Assent to Participate in a Research Study Minor Subjects (7-14 yrs)
SEARCH 4 Registry Study – In-Person Visit

INSTITUTION IRB Study #

Consent Form Version Date:

Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit (Population-based Diabetes Youth Registry)

SEARCH Site Principal Investigators:

Funding Source and/or Sponsor: National Center for Chronic Disease Prevention and Health Promotion (GRANT #1U18DP006031-01)

Study Contact telephone number: [Center-specific]

Study Contact email: [Center-specific]

Names, degrees, and affiliations of the researchers conducting the study:

[Center-specific]

The people named above are doing a research study.

These are some things we want you to know about research studies:
Your parent needs to say it is okay for you to be in this study. You do not have to be in this study if you don't want to, even if your parent says it is okay for you to be in the study.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

Sometimes good things happen to people who take part in studies, and sometimes things we may not like happen. We will tell you more about these things below.

Why are they doing this research study?
The reason for doing this study is to find out how many young people have diabetes in your area.
We want to learn more about the types of diabetes young people have. We want to learn more about your health, and how diabetes affects you and your family.

Why are you being asked to be in this research study?
You are being asked to be in this study because you have diabetes and you found out you had diabetes when you were a child.

How many people will take part in this study?
A total of about 832 people at five sites across the US will take part in the Registry Study visit, including about XXX people from the (Site Specific) SEARCH site.

What will happen during this study?
During this study we will ask to:

- Measure you and check your blood pressure. This will be a lot like when they measure you at your doctor's office.
- Take some blood from your arm with a needle and do some special tests that tell us about your diabetes.
- Take some blood from your arm with a needle and 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.
- Test some of your urine to see if diabetes is changing the way your kidneys work.
- This study visit will last about 60 minutes.

Who will be told the things we learn about you in this study?
SEARCH staff will keep the things we learn private, but we must report to the state if we feel you are being hurt or if you tell us you are planning to hurt yourself or others. If you tell us you are planning to hurt yourself or others, we will also tell your parents.

When you start in SEARCH, a special number is given to you. The number is used to mark all the forms and blood tests we do with you. The special number and the forms will be sent to Wake Forest University. Blood and urine will be sent to the University of Washington to test or store. The list showing the special number given to you will be kept in a file and saved with a password.

What are the good things that might happen?
People may have good things happen to them because they are in research studies. These are called "benefits." You will not benefit from being in this research study.

What are the bad things that might happen?
Sometimes things happen to people in research studies that may make them feel bad. These are
called "risks." These are the risks of this study:

- It may hurt when you have your blood drawn and you may get a bruise. We can put some medicine on your skin to make it hurt less.
- You need to come to the visit without eating anything the night before your visit. This may affect your blood sugar. We will test your blood sugar and you may take your diabetes medicine or eat a snack to help your blood sugar.

Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. You should report any problems to the researcher

What if your parents don't want you to be in this study?

It is okay if you or your parents don't want to be in this study. This will not affect the care you get.

Will you get any money or gifts for being in this research study?

You will be paid $80 for completing the study visit.

You may also be paid $5 for providing updated contact information in the future.

Will it cost you anything for your child to be in this study?

There will be no costs for being in the study

Who should you ask if you have any questions?

If you have questions you should ask the people listed on the first page of this form. You can contact [Center-specific] anytime.

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Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit (IPV) (Population-based Diabetes Youth Registry)

Principal Investigators: [Center-specific]

If you sign your name below, it means that you agree to take part in this research study.

_____ _____
Sign your name here if you want to be in the study *Date*

_____
Print your name here if you want to be in the study

_____ _____
Signature of Research Team Member Obtaining Assent *Date*

_____
Printed Name of Research Team Member Obtaining Assent

KAISER FOUNDATION HOSPITALS PATIENT'S NAME_____

SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP M.R. #_____

INFORMED CONSENT TO PARTICIPATE IN RESEARCH STUDY OF DIABETES INCIDENCE, COMPLICATIONS, AND QUALITY OF CARE SEARCH FOR DIABETES IN YOUTH (SEARCH), REGISTRY STUDY

Consent for Registry Visit
For Persons with Diabetes 18 years of age or older

SPONSOR: **Centers for Disease Control and Prevention**

INVESTIGATOR: **Jean M. Lawrence, ScD, MPH, MSSA**
Kaiser Permanente Southern California Department of Research & Evaluation
100 S. Los Robles Ave., 4th Floor
Pasadena CA 91101

TELEPHONE: **(626) 564-3106**

You are being invited to be in a research study. Taking part in this study is voluntary.

This informed consent form tells you about the purpose, risks, and benefits of this research study. You may ask questions and take time to think about the study before you decide to join it. You should decide if you want to participate in the study only when you have received all the information you need.

Your doctor or health care provider may be working on this research study. He or she is interested in your healthcare as well as the conduct of this study. If that makes you feel the doctor can't be objective about the best care for you, you may ask for another doctor or staff member who is not involved in this research.

Kaiser Permanente is being reimbursed by the study sponsor, Centers for Disease Control and Prevention, to conduct this study.

PURPOSE AND BACKGROUND

The purpose of this research study being conducted by Kaiser Permanente, and in four other locations in the United States, is to improve our understanding of the incidence, natural history, complications, and quality of care for children, adolescents, and young adults with diabetes. You were asked to take part in the SEARCH study because you have diabetes. Dr. Jean Lawrence is the lead investigator for this study for Kaiser Permanente. This study is sponsored by the Centers for Disease Control.

Diabetes is the third most common life-long disease in people under 20 years of age. The total number of persons with diabetes in this age group is increasing. Also, types of diabetes that have not been seen in young people are now being seen. These changes have resulted in gaps in knowledge about the total number of persons and types of diabetes in the United States, the type of care young people with diabetes receive, and the effect diabetes has on their lives. This research study will collect information to answer these questions.

This study will include over 7,000 children and youth with diabetes who were members of Kaiser Permanente Southern California when they were diagnosed with diabetes. A member of the SEARCH research team has discussed the requirements for participating in this study with you. Before agreeing to participate in this research study, it is important that you understand this form or have a member of the study staff read it to you.

Before agreeing to participate in this research study, it is important that you read and understand this form or have a member of the study staff read it to you.

If you have personal, religious, cultural, or ethical beliefs that you think might limit the types of tests you would agree to receive, please discuss them fully with your physicians or appropriate members of the research team before entering this study.

This consent form may contain some words that are not familiar to you. Please discuss any questions you have about this study with the research staff members before you sign this form.

STUDY PROCEDURES

The SEARCH Registry visit includes a brief physical examination, collecting a blood and urine sample, and completing one or more questionnaires. You can agree to participate in all or only some parts of the study.

A research team member has set up an appointment for you. The appointment will be in the morning or early afternoon. You will come to the appointment after not having anything to eat or drink other than water for 10 hours. You will not take your usual diabetes medications until after your blood has been drawn. The study visits will take approximately 1-2hours.

Before your scheduled appointment, you will be mailed a container with detailed instructions to collect the first morning urine the day of your study visit. You will be asked to bring this urine container with you to your visit. We may ask you to repeat the urine collection for research purposes; we will not know if this additional urine sample will be needed until the sample is reviewed by the laboratory.

PHYSICAL EXAMINATION

The physical examination includes measurements of height, weight, waist, blood pressure, and examination of the skin on the neck. The time to complete this part of the visit is approximately 30 minutes.

COLLECTION OF BLOOD AND URINE SAMPLES

Blood will be taken to measure blood sugar, hemoglobin Alc (a measure of long-term blood sugar control), C-peptide (a measure of internal insulin production), different types of cholesterol (fat), and diabetes autoantibodies (markers in the blood for type 1 diabetes). Two genetic markers for diabetes (HLA and ZNT8) will also be tested. The total amount of blood drawn for these tests are based on your weight but will not exceed 3 tablespoons.

A first morning urine sample will be requested and tested to see if diabetes is affecting your kidneys. After these tests are done, you will be given a snack. You may also bring your own snack to the Registry visit. After your snack, you will take your usual diabetes medicine and have your medicines recorded by trained staff.

SAVING / STORAGE OF BLOOD AND URINE

If you agree, your blood and urine will be saved for the duration of the study at the University of Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to learn more about the types of diabetes and when someone has or is at risk to get the complications of diabetes. If the results of the tests affect your health, you will be informed of the test results.

☐ I agree to have my blood and urine saved and used in the future for new tests as they are developed to learn more about the types of diabetes and the risk of developing complications of diabetes.
_____ Initials

☐ I do not agree to have my blood and urine saved and used in the future for new tests as they are developed to learn more about the types of diabetes and the risk of developing complications of diabetes.
_____ Initials

SAVING / STORAGE OF DNA

DNA is found in all cells. DNA makes up genes. Genes determine height, hair color, and all other body traits. The DNA in each person's body is different from every other person's DNA (except identical twins or triplets who have the same DNA). The differences may be why some people are more likely to get certain diseases like diabetes.

