïc cung caáp trong cuoäc nghieân cöùu naøy.
5. Caùc nhaø cung caáp dòch vuï y teá khaùc lieân heä ñeán vieäc chaêm soùc söùc khoûe cho quyù vò/con quyù vò.
6. Vieän Y Teá Quoác Gia vaø caùc toå chöùc ñöôïc caáp quyõ cho caùc hoaït ñoäng quaûn lyù nghieân cöùu (ví duï, theo doõi toång quaùt caùc hoaït ñoäng nghieân cöùu).
7. Nhöõng ngöôøi/toå chöùc khaùc ñöôïc quy ñònh bôûi luaät phaùp.

Quy Ñònh veà Quyeàn Rieâng Tö ñöôïc aùp duïng cho caùc baùc só, beänh vieän, vaø caùc nhaø cung caáp dòch vuï y teá khaùc. Moät soá trong nhöõng nhoùm keå treân khoâng baét buoäc phaûi theo Quy Ñònh veà Quyeàn Rieâng Tö, do ñoù hoï coù theå chia seû thoâng tin veà quyù vò/con quyù vò vôùi ngöôøi khaùc neáu luaät phaùp cho pheùp. Tuy nhieân, caùc quy ñònh khaùc veà vieäc baûo veä quyeàn rieâng tö vaãn coù theå ñöôïc aùp duïng.

Hoà Sô Nghieân Cöùu

Quyù vò coù quyeàn xem vaø chuïp baûn sao caùc thoâng tin coù theå ñöôïc söû duïng hay tieát loä. Tuy nhieân, trong moät soá loaïi nghieân cöùu, coù theå quyù vò/con quyù vò seõ khoâng ñöôïc pheùp xem vaøi hoà sô nghieân cöùu trong khi cuoäc nghieân cöùu ñang ñöôïc tieán haønh. Ñieàu naøy khoâng aûnh höôûng ñeán quyeàn cuûa quyù vò ñeå xem hoà sô y teá (hoà sô beänh vieän) cuûa quyù vò/con quyù vò.

Nhöõng ngöôøi nghieân cöùu coù theå xuaát baûn hay trình baøy caùc keát quaû nghieân cöùu. Danh taùnh cuûa quyù vò/con quyù vò seõ khoâng ñöôïc tieát loä khi xuaát baûn hay trình baøy nhöõng keát quaû naøy.

Quy Ñònh veà Quyeàn Rieâng Tö cuûa Lieân Bang khoâng aùp duïng cho caùc thoâng tin y teá naøo ñöôïc xoùa boû taát caû caùc chi tieát coù theå söï duïng ñeå nhaän bieát danh taùnh cuûa beänh nhaân. Nhöõng ngöôøi nghieân cöùu coù theå quyeát ñònh xoùa boû taát caû caùc chi tieát nhaän dieän quyù vò/con quyù

vò. Baèng caùch naøy, ngöôøi nghieân cöùu vaø nhaø taøi trôï coù theå töï do söû duïng vaø chia seû thoâng tin naøy trong phaïm vi luaät phaùp cho pheùp, keå caû söû duïng thoâng tin trong caùc cuoäc nghieân cöùu khaùc.

Thuû Tuïc Cho Pheùp Tham Gia Nghieân Cöùu

Neáu quyù vò ñoàng yù tham gia hay cho pheùp con mình tham gia vaøo cuoäc nghieân cöùu naøy, quyù vò seõ ñöôïc yeâu caàu kyù teân vaøo **maãu öng thuaän tham gia nghieân cöùu.** Maãu öng thuaän tham gia nghieân cöùu cho bieát thoâng tin chi tieát vaø giaûi thích caùc nguy cô vaø lôïi ích cuûa cuoäc nghieân cöùu. Maãu naøy cuõng giaûi thích veà muïc ñích nghieân cöùu, nhöõng gì seõ xaûy ra trong khi tham gia, vaø caùc thoâng tin quan troïng khaùc quyù vò caàn bieát.