If you agree, DNA will be saved at the University of Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to tell your type of diabetes and the risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and being overweight. The total amount of blood required is approximately 1¾ teaspoons (8.5 cc).

☐ I agree to have my DNA stored for the duration of the study at the University of

Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to define the type of diabetes and the risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and obesity.
_____ Initials

☐ I do not agree to have my DNA stored for the duration of the study at the University of Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to define the type of diabetes and the risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and obesity.
_____ Initials

CENTRAL STORAGE FACILITY AT THE NATIONAL INSTITUTES OF HEALTH

We are asking if you would agree that you blood, urine and DNA samples and data that are collected for the study may be sent to the central storage facility at the National Institute of Diabetes, Digestive and Kidney Diseases or NIDDK. This is a research resource supported by the National Institutes of Health or NIH. The facility collects, stores, and distributes biological samples and associated data from people with many kinds of disorders and from healthy people.

The purpose of this collection is to make samples and data available for use in research of the study of diabetes, obesity, and heart disease and their complications after the current study is completed. Sending data and samples may give scientists valuable research material that can be used to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists who want to use the samples and study data have to go through a formal proposal process and all proposals are reviewed by an external panel of experts.

Your samples and data will be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know the name, date of birth, medical record number, social security number, etc., of the person who donated the sample. Your donation is voluntary, and if you choose not to participate there will be no penalty or loss of benefits to which you are entitled. If you agree donate your samples, you can change your mind up until the end of the SEARCH study. When study researchers receive written instructions from you, they will destroy your sample and all information that identifies you.

Storage of blood, urine and study data

☐ I agree for my blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility. _____ Initials

☐ I do not agree for my blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility. _____ Initials

Storage of DNA

☐ I agree for my DNA to be donated to the NIDDK storage facility. _____ Initials

☐ I do not agree for my DNA to be donated to the NIDDK storage facility. _____ Initials

FULL GENE ANALYSIS (LOOKING AT ALL OF YOUR GENES) AND THE NATIONAL STORAGE CENTER (NIH/dbGaP)

As a part of the SEARCH study, your DNA may be analyzed to identify a complete picture of your genetic makeup. This is called Genome Wide Association (GWAS). This information would be sent to a national data bank to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies or diabetes or other conditions. No personal information would be included, such as name, date of birth, or address. Thus, researchers would not be able to link this information back to you.

☐ I agree to allow my information about my DNA to be included in the NIH data bank. _____ Initials

☐ I do not agree to allow my information about my DNA to be included in the NIH data bank. _____ Initials

MEDICAL RECORDS REVIEW

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 laboratory and other test results.

CONTACT BY THE SEARCH STUDY IN THE FUTURE

The researchers conducting the SEARCH study may wish to call you as new studies are developed to let you know about these new studies and ask you if you would like to participate in these studies. As with this study, taking part in any future study is voluntary. Taking part in the present study does not mean that you are agreeing to take part in any future study.

☐ I agree to be called in the future. _____ Initials

☐ I do not agree to be called in the future. _____ Initials

RELEASE OF TEST RESULTS

The results of tests that may be important to your health will be mailed to you once the samples are tested at the laboratory. Some participants like their physician to have copies of these test results as well. Please check one of the two boxes below to

give the study permission to release your test results to your physician if you would like us to do this.

☐ I agree to have the test results sent to my physician. _____ Initials

☐ I do not agree to have the test results sent to my physician. _____ Initials

RISKS, DISCOMFORTS, AND PRECAUTIONS

The risks from drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the possibility of these risks, blood will be drawn by experienced medical staff.

The blood tests require that you not eat any food overnight (you may drink water). In order to prevent low or high blood sugars, your blood sugar will be checked by finger-stick and diabetes medicine will be given as needed to control your blood sugar.

Some of the tests will look for the presence of or risk of developing the complications of diabetes. If these tests identify complications of diabetes or risk of developing the complications, the results may make you anxious. If this happens, you will be referred to local mental health professionals for evaluation and treatment.

This research study includes genetic testing of blood samples that we ask you to provide. You are free to refuse to take part in this genetic testing. It is your choice. A federal law called the Genetic Information Nondiscrimination Act (GINA) limits the use of genetic information by employers with 15 or more employees and by health insurers and group or individual health plans. GINA generally makes it illegal to discriminate against you based on your genetic information. If you agree to take part in genetic testing, the genetic information we collect or obtain through this research will not affect your eligibility for future medical care, membership in Kaiser Foundation Health Plan, or cost of your premiums or benefits.

The researchers have taken steps to minimize the risks of this study, and it is not expected that you will experience any adverse effects. However, you may still encounter problems or side effects. If this happens, please tell the researchers about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

WHAT ARE THE POSSIBLE BENEFITS IF I JOIN THIS STUDY?

There are no direct benefits to you from participating in this study. However, your results from this study may more clearly define your type of diabetes and the presence or absence of some of the complications of diabetes. You will also learn if your laboratory tests are outside the normal range. If you give permission, some of this information will be shared with your health care professionals, which could impact the management of your diabetes.

ALTERNATIVES

There are no treatments involved in this study, and participation is entirely voluntary. You may choose not to participate in this study. Your decision to participate or not to participate will not affect your future medical care. You may withdraw from this study at any time.

COST

There is no cost to you to participate in this study.

COMPENSATION

To reimburse you for your time to complete the Registry visit, you will receive up to $80.00 in gift cards or a check.

You will receive:
$30.00 for completing the survey(s),
$30.00 for completing the physical examination,
$20.00 for having your blood drawn

We may ask you to provide another sample of your urine in the future. You will be paid $20.00 for providing this additional urine sample.

CONFIDENTIALITY

Only SEARCH project staff will be able to view the information that you give to us. Information that would identify you will not be released without your consent. All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means that anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. Under the law, we must report if you tell us you are planning to cause serious harm to yourself or others.

A special number will be assigned to you upon entering the study. This number will be used instead of your name to identify the information and laboratory tests collected during the study. The list containing the special number assigned to you will be kept in a password-protected database in the Department of Research & Evaluation at Kaiser Permanente Southern California. Thus, no one other than the research staff will be able to link any of the information collected in the study to you.

It is possible that members of the research team might use e-mail to contact you for study purposes, for example to remind you of a scheduled visit. We will not do this if you do not give us permission, and we will never put your private health information in an e-mail. However if you give us permission to contact you using e-mail, Kaiser Permanente cannot guarantee that the message will get to you or that the message will not go to someone else by mistake.

The information from the research study may be presented or published; however, you will not be identified in such publications. When the study is over, your information will be kept in a computer database for a period of time required by the funding agency and then will be destroyed.

RIGHT TO WITHDRAWAL

You may leave this study at any time. Leaving the study will have no effect on your ability to get medical care or health insurance nor will it have any effect on the kind of care your health care professionals are giving to you. In order to withdraw from this study, please contact the Principal Investigator whose contact information is on the signature page. If you withdraw from this study, no further tests will be done on the stored samples that you provided. However, survey data and other tests conducted on samples collected at the visit will still be included in the dataset to be used for future studies. You will no longer be contacted to participate in this study.

The Centers for Medicare and Medicaid Services requires compliance with Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (the MMSEA) which amended the Medicare Secondary Payer statute. Section II J requires sponsors of clinical trials to report payments made to Medicare beneficiaries for treatment, complications, and injuries that arise from clinical trials. When required, information about Medicare beneficiaries' participation in a research study, medical services received, Medicare claims, and other information, will be released to the Centers for Medicare and Medicaid Services and its agents and/or contractors. Information disclosed may be re-disclosed by the recipient and may no longer be protected by law.

WHAT DOES MY SIGNATURE ON THIS FORM MEAN?

My signature on this form would mean that I acknowledge:

1. Personal information about me that is collected in this study will be protected to the full extent of the law. No information from this study that could be linked to me will be released without my consent.

2. The results of this study may be reported in articles, books or at meetings. My identity will not be revealed at any time. Research records will be kept confidential to the extent provided by law. All study records will be kept in a locked room and accessed only by staff working on this research study.

3. Being in this study is my choice. I may decide to leave this study at any time. If I choose not to be in the study or leave the study, it will not affect my insurance benefits or my future medical care at Kaiser Permanente.

4. I may be asked to leave the study at any time for medical reasons, if the researcher feels that it is in my best interest, or if the study is stopped.