Muoán tham gia vaøo cuoäc nghieân cöùu, quyù vò cuõng phaûi kyù teân vaøo giaáy cho pheùp naøy (Giaáy Cho Pheùp Söû Duïng, Taïo Laäp, Vaø Chia Seû Caùc Thoâng Tin Y Teá Cho Muïc Ñích Nghieân Cöùu). Neáu quyù vò khoâng muoán kyù giaáy pheùp naøy, caùc dòch vuï chaêm soùc vaø ñieàu trò ñöôïc caáp cho quyù vò hay con cuûa quyù vò seõ khoâng bò aûnh höôûng.

Giaáy Cho Pheùp Naøy Seõ Coù Hieäu Löïc Trong Bao Laâu? Neáu Quyù Vò Ñoåi YÙ Thì Sao?

Giaáy cho pheùp naøy seõ khoâng bao giôø heát hieäu löïc, nhöng quyù vò coù theå huûy boû noù vaøo baát cöù luùc naøo.

Neáu quyù vò ñoåi yù vaø muoán huûy boû giaáy cho pheùp naøy, xin vieát thö baùo cho chuùng toâi bieát. Vieát thö cho Ngöôøi Nghieân Cöùu Chính (tieáng Anh vieát taét laø PI):

[Teân vaø Ñòa Chæ cuûa PI] **Catherine Pihoker, MD, Seattle Children's, 4800 Sand Point Way NE/OC.7.820, Seattle, WA 98105-0371**
[Name and Address of PI].

Neáu quyù vò huûy boû giaáy cho pheùp naøy vaø quyù vò/con quyù vò laø beänh nhaân taïi Beänh Vieän Nhi Ñoàng xin gôûi moät baûn sao cuûa thö baùo huûy boû ñeán:

Director of Health Information and Privacy, Health Information Management, OC.6.820, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

Neáu quyù vò huûy boû giaáy cho pheùp naøy, chuùng toâi seõ khoâng thu thaäp theâm thoâng tin y teá veà quyù vò/con quyù vò nöõa ñeå söû duïng trong cuoäc nghieân cöùu. Tuy nhieân, caùc thoâng tin y teá ñaõ thu thaäp ñöôïc trong khi quyù vò coøn cho pheùp thì vaãn coù theå ñöôïc chia seû hay söû duïng. Thí duï, nhöõng ngöôøi nghieân cöùu coù theå caàn söû duïng hay chia seû thoâng tin:

- vì lyù do an toaøn;
- ñeå kieåm laïi caùc döõ lieäu trong cuoäc nghieân cöùu;
- theo quy ñònh cuûa luaät phaùp.

Neáu quyù vò ñoàng yù tham gia hay cho con quyù vò tham gia, quyù vò seõ ñöôïc giao moät baûn sao cuûa giaáy cho pheùp naøy sau khi kyù xong.

Lôøi Cho Pheùp

Toâi ñoàng yù cho pheùp söû duïng, taïo laäp, vaø chia seû caùc thoâng tin y teá cuûa toâi/con toâi cho muïc ñích thöïc hieän cuoäc nghieân cöùu naøy (xem teân ñeà taøi ôû trang 1). Ñoái vôùi beänh nhaân cuûa Beänh Vieän Nhi Ñoàng, soá hoà sô y teá seõ ñöôïc ghi treân maãu naøy ñeå coù theå ñöa baûn sao cuûa maãu naøy vaøo hoà sô y teá cuûa beänh nhaân.

Teân Hoï (In Hoa) cuûa Ngöôøi Tham Gia Nghieân Cöùu Printed Name of Participant	Chöõ Kyù cuûa Ngöôøi Tham Gia Nghieân Cöùu (neáu ngöôøi tham gia töø 18 tuoåi trôû leân) Signature of Participant (if 18 years or Older)
Ngaøy Date	Giôø Time
Teân Hoï (In Hoa) cuûa Phuï Huynh hay Ñaïi Dieän Hôïp Phaùp cuûa Ngöôøi Tham Gia Nghieân Cöùu Printed Name of Participant's Parent or Legal Representative	Chöõ Kyù cuûa Phuï Huynh hay Ñaïi Dieän Hôïp Phaùp cuûa Ngöôøi Tham Gia Nghieân Cöùu (neáu ngöôøi tham gia döôùi 18 tuoåi) Signature of Research Participant's Parent or Legal Representative (if younger than18 years)
Ngaøy Date	Giôø Time