5. My questions regarding this study have been answered. If I have any questions about this study or if I experience a study-related injury, I may contact

Jean M. Lawrence, ScD, MPH, SEARCH Study Principal Investigator
(626) 564-3106 or Jean.M.Lawrence@kp.org

If I have any questions about my rights as a research subject, I may contact

Armida Ayala, PhD, Director, Human Research Subjects Protection Office at 626-405-3665 or armida.ayala@kp.org

6. If I am injured by being in this study, the physicians and/or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals will provide medical care and treatment according to the terms of my plan benefits. These benefits are described in my Evidence of Coverage or Summary Plan Description. I may have to pay co-payments, coinsurance and/or deductibles. No additional financial payment is available

I have read the entire consent, including the Supplemental HIPAA Authorization and Experimental Subject's Bill of Rights and voluntarily consent to participate in this research study conducted by the physicians or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals.

Your signature shows that the research study has been explained to you and all of your questions have been answered. ***If you still have questions or do not understand what this study is about, do not sign this form***. Give this form back to the study staff and get more information.

A copy of this signed and dated Informed Consent Form will be given to me for my records

Printed First and Last Name of Participant/ Legally Authorized Representative	Relationship to Participant
Signature of Participant/Legally Authorized Representative	Date
Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date

AUTHORIZATION TO USE YOUR PRIVATE HEALTH INFORMATION

What is private health information?

Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- Your past, present and future health information is used by the SEARCH study but is not disclosed with identifiers;
- Your date of birth is used by the SEARCH study and disclosed to collaborating researchers at Wake Forest University, School of Medicine;
- Your address is used by the SEARCH study local research staff to send out letters and cards for the study but is not disclosed;
- Your social security number may be used by the SEARCH staff and disclosed to the National Center for Health Statistics;
- Your phone number is used by the SEARCH study local research staff but it is not disclosed;
- Your medical record number is used by the SEARCH staff, but it is not disclosed;
- The results of your medical tests and lab work done for this research study are disclosed to the data coordinating center at Wake Forest University, School of Medicine but without identifiers. Laboratory tests performed by collaborating researchers at the University of Washington, Northwest Lipid Research Laboratory are completed without identifiers.

Who else will see my information?

This information may be shared with the following:

- The study sponsor, the Centers for Disease Control and Prevention;
- The study's data coordinating center Wake Forest University, School of Medicine;
- The Kaiser Permanente Southern California Institutional Review Board (IRB);
- Kaiser Permanente Principal Investigator, co-Investigators, research project manager and other research staff (research assistants, associates, programmers and biostatisticians);

Once we have shared your information we cannot be sure that it will stay private. If ***you*** share your information with people outside the research team, it will no longer be private. Your child's name will not be used in any report that is written. Your name will not be used in any report or publication that is written.

How long will Kaiser Permanente researchers and the affiliated researchers noted above use and share my information?

Your information will be used until the research is completed. This authorization will expire at the end of the study.

What if I change my mind about sharing my research information?

If you decide not to share your information anymore:

- The research team can continue to use any of the private information that they already have.
- You will no longer be contacted as part of this research study.
- Decisions about sharing your research information will not affect your medical care or health care coverage.
- You must write to the study Principal Investigator and tell her that you no longer want to share your information. Write to the study principal investigator at:

Jean M. Lawrence, ScD, MPH, MSSA
Department of Research & Evaluation
Southern California Permanente Medical Group
100 South Los Robles Ave., 4th Floor
Pasadena, California 91101

Do I have the right to see and copy my research information?

The results of your laboratory tests will be sent to you (except for genetic test results other than monogenic forms of diabetes) and, if you have provided written authorization, copies of the test results sent to you will also be sent to your health care provider, including specific genetic test results for monogenic diabetes. In addition, you and your physician must be notified if your laboratory test results are above alert values described in the study protocol.

If you agree to share your information, you should sign this form below. You will be given a copy of this form.

I agree to share my information as described in this form

Printed First and Last Name of Participant/ Legally Authorized Representative	Relationship to Participant
Signature of Participant/Legally Authorized Representative	Date

If you have questions or concerns about your privacy and the use of your protected health information, contact the investigator at the telephone number listed in the consent form.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Original – Chart or Study Copy - Patient

KAISER FOUNDATION HOSPITALS PATIENT'S NAME_____

SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP M.R. #_____

INFORMED CONSENT TO PARTICIPATE IN RESEARCH STUDY OF DIABETES INCIDENCE, COMPLICATIONS, AND QUALITY OF CARE SEARCH FOR DIABETES IN YOUTH (SEARCH), REGISTRY STUDY

Parent/Guardian Consent for Registry Visit
For Persons with Diabetes less than 18 years of age

SPONSOR: **Centers for Disease Control and Prevention**

INVESTIGATOR: **Jean M. Lawrence, ScD, MPH, MSSA Kaiser Permanente**
Southern California Department of Research & Evaluation
100 S. Los Robles Ave., 4th Floor
Pasadena CA 91101

TELEPHONE: **(626) 564-3106**

Your child is being invited to be in a research study. Taking part in this study is voluntary.

This informed consent form tells you about the purpose, risks, and benefits of this research study. You may ask questions and take time to think about the study before you decide to join it. You should decide if you want to participate in the study only when you have received all the information you need.

Your doctor or health care provider may be working on this research study. He or she is interested in your\your child's healthcare as well as the conduct of this study. If that makes you feel the doctor can't be objective about the best care for your child, you may ask for another doctor or staff member who is not involved in this research.

Kaiser Permanente is being reimbursed by the study sponsor, Centers for Disease Control and Prevention, to conduct this study.

PURPOSE AND BACKGROUND

The purpose of this research study being conducted by Kaiser Permanente, and in four other locations in the United States, is to improve our understanding of the incidence, natural history, complications, and quality of care for children, adolescents, and young adults with diabetes. You and your child were asked to take part in the SEARCH study because your child has diabetes. Dr. Jean Lawrence is the lead investigator for this study for Kaiser Permanente. This study is sponsored by the Centers for Disease

Control.

Diabetes is the third most common life-long disease in people under 20 years of age. The total number of persons with diabetes in this age group is increasing. Also, types of diabetes that have not been seen in young people are now being seen. These changes have resulted in gaps in knowledge about the total number of persons and types of diabetes in the United States, the type of care young people with diabetes receive, and the effect diabetes has on their lives. This research study will collect information to answer these questions.

This study will include over 7,000 children and youth with diabetes who were members of Kaiser Permanente Southern California when they were diagnosed with diabetes. A member of the SEARCH research team has discussed the requirements for participating in this study with you and your child. Before agreeing to participate in this research study, it is important that you/your child read and understand this form or have a member of the study staff read it to you/your child.

If you/your child have personal, religious, cultural, or ethical beliefs that you think might limit the types of tests you would agree to have your child receive, please discuss them fully with your/your child's physicians or appropriate members of the research team before entering this study.

This consent form may contain some words that are not familiar to you or to your child. Please discuss any questions you or your child may have about this study with the research staff members before you sign this form.

STUDY PROCEDURES

The SEARCH Registry visit includes a brief physical examination, collecting a blood and urine sample, and completing one or more questionnaires. You and your child can agree to participate in all or only some parts of the study.

A research team member has set up an appointment for your child. The appointment will be in the morning or early afternoon. Your child will come to the appointment after not having anything to eat or drink other than water for 10 hours. Your child will not take their usual diabetes medications until after their blood has been drawn. The study visits will take approximately 1-2hours.

Before your child's scheduled appointment, you will be mailed a container with detailed instructions to collect the first morning urine the day of the study visit. You will be asked to bring this urine container with you to your child's visit. We may ask your child to repeat the urine collection for research purposes; we will not know if this additional urine sample will be needed until the sample is reviewed by the laboratory

PHYSICAL EXAMINATION

The physical examination includes measurements of height, weight, waist, blood pressure, and examination of the skin on the neck. The time to complete this part of the visit is approximately 30 minutes.

COLLECTION OF BLOOD AND URINE SAMPLES

Blood will be taken to measure blood sugar, hemoglobin Alc (a measure of long-term blood sugar control), C-peptide (a measure of internal insulin production), different types of cholesterol (fat), and diabetes autoantibodies (markers in the blood for type 1 diabetes). Two genetic markers for diabetes (HLA and ZNT8) will also be tested. The total amount of blood drawn for these tests is based on your child's weight but will not exceed 3 tablespoons.

A first morning urine sample will be requested and tested to see if diabetes is affecting your child's kidneys. After these tests are done, your child will be given a snack. You may also bring your own snack to the Registry visit. After your snack, your child will take his or her usual diabetes medicine and have his or her medicines recorded by trained staff.

SAVING / STORAGE OF BLOOD AND URINE

If you agree, your child's blood and urine will be saved for the duration of the study at the University of Washington, Northwest Lipid Research Laboratories and used in the future, as new tests are developed to learn more about the types of diabetes and when someone has or is at risk to get the complications of diabetes. If the results of the tests affect your child's health, you will be informed of the test results.

☐ I agree to have my child's blood and urine saved and used in the future for new tests as they are developed to learn more about the types of diabetes and the risk of developing complications of diabetes.
_____ Initials

☐ I do not agree to have my child's blood and urine saved and used in the future for new tests as they are developed to learn more about the types of diabetes and the risk of developing complications of diabetes.
_____ Initials

SAVING / STORAGE OF DNA

DNA is found in all cells. DNA makes up genes. Genes determine height, hair color, and all other body traits. The DNA in each person's body is different from every other person's DNA (except identical twins or triplets who have the same DNA). The differences may be why some people are more likely to get certain diseases like diabetes.

If you agree, your child's DNA will be saved at the University of Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to tell your child's type of diabetes and the risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and being overweight. The total amount of blood required is approximately 1¾ teaspoons (8.5 cc).

☐ I agree to have my child's DNA stored for the duration of the study at the University of Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to define the type of diabetes and the risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and obesity. _____ Initials

☐ I do not agree to have my child's DNA stored for the duration of the study at the University of Washington, Northwest Lipid Research Laboratories and used in the future as new tests are developed to define the type of diabetes and the risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and obesity. _____ Initials

CENTRAL STORAGE FACILITY AT THE NATIONAL INSTITUTES OF HEALTH

We are asking if you would agree that your child's blood, urine and DNA samples and data that are collected for the study may be sent to the central storage facility at the National Institute of Diabetes, Digestive and Kidney Diseases or NIDDK. This is a research resource supported by the National Institutes of Health or NIH. The facility collects, stores, and distributes biological samples and associated data from people with many kinds of disorders and from healthy people.

The purpose of this collection is to make samples and data available for use in research of the study of diabetes, obesity, and heart disease and their complications after the current study is completed. Sending data and samples may give scientists valuable research material that can be used to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists who want to use the samples and study data have to go through a formal proposal process and all proposals are reviewed by an external panel of experts.

Your child's samples and data will be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know the name, date of birth, medical record number, social security number, etc., of the person who donated the sample. Your child's donation is voluntary, and if you choose not to participate there will be no penalty or loss of benefits to which your child is entitled. If you agree donate your child's samples, you can change your mind up until the end of the SEARCH study. When study researchers receive written instructions from you, they will destroy your child's sample and all information that identifies your child.

Storage of blood, urine and study data

☐ I agree for my child's blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility. _____ Initials

☐ I do not agree for my child's blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility. _____ Initials

Storage of DNA

☐ I agree for my child's DNA to be donated to the NIDDK storage facility. _____ Initials

☐ I do not agree for my child's DNA to be donated to the NIDDK storage facility. _____ Initials

FULL GENE ANALYSIS (LOOKING AT ALL OF YOUR GENES) AND THE NATIONAL STORAGE CENTER (NIH/dbGaP)

As a part of the SEARCH study, your child's DNA may be analyzed to identify a complete picture of his or her genetic makeup. This is called Genome Wide Association (GWAS). This information would be sent to a national data bank to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies or diabetes or other conditions. No personal information would be included, such as name, date of birth, or address. Thus, researchers would not be able to link this information back to your child.

☐ I agree to allow my child's information about his/her DNA to be included in the NIH data bank. _____ Initials

☐ I do not agree to allow my child's information about his/her DNA to be included in the NIH data bank. _____ Initials

MEDICAL RECORDS REVIEW

It may be necessary to review your child's 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 laboratory and other test results

CONTACT BY THE SEARCH STUDY IN THE FUTURE

The researchers conducting the SEARCH study may wish to call you as new studies are developed to let you know about these new studies and ask you if your child would like to participate in these studies. As with this study, taking part in any future study is voluntary. Taking part in the present study does not mean that you

are agreeing to take part in any future study. If this study is developed after your child turns 18 years, we may contact your child directly.

☐ I agree to be called in the future. _____ Initials

☐ I do not agree to be called in the future. _____ Initials

RELEASE OF TEST RESULTS

The results of tests that may be important to your child's health will be mailed to you once the samples are tested at the laboratory. If your child turns 18 years before the test results become available, the results will only be mailed to your child. Some participants like their child's physician to have copies of these test results as well. Please check one of the two boxes below to give the study permission to release test results to your child's physician if you would like us to do this.

☐ I agree to have the test results sent to my child's physician. _____ Initials

☐ I do not agree to have the test results sent to my child's physician. _____ Initials

RISKS, DISCOMFORTS, AND PRECAUTIONS

The risks from drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the possibility of these risks, blood will be drawn by experienced medical staff.

The blood tests require that your child not eat any food overnight (the child may drink water). In order to prevent low or high blood sugars, your child's blood sugar will be checked by finger-stick and diabetes medicine will be given as needed to control your child's blood sugar.

Some of the tests will look for the presence of or risk of developing the complications of diabetes. If these tests identify complications of diabetes or risk of developing the complications, the results may make you or your child anxious. If this happens, you or your child will be referred to local mental health professionals for evaluation and treatment.

This research study includes genetic testing of blood samples that we ask you to provide. You are free to refuse to take part in this genetic testing. It is your choice. A federal law called the Genetic Information Nondiscrimination Act (GINA) limits the use of genetic information by employers with 15 or more employees and by health insurers and group or individual health plans. GINA generally makes it illegal to discriminate against you based on your genetic information. If you agree to have your child take part in genetic testing, the genetic information we collect or obtain through this research will not affect your child's eligibility for future medical care, membership in Kaiser Foundation Health Plan, or the cost of your premiums or benefits.

The researchers have taken steps to minimize the risks of this study, and it is not expected that your child will experience any adverse effects. However, your child may still encounter problems or side effects. If this happens, please tell the researchers about any injuries, side effects, or other problems that your child has during this study. You should also tell your child's regular doctors.

WHAT ARE THE POSSIBLE BENEFITS IF I JOIN THIS STUDY?

There are no direct benefits to you or your child from participating in this study. However, your child's results from this study may more clearly define your child's type of diabetes and the presence or absence of some of the complications of diabetes. You will also learn if your child's laboratory tests are outside the normal range. If you give permission, some of this information will be shared with your child's health care professionals, which could impact the management of your child's diabetes.

ALTERNATIVES

There are no treatments involved in this study, and participation is entirely voluntary. You may choose not to participate or not to have your child participate in this study. Your decision to participate or not to participate will not affect your future medical care or your child's future medical care. You may withdraw your child from this study at any time.

COST

There is no cost to you/your child to participate in this study.

COMPENSATION

To reimburse you for your time to complete the Registry visit, you and your child will receive up to $80.00 in gift cards or a check.

You will receive:
$30.00 for completing the surveys;
$30.00 for completing the physical examination;
$20.00 for having your child's blood drawn;

We may ask your child to provide another sample of your child's urine in the future. You will be paid $20.00 for providing this additional urine sample.

CONFIDENTIALITY

Only SEARCH project staff will be able to view the information that you give to us. Information that would identify you/your child will not be released without your consent. All answers that you/your child give will be kept private. This is so because this

study has been given a Certificate of Confidentiality. This means that anything you or you and your child tell us will not have to be given out to anyone, even if a court orders us to do so, unless you or you and your child say it's okay. Under the law, we must report if you or your child tells us you or your child is planning to cause serious harm to yourself or others.

A special number will be assigned to your child upon entering the study. This number will be used instead of your child's name to identify the information and laboratory tests collected during the study. The list containing the special number assigned to your child will be kept in a password-protected database in the Department of Research & Evaluation at Kaiser Permanente Southern California. Thus, no one other than the research staff will be able to link any of the information collected in the study to you or your child.

It is possible that members of the research team might use e-mail to contact you for study purposes, for example to remind you of a scheduled visit. We will not do this if you do not give us permission, and we will never put your private health information in an e-mail. However if you give us permission to contact you using e-mail, Kaiser Permanente cannot guarantee that the message will get to you or that the message will not go to someone else by mistake.

The information from the research study may be presented or published; however, your child will not be identified in such publications. When the study is over, your child's information will be kept in a computer database for a period required by the funding agency and then will be destroyed.