Ngöôøi Nghieân Cöùu Laøm Thuû Tuïc Xin Pheùp

Teân Hoï (In Hoa) cuûa Thaønh Vieân Nhoùm Nghieân Cöùu* Printed Name of Research Team Member*	Chöõ Kyù cuûa Thaønh Vieân Nhoùm Nghieân Cöùu Signature of Research Team Member
Ngaøy Date	Giôø Time

***PHAÀN HÖÔÙNG DAÃN DAØNH CHO NGÖÔØI NGHIEÂN CÖÙU**
***INSTRUCTIONS TO RESEARCHER**

1. Löu baûn goác coù chöõ kyù cuûa giaáy naøy vaøo Hoà Sô Nghieân Cöùu

☐ File signed original of this form in Research File

2. Ñöa baûn sao cuûa giaáy coù chöõ kyù cho Ngöôøi Tham Gia Nghieân Cöùu/Phuï Huynh

☐ Provide copy of signed form to Research Participant/Parent

Daønh Cho Beänh Nhaân Taïi Beänh Vieän Nhi Ñoàng (For Children's Patients)

3. Ñieàn vaøo hay daùn nhaõn ghi thoâng tin cuûa beänh nhaân:

☐ Complete or attach patient label:

Soá Hoà Sô Y Teá cuûa Ngöôøi Tham Gia Nghieân Cöùu _____
Participant's Medical Record #

Ngaøy Sinh cuûa Ngöôøi Tham Gia Nghieân Cöùu _____/_____/_____
Participant's Date of Birth

4. Göûi baûn sao cuûa giaáy coù chöõ kyù ñeán Phoøng Löu Tröõ Hoà Sô Y Teá: Mailstop OC.6.820

☐ **Send copy of the signed form to Health Information Filing: Mailstop OC.6.820**

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Institutional Review Board
Kaiser Permanente Southern California

Reapproval Notice

September 24, 2013

KPSC Principal Investigator
Jean Lawrence, ScD MPH, MSSA
Research & Evaluation, Los Robles/2

KPSC Co-Investigator(s)
Kristi Reynolds, PhD

Non KPSC Co-Investigator(s)
David Pettitt, Sansum Medical Research Institute

Study Title: SEARCH for Diabetes in Youth, Phase 3: California Center (#5836)

Study Expiration Date: 08/25/2014

On **September 17, 2013**, the convened Kaiser Permanente Southern California (KPSC) Institutional Review Board (IRB) reviewed your continuing review report, including a summary of protocol deviation for the report period of 10/16/2012 to 09/25/2013 and reapproved the above referenced study from **09/17/2013 to 08/25/2014**. The research continues to satisfy the requirements of DHHS 45 CFR 46.404, research/clinical investigation not involving greater than minimal risk. The KPSC IRB determined that the permission, including signed informed consent, of one parent is required.

In addition, the KPSC IRB re-approved the written informed consent form(s) and written Privacy Rule Authorization section from **09/17/2013 to 08/25/2014**. You will receive the informed consent document(s) via email.

In accordance with DHHS 45 CFR 46.408, the KPSC IRB has determined that assent of children age 7 and older is a necessary condition for proceeding with this research/clinical investigation. In all cases, regardless of whether the KPSC IRB requires assent, the KPSC IRB expects that investigators will provide children with developmentally appropriate information about their diagnosis, treatment and proposed research participation. In particular investigators should explain the purpose as well as the incremental procedures, risks and benefits of the clinical trial, and offer an opportunity for children to ask questions.

If you have any further questions, please contact Vonee So, IRB staff at (626) 405-5996 (or tie line 8/335-5996)

Sincerely,

Armida Ayala, MHA, PhD
Director, KPSC Human Research Subjects Protection
Office/Institutional Review Board (IRB)

Cc
Sharon Figgins
Area Research Chairperson

Academic Affairs
Pharmacy Services Director