RIGHT TO WITHDRAWAL

You and your child may leave this study at any time. Leaving the study will have no effect on your ability or your child's ability to get medical care or health insurance nor will it have any effect on the kind of care your health care professionals are giving to you and your child. In order to withdraw from this study, please contact the Principal Investigator whose contact information is on the signature page. If you withdraw from this study, no further tests will be done on the stored samples that you provided. However, survey data and other tests conducted on samples collected at the visit will still be included in the dataset to be used for future studies. You will no longer be contacted to participate in this study.

WHAT DOES MY SIGNATURE ON THIS FORM MEAN?

My signature on this form would mean that I acknowledge:

1. Personal information about my child that is collected in this study will be protected to the full extent of the law. No information from this study that could be linked to me or my child will be released without my consent.

2. The results of this study may be reported in articles, books or at meetings. My child's identity will not be revealed at any time. Research records will be kept confidential to the extent provided by law. All study records will be kept in a locked room and accessed only by staff working on this research study.

3. Being in this study is my/my child's choice. I/my child may decide to leave this study at any time. If I/my child choose(s) not to be in the study or leave the study, it will not affect my/my child's insurance benefits or my/my child's future medical care at Kaiser Permanente.

4. My child may be asked to leave the study at any time for medical reasons, if the researcher feels that it is in my child's best interest, or if the study is stopped.

5. My questions regarding this study have been answered. If my child or I have any questions about this study or if my child experiences a study-related injury, I may contact

   Jean M. Lawrence, ScD, MPH, SEARCH Study Principal Investigator
   (626) 564-3106 or Jean.M.Lawrence@kp.org

   If I have any questions about my rights as a research subject, I may contact

   Armida Ayala, PhD, Director, Human Research Subjects Protection Office at 626-405-3665 or armida.ayala@kp.org

6. If I am injured by being in this study, the physicians and/or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals will provide medical care and treatment according to the terms of my plan benefits. These benefits are described in my Evidence of Coverage or Summary Plan Description. I may have to pay co-payments, coinsurance and/or deductibles. No additional financial payment is available

I have read the entire consent, including the Supplemental HIPAA Authorization and Experimental Subject's Bill of Rights and voluntarily consent to participate in this research study conducted by the physicians or employees of Southern California Permanente Medical Group and/or Kaiser Foundation Hospitals.

Your signature shows that the research study has been explained to you and all of your questions have been answered. ***If you still have questions or do not understand what this study is about, do not sign this form.*** Give this form back to the study staff and get more information.

A copy of this signed and dated Informed Consent Form will be given to me for my records

Printed First and Last Name of Parent of Legal Guardian

Signature of Parent or Legal Guardian Date

Printed Child's First and Last Name

Assent of Child Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

AUTHORIZATION TO USE YOUR CHILD'S PRIVATE HEALTH INFORMATION

What is private health information?

Private health information is any information that can be traced back to you or your child. We need your authorization (permission) to use your child's private health information in this research study. The private health information that we will use and share for this study includes:

- Your child's past, present and future health information is used by the SEARCH study but is not disclosed with identifiers;
- Your child's date of birth is used by the SEARCH study and disclosed to collaborating researchers at Wake Forest University, School of Medicine;
- Your address is used by the SEARCH study local research staff to send out letters and cards for the study, but is not disclosed;
- Your child's social security number may be used by the SEARCH staff and disclosed to the National Center for Health Statistics;
- Your phone number is used by the SEARCH study local research staff but it is not disclosed;
- Your child's medical record number is used by the SEARCH staff, but it is not disclosed;
- The results of your child's medical tests and lab work done for this research study are disclosed to the data coordinating center at Wake Forest University, School of Medicine but without identifiers. Laboratory tests performed by collaborating researchers at the University of Washington, Northwest Lipid Research Laboratory are completed without identifiers.

Who else will see my child's information?

This information may be shared with the following:

- The study sponsor, the Centers for Disease Control and Prevention;
- The Kaiser Permanente Southern California Institutional Review Board (IRB);
- The study's data coordinating center Wake Forest University, School of Medicine;

- Kaiser Permanente Principal Investigator, co-Investigators, research project manager and other research staff (research assistants, associates, programmers and biostatisticians);

Once we have shared your child's information we cannot be sure that it will stay private. If ***you*** share your child's information with people outside the research team, it will no longer be private. Your child's name will not be used in any report that is written. Your child's name will not be used in any report or publication that is written.

How long will Kaiser Permanente researchers and the affiliated researchers noted above use and share my child's information?

Your child's information will be used until the research is completed. This authorization will expire at the end of the study.

What if I change my mind about sharing my child's research information?

If you decide not to share your child's information anymore:

- The research team can continue to use any of the private information that they already have.
- You will no longer be contacted as part of this research study.
- Decisions about sharing your child's research information will not affect your child's medical care or health care coverage.
- You must write to the study Principal Investigator and tell her that you no longer want to share your child's information. Write to the study principal investigator at:

Jean M. Lawrence, ScD, MPH, MSSA
Department of Research & Evaluation
Southern California Permanente Medical Group
100 South Los Robles Ave., 4th Floor
Pasadena, California 91101

Do I have the right to see and copy my child's research information?

The results of your child's laboratory tests will be sent to you (except for genetic test results other than monogenic forms of diabetes) and, if you have provided written authorization, copies of the test results sent to you

will also be sent to your child's health care provider, including specific genetic test results for monogenic diabetes. In addition, you and your physician must be notified if your child's laboratory test results are above alert values described in the study protocol.

If you agree to share your child's information, you should sign this form below. You will be given a copy of this form.

I agree to share my child's information as described in this form.

Printed First and Last Name of Participant/ Legally Authorized Representative	Relationship to Participant
Signature of Participant/Legally Authorized Representative	Date

If you have questions or concerns about your privacy and the use of your protected health information, contact the investigator at the telephone number listed in the consent form.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Original – Chart or Study Copy - Patient

Consent to Participate in a Research Study
Adult Subjects, SEARCH 4 Registry Study Visit

UNC IRB Study #10-2341
Consent Form Version Date: February 2016

Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

People in charge of the study:
University of North Carolina-Chapel Hill, Coordinating Site: Elizabeth Mayer-Davis, PhD (919-966-1991)
Greenville Health System, Data Collection Site: Bryce Nelson, MD (864-454-5100)
Medical University of South Carolina, Data Collection Site: Deborah Bowlby, MD (843-792-6807)
University of South Carolina, Data Collection Site: Christine Turley, MD (803-576-5926)
Study Contact telephone number: local numbers given above or studywide toll-free at 866-595-2397
Study Contact email: search.study@unc.edu

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or your health care provider. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn about diabetes in children and young adults. Diabetes is the third most common life-long disease in people under 20 years of age. We are asking you and others with diabetes to be in the research, because we want to count the number of children and teens with diabetes. We also want to learn more about all the types of diabetes that affect children and teens.

You are being asked to be in the study because you have diabetes and were under age 20 and living in South Carolina around the time you developed diabetes.

Are there any reasons you should not be in this study?
You should not complete a study visit if you are currently pregnant. You may take part in the study visit when it has been at least four months after the end of your pregnancy.

How many people will take part in this study?
About 832 people at five sites across the US will take part in the Registry Study visit, including approximately 207 people from the Carolina SEARCH site.

How long will your part in this study last?
The Registry Study visit will take about an hour. We may contact you every year to be sure we have your correct contact information. If your address/phone number has changed, we may attempt to update your contact information through a public database, such as LexisNexis. If you agree to have a sample of your blood, urine or DNA stored following the Registry Study visit, it will be saved for 10 years after the end of funding for follow-up of SEARCH participants. After this time, stored samples will be destroyed.

What will happen if you take part in the study?
These are the things that will happen during the study:

- Fast for 8-10 hours before the visit (no food or drinks, except water). You will not take your usual diabetes medicines until after you have eaten at your visit.
- Bring in a urine sample to be tested for albumin and creatinine to see how well your kidneys are working. (You will be mailed a container with detailed instructions before your appointment).
- Measure height, weight, waist, and blood pressure. Each will be done 2-3 times.
- Look at the skin on the back of neck.
- Blood will be taken from your arm to measure blood sugar, hemoglobin A1c (measures average blood sugar over past 3 months), different types of cholesterol (fat), c-peptide (measures your own insulin production), cystatin-C and creatinine (measures kidney function), and diabetes antibodies (markers in the blood for type 1 diabetes). The total amount of blood drawn will be based on weight tables and will not exceed 3 tablespoons.

  If you agree, results commonly used in clinical practice (HbA1c, cholesterol, c-peptide, diabetes antibodies, and urine albumin/creatinine) will be shared with your doctor.

  Mark the line that best matches your choice:
  _____ OK to share results of the tests with my doctor
  _____ Not OK to share results of the test with my doctor

- A sample of your blood, urine, and DNA may be saved after the visit, if you agree by signing the Stored Specimens Consent Form. Some of these saved samples may be used in the future for tests related to diabetes.
- After the blood and urine samples are obtained, you can take your pills or insulin and you will be given a snack.
- You will be asked questions about your diabetes, medical care, current medications, family history of diabetes, education, family income level and health insurance.

Contact in the Future

The researchers will call you as new studies are developed in the future to let you know about new studies and ask you to take part in these studies. As with this study, taking part in any future study is voluntary. Taking part in the present study does not mean that you are agreeing to take part in any future study.

Mark the line that best matches your choice:

_____ OK to contact me in the future to tell me about other studies
_____ Not OK to contact me in the future to tell me about other studies

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved with being in this study?

The risks from drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the chance of these risks, blood will be drawn by experienced staff and a local numbing medicine may be placed on the skin before the blood is drawn to decrease any pain. The total amount of blood that will be obtained will be no more than 3 tablespoons (45cc) depending on your age and body size. When drawing your blood, our research staff will follow all necessary safety precautions. In the highly unlikely event that our research staff is accidentally exposed to your bodily fluids (blood or urine), we will abide by the South Carolina law that provides for testing of blood to minimize threats to the health of the staff. You will be notified should this testing be necessary and the results will be reported as required by law.

The blood tests require that you not eat any food or drink anything other than water overnight. In order to limit low or high blood sugars, your blood sugar will be checked and your diabetes medication or a fast-acting carbohydrate will be given as needed.

Some of the tests will look for the presence or risk of developing of the complications of diabetes. If these tests identify complications of diabetes or risk of developing the complications, the results may make you anxious. If this happens, you will be referred to your diabetes care provider or a local mental health professional.

Other possible risks include loss of privacy or confidentiality. Loss of privacy might happen if someone could overhear or see you taking part in the study. To limit this, we will do the study visit in a private location. Information collected will be stored in a locked filing cabinet or in a password-protected electronic file.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

If you choose not to be in the study, how does this affect your medical care?

You can still receive evaluation and treatment for your condition if you do not participate in this study. Your decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

SEARCH staff will keep the information collected, tests done, and samples stored strictly private. This is so because the study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

When you enter the study, a special number will be given to you. The number will be used to identify the information and laboratory tests that will be done during this study. The special number and the information collected during this study will be sent to Wake Forest University in order to study the information. Blood and urine specimens will be sent to the University of Washington for testing or storage. The list containing the special number assigned to you will be kept in a secure, password-protected database at the Carolina SEARCH site. Thus, no one other than the study investigators (Dr. Mayer-Davis at the University of North Carolina (UNC), Dr. Nelson at Greenville Health System (GHS), Dr. Bowlby at the Medical University of South Carolina (MUSC), Dr. Turley at the University of South Carolina (USC)) and the SEARCH Carolina research team will be able to access this database and link the information collected in the study to you. Paper forms collected during the study will be stored in a locked filing cabinet.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill and your local data collection site (GHS, MUSC, or USC) will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the UNC-Chapel Hill or your local data collection site (GHS, MUSC, or USC), research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill and your local data collection site (GHS, MUSC or USC) have not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty.

Will you receive anything for being in this study?
You will be receiving $60 in gift cards for completing the study visit, plus an extra $20 for bringing in your first morning urine collection. In the rare circumstance that a blood redraw or repeat urine collection is necessary; you would receive an additional $20 gift card.

If you traveled a significant distance to complete this study visit, you will be provided additional incentive to assist with travel costs. This additional incentive will be: two $20 gift cards if you traveled 70-100 miles round trip, three $20 gift cards if you traveled 101-150 miles round trip, or four $20 gift cards if you traveled more than 151 miles round trip. Travel distance will be determined based on your current home address and the location of the SEARCH visit.

Will it cost you anything to be in this study?
There will be no costs for being in the study.

What if you are a student at UNC, MUSC or USC?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades. You will not be offered or receive any special consideration if you take part in this research.

What if you are an employee at MUSC, GHS, or USC?
Taking part in this research is not a part of your job duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the Centers for Disease Control and Prevention and the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at Greenville Health System (864-522-2097; email: jhayes@ghs.org) or at UNC-Chapel Hill (919-966-3113; email: IRB_subjects@unc.edu.

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Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

Principal Investigators:
Elizabeth Mayer-Davis, PhD (UNC-Chapel Hill Coordinating Site);
Bryce Nelson, MD, PhD (GHS data collection site)
Deborah Bowlby, MD (MUSC data collection site)
Christine Turley, MD (USC data collection site)

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

Assent to Participate in a Research Study
Adolescent Subjects age 15-17, Registry Study Visit

UNC IRB Study #10-2341
Assent Form Version Date: February 2016

Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

SEARCH Carolina Site Principal Investigators:
University of North Carolina-Chapel Hill, Coordinating Site: Elizabeth Mayer-Davis, PhD (919-966-1991)
Greenville Health System, Data Collection Site: Bryce Nelson, MD (864-454-5100)
Medical University of South Carolina, Data Collection Site: Deborah Bowlby, MD (843-792-6807)
University of South Carolina, Data Collection Site: Christine Turley, MD (803-576-5926)
Funding Source and/or Sponsor: Centers for Disease Control and Prevention and National Institutes of Health/NIDDK
Study Contact telephone number: local numbers given above or studywide toll-free at 866-595-2397
Study Contact email: search.study@unc.edu

What are some general things you should know about research studies?
You are being asked to take part in a research study. Your parent, or guardian, needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or your health care provider. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn about diabetes in children and young adults. Diabetes is the third most common life-long disease in people under 20 years of age. We are asking you and others with diabetes to be in the research because we want to count the number of

children and teens with diabetes. We also want to learn more about the types of diabetes that affect children and teens.

You are being asked to be in the study because you have diabetes and were under age 20 and living in South Carolina around the time you developed diabetes.

Are there any reasons you should not be in this study?
You should not do a study visit if you are pregnant. You may take part in the study visit when it has been at least four months after the end of your pregnancy.

How many people will take part in this study?
About 832 people at five sites across the US will take part in the Registry Study visit, including about 207 people from the Carolina SEARCH site.

How long will your part in this study last?
The Registry Study visit will take about an hour. We may contact your parent every year to be sure we have your correct contact information. If you agree to have a sample of your blood, urine or DNA stored after the Registry Study visit, it will be saved for 10 years after the end of funding for follow-up of SEARCH participants. After this time, stored samples will be destroyed.

What will happen if you take part in the study?
These are the things that will happen during the study:

- Fast for 8-10 hours before the visit (no food or drinks, except water). You will not take your usual diabetes medicines until after you have eaten at your visit.
- Bring in a urine sample to be tested for albumin and creatinine to see how well your kidneys are working. (You will be mailed a container with detailed instructions before your appointment).
- Measure height, weight, waist, and blood pressure. Each will be done 2-3 times.
- Look at the skin on back of neck
- Blood will be taken from your arm to test blood sugar, hemoglobin A1c (measures average blood sugar over past 3 months), different types of fat, c-peptide (measures your own insulin production), cystatin-C and creatinine (measures kidney function), and diabetes antibodies (markers in the blood for type 1 diabetes). The total amount of blood drawn will be based on weight tables and will not exceed 3 tablespoons.
- If you agree, results commonly used in clinical practice (hemoglobin A1c, cholesterol, c-peptide, diabetes antibodies, and urine albumin/creatinine) will be shared with your doctor.

Mark the line that best matches your choice:

_____ OK to share results of the tests with my doctor
_____ Not OK to share results of the test with my doctor

- A sample of your blood, urine, and DNA may be saved after the visit, if you agree by signing the Stored Specimens Consent Form. Some of these saved samples may be used in the future for tests related to diabetes.
- After the blood and urine samples are obtained, you can take your pills or insulin and you will be given a snack.
- You will be asked questions about your diabetes, medical care, current medications, family history of diabetes, education, family income level, and health insurance.

Contact in the Future

The researchers will call your parent as new studies are developed in the future to let you know about new studies and ask you to take part in these studies. As with this study, taking part in any future study is voluntary. Taking part in the present study does not mean that you are agreeing to take part in any future study.

Mark the line that best matches your choice:

_____ OK to contact me in the future to tell me about other studies
_____ Not OK to contact me in the future to tell me about other studies

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved with being in this study?

The risks from drawing blood include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the chance of these risks, blood will be drawn by experienced staff and a local numbing medicine may be used before the blood is drawn to decrease any pain. The total amount of blood that will be drawn will be no more than 3 tablespoons (45cc) depending on your age and body size. When drawing your blood, our research staff will follow all necessary safety precautions. In the highly unlikely event that our study staff is accidentally exposed to your bodily fluids (blood or urine), we will abide by the South Carolina law that provides for testing of blood to minimize threats to the health of the staff. You will be notified should this testing be necessary and the results will be reported as required by law.

You need to not eat any food or drink anything other than water overnight before you have the blood tests. In order to limit low or high blood sugars, your blood sugar will be checked and your diabetes medicine or a fast-acting carbohydrate will be given as needed.

Some of the tests will look for the presence or risk of getting problems from diabetes. If these tests identify problems from diabetes or risk of getting these problems, the results may make you worried. If this happens, you will be referred to your diabetes care provider or a local mental health professional.

Other possible risks include loss of privacy or confidentiality. Loss of privacy might happen if someone could overhear or see you taking part in the study. To limit this, we will do the study visit in a private location. Information collected will be stored in a locked filing cabinet or in a password-protected electronic file.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

If you choose not to be in the study, how does this affect your medical care?
Whether you decide to take part or decline to take part in this study, your decision will not affect your medical care.

What if we learn about new findings or information during the study?
You will be given any new information gained during the study that might affect your willingness to continue to take part.

How will your privacy be protected?
SEARCH staff will keep the information collected, tests done, and samples stored strictly private. This is so because the study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

When you enter the study, a special number will be given to you. The number will be used to identify the information and laboratory tests that will be done during this study. The special number and the information collected during this study will be sent to Wake Forest University in order to study the information. Blood and urine specimens will be sent to the University of Washington for testing or storage. The list containing the special number assigned to you will be kept in a secure, password-protected database at the Carolina SEARCH site. So, no one other than the study investigators (Dr. Mayer-Davis at the University of North Carolina (UNC), Dr. Nelson at Greenville Health System (GHS), Dr. Bowlby at the Medical University of South Carolina (MUSC), Dr. Turley at the University of South Carolina (USC)) and the SEARCH Carolina research team will be able to access this database and link the information collected in the study to you. Paper forms collected during the study will be stored in a locked filing cabinet.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill and your local data collection site (GHS, MUSC, or USC) will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of UNC-Chapel Hill or your local data collection site (GHS, MUSC, or USC), research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, or your parents can withdraw you, without penalty.

Will you receive anything for being in this study?
You will get $40 in gift cards for taking part in this study along with an extra $20 gift card for bringing in your first morning urine collection. Your parents will also get $20 in gift cards at the end of the visit. In the rare circumstance that a blood redraw or repeat urine is necessary; you would receive an additional $20 gift card.

Your parents will also get additional incentive to assist with travel costs, if you and your parent traveled a significant distance to do the study visit. This additional incentive will be: two $20 gift cards if you traveled 70-100 miles round trip, three $20 gift cards if you traveled 101-150 miles round trip, or four $20 gift cards if you traveled more than 151 miles round trip. Travel distance will be determined based on your current home address and the location of the SEARCH visit.

Who is sponsoring this study?
This research is funded by the Centers for Disease Control and Prevention and the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at Greenville Health System (864-522-2097;email jhayes@ghs.org) or at UNC-Chapel Hill (919-966-3113; email: IRB_subjects@unc.edu).

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Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

Principal Investigators:
Elizabeth Mayer-Davis, PhD (UNC-Chapel Hill Coordinating Site);
Bryce Nelson, MD, PhD (GHS data collection site)
Deborah Bowlby, MD (MUSC data collection site)
Christine Turley, MD (USC data collection site)

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Your signature if you agree to be in the study Date

_____
Printed name if you agree to be in the study

_____ _____
Signature of Research Team Member Obtaining Assent Date

_____
Printed Name of Research Team Member Obtaining Assent

Parental Permission for a Minor Child to Participate in a Research Study
SEARCH 4 Registry Study Visit

UNC IRB Study #10-2341
Consent Form Version Date: February 2016

Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

SEARCH Carolina Site Principal Investigators:
University of North Carolina-Chapel Hill, Coordinating Site: Elizabeth Mayer-Davis, PhD (919-966-1991)
Greenville Health System, Data Collection Site: Bryce Nelson, MD (864-454-5100)
Medical University of South Carolina, Data Collection Site: Deborah Bowlby, MD (843-792-6807)
University of South Carolina, Data Collection Site: Christine Turley, MD (803-576-5926)
Funding Source and/or Sponsor: Centers for Disease Control and Prevention and National Institutes of Health/NIDDK
Study Contact telephone number: local numbers given above or studywide toll-free at 866-595-2397
Study Contact email: search.study@unc.edu

What are some general things you and your child should know about research studies?

You are being asked to allow your child to take part in a research study. To join the study is voluntary. You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason. Even if you give your permission, your child can decide not to be in the study or to leave the study early.

Research studies are designed to obtain new knowledge that may help other people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher or with the health care provider. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study. You will be given a copy of this permission form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you or your child have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn about diabetes in children and young adults. Diabetes is the third most common life-long disease in people under 20 years of age. We are

asking your child and other youth with diabetes to be in the research, because we want to count the number of children and teens with diabetes. We also want to learn more about all the types of diabetes that affect children and teens.

Your child is being asked to be in the study because he/she has diabetes and was under age 20 and living in South Carolina around the time the diabetes started.

Are there any reasons your child should not be in this study?
Your child should not complete a study visit if currently pregnant. She may take part in the study visit when it has been at least four months after the end of the pregnancy.

How many people will take part in this study?
About 832 people at five sites across the US will take part in the Registry Study visit, including approximately 207 people from the Carolina SEARCH site.

How long will your child's part in this study last?
The Registry Study visit will take about an hour. We may contact you every year to be sure we have your correct contact information. If your address/phone number has changed, we may attempt to update your contact information through a public database, such as LexisNexis. If you and your child agree to have a sample of blood, urine or DNA stored following the Registry Study visit, it will be saved for 10 years after the end of funding for follow-up of SEARCH participants. After this time, stored samples will be destroyed.

What will happen if your child takes part in the study?
These are the things that will happen during the study:

- Your child will fast for 8-10 hours before the visit (no food or drinks, except water). Your child will not take your usual diabetes medicines until after he/she has eaten at the study visit.
- Bring in a sample of your child's urine to be tested for albumin and creatinine to see how well his/her kidneys are working. (You will be mailed a container with detailed instructions before your appointment).
- Measure your child's height, weight, waist and blood pressure. Each will be done 2-3 times.
- Look at the skin on the back of your child's neck.
- Blood will be taken from your child's arm to measure blood sugar, hemoglobin A1c (measures average blood sugar over past 3 months), different types of cholesterol (fat), c-peptide (measures your child's own insulin production), cystatin-C and creatinine (measures of kidney function), and diabetes antibodies (markers in the blood for type 1 diabetes). The total amount of blood drawn will be based on weight tables and will not exceed 3 tablespoons.

  If you agree, results commonly used in clinical practice (hemoglobin A1c, cholesterol, c-peptide, diabetes antibodies, and urine albumin/creatinine) will be shared with your child's doctor.

Mark the line that best matches your choice:

_____ OK to share results of the tests with my child's doctor
_____ Not OK to share results of the test with my child's doctor

- A sample of your child's blood, urine, and DNA may be saved after the visit, if you agree by signing the Stored Specimens Consent Form. Some of these saved samples may be used in the future for tests related to diabetes.
- After the blood and urine samples are obtained, your child can take his/her pills or insulin and will be given a snack.
- You will be asked questions about your child's diabetes, medical care, current medications, family history of diabetes, education, family income level and health insurance.

Contact in the Future

The researchers will call you as new studies are developed in the future to let you know about new studies and ask your child to take part in these studies. As with this study, taking part in any future study is voluntary. Taking part in the present study does not mean that you are agreeing to take part in any future study.

Mark the line that best matches your choice:

_____ OK to contact me/my child in the future to tell me about other studies
_____ Not OK to contact me/my child in the future to tell me about other studies

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. Your child will not benefit personally from being in this research study.

What are the possible risks or discomforts involved with being in this study?

The risks from drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the possibility of these risks, blood will be drawn by experienced staff and a local numbing medicine may be placed on the skin before the blood is drawn to decrease any pain. The total amount of blood that will be obtained will be no more than 3 tablespoons (45cc) depending on your child's age and body size. When drawing your child's blood, our research staff will follow all necessary safety precautions. In the highly

unlikely event that our research staff is accidentally exposed to your child's bodily fluids (blood or urine), we will abide by the South Carolina law that provides for testing of blood to minimize threats to the health of the staff. You will be notified should this testing be necessary and the results will be reported as required by law.

The blood tests require that your child not eat any food or drink anything other than water overnight. In order to limit low or high blood sugars, your child's blood sugar will be checked and his/her diabetes medication or a fast-acting carbohydrate will be given as needed.

Some of the tests will look for the presence or risk of developing of the complications of diabetes. If these tests identify complications of diabetes or risk of developing the

complications, the results may make you or your child anxious. If this happens, you will be referred to your child's diabetes care provider or a local mental health professional.
Other possible risks include loss of privacy or confidentiality. Loss of privacy might happen if someone could overhear or see you taking part in the study. To limit this, we will do the study visit in a private location. Information collected will be stored in a locked filing cabinet or in a password-protected electronic file.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

If you choose not to give permission for your child to be in the study, how does this affect your child's medical care?
You can still receive evaluation and treatment for your condition if you do not participate in this study. Your decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

What if we learn about new findings or information during the study?
You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will your child's privacy be protected?
SEARCH staff will keep the information collected, tests done, and samples stored strictly private. This is so because the study has been given a Certificate of Confidentiality. This means anything you or your child tells us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

When you enter the study, a special number will be given to your child. The number will be used to identify the information and laboratory tests that will be done during this study. The special number and the information collected during this study will be sent to Wake Forest University in order to study the information. Blood and urine specimens will be sent to the University of Washington for testing or storage. The list containing the special number assigned to your child will be kept in a secure, password-protected database at the Carolina SEARCH site. Thus, no one other than the study investigators (Dr. Mayer-Davis at the University of North Carolina (UNC), Dr. Nelson at Greenville Health System (GHS), Dr. Bowlby at the Medical University of South Carolina (MUSC), Dr. Turley at the University of South Carolina (USC)) and the SEARCH Carolina research team will be able to access this database and link the information collected in the study to your child. Paper forms collected during the study will be stored in a locked filing cabinet.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill and your local data collection site (GHS,

MUSC, or USC) will take steps allowable by law to protect the privacy of personal information. In some cases, your child's information in this research study could be reviewed by representatives of UNC-Chapel Hill or your local data collection site (GHS, MUSC, or USC), research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if your child is injured by this research?
All research involves a chance that something bad might happen. This may include the risk of personal injury. In spite of all safety measures, your child might develop a reaction or injury from being in this study. If such problems occur, the researchers will help your child get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill and your local data collection site (GHS, MUSC, or USC) have not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you and your child do not give up any of your legal rights.

What if you or your child wants to stop before your child's part in the study is complete?
You can withdraw your child from this study at any time, without penalty.

Will you or your child receive anything for being in this study?
You will receive a $20 gift card for completing the study visit. Your child will get $40 in gift cards for completing the study visit and an extra $20 gift card for bringing in the first morning urine collection. In the rare circumstance that a blood redraw or repeat urine is necessary, your child would receive an additional $20 gift card.

If you traveled a significant distance to complete this study visit, you will be provided additional incentive to assist with travel costs. This additional incentive will be: two $20 gift cards if you traveled 70-100 miles round trip, three $20 gift cards if you traveled 101-150 miles round trip, or four $20 gift cards if you traveled more than 151 miles round trip. Travel distance will be determined based on your current home address and the location of the SEARCH visit.

Will it cost you anything for your child to be in this study?
There will be no costs for being in the study

What if you are a student at MUSC or USC?
You may choose not to give permission for your child to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades. You will not be offered or receive any special consideration if your child takes part in this research.

What if you are an employee at MUSC, GHS, or USC?
Your child's taking part in this research is not a part of your job duties, and refusing to give permission will not affect your job. You will not be offered or receive any special job-related consideration if your child takes part in this research.

Who is sponsoring this study?

This research is funded by the Centers for Disease Control and Prevention and the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you or your child has questions about this study?

You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you or your child has questions about his/her rights as a research subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you or your child has questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at Greenville Health System (864-522-2097; email jhayes@ghs.org or UNC-Chapel Hill (919-966-3113 or by email to IRB_subjects@unc.edu).

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Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

Principal Investigators:
Elizabeth Mayer-Davis, PhD (UNC-Chapel Hill Coordinating Site);
Bryce Nelson, MD, PhD (GHS data collection site)
Deborah Bowlby, MD (MUSC data collection site)
Christine Turley, MD (USC data collection site)

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Printed Name of Research Subject (Child)

_____ _____
Signature of Parent Date

_____
Printed Name of Parent

_____ _____
Signature of Research Team Member Obtaining Permission Date

_____
Printed Name of Research Team Member Obtaining Permission

Assent to Participate in a Research Study
Minor Subjects (7-14 yrs), SEARCH 4 Registry Study Visit

UNC IRB Study #10-2341
Consent Form Version Date: February 2016

Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

People in charge of the study:
University of North Carolina-Chapel Hill, Coordinating Site: Elizabeth Mayer-Davis, PhD (919-966-1991)
Greenville Health System, Data Collection Site: Bryce Nelson, MD (864-454-5100)
Medical University of South Carolina, Data Collection Site: Deborah Bowlby, MD (843-792-6807)
University of South Carolina, Data Collection Site: Christine Turley, MD (803-576-5926)
Study Contact telephone number: local numbers given above or studywide toll-free at 866-595-2397
Study Contact email: search.study@unc.edu

The people named above are doing a research study.

These are some things we want you to know about research studies:
Your parent needs to say it is okay for you to be in this study. You do not have to be in this study if you don't want to, even if your parent says it is okay for you to be in the study.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

Sometimes good things happen to people who take part in studies, and sometimes things we may not like happen. We will tell you more about these things below.

Why are they doing this research study?
The reason for doing this study is to find out how many young people have diabetes in your area. We want to learn more about the types of diabetes young people have. We want to learn more about your health, and how diabetes affects you and your family.

Why are you being asked to be in this research study?
You are being asked to be in this study because you have diabetes and you found out you had diabetes when you were a child.

How many people will take part in this study?
About 832 people at five sites in the U.S. will take part in this study, including about 207 people from South Carolina.

What will happen during this study?

During this study we will ask to:

- Measure you and check your blood pressure. This will be a lot like when they measure you at your doctor's office.
- Take some blood from your arm with a needle and do some special tests that tell us about your diabetes.
- Take some blood from your arm with a needle and look at some of the genes that we know have something to do with diabetes. If you agree, a sample from this blood will be kept in a freezer until we do tests on it.
- Test some of your urine to see if diabetes is changing the way your kidneys work.
- Have your parent/guardian fill in some forms about how to best contact you and also about who you see for your diabetes care.

- This study visit will last about 60 minutes.

Who will be told the things we learn about you in this study?

SEARCH staff will keep the things we learn private, but we must report to the state if we feel you are being hurt or if you tell us you are planning to hurt yourself or others. If you tell us you are planning to hurt yourself or others, we will also tell your parents.

When you start in SEARCH, a special number is given to you. The number is used to mark all the forms and blood tests we do with you. The special number and the forms will be sent to Wake Forest University. Blood and urine will be sent to the University of Washington to test or store. The list showing the special number given to you will be kept in a password-protected database. Only the people listed on the first page or others working with the Carolina study site will be able to see this list.

What are the good things that might happen?

People may have good things happen to them because they are in research studies. These are called "benefits." You will not benefit from being in this research study.

What are the bad things that might happen?

Sometimes things happen to people in research studies that may make them feel bad. These are called "risks." These are the risks of this study:

- It may hurt when you have your blood drawn and you may get a bruise. We can put some medicine on your skin to make it hurt less.
- You need to come to the visit without eating anything the night before your visit. This may affect your blood sugar. We will test your blood sugar and you may take your diabetes medicine or eat a snack to help your blood sugar.

Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. You should report any problems to the researcher

What if you or your parents don't want you to be in this study?
It is okay if you or your parents don't want to be in this study. This will not affect the care you get.

Will you get any money or gifts for being in this research study?
You will receive $40 in store gift cards for being in this study plus an extra $20 for bringing in your first morning urine collection. If we are not able to get your blood and you return for a 2nd blood draw or you need to do a 2nd urine collection, you will get another $20 gift card.

Your parents will get $20 in gift cards for being in the study.

Who should you ask if you have any questions?
If you have questions you should ask the people listed on the first page of this form. If you have other questions, complaints or concerns about your rights while you are in this research study you may contact the Institutional Review Board at Greenville Health System (864-522-2097; email: jhayes@ghs.org) or at UNC-Chapel Hill (919-966-3113; email:IRB_subjects@unc.edu).

Title of Study: SEARCH for Diabetes in Youth 4 (SEARCH 4), Registry Study Visit

Principal Investigators:
Elizabeth Mayer-Davis, PhD (UNC-Chapel Hill Coordinating Site);
Bryce Nelson, MD, PhD (GHS data collection site)
Deborah Bowlby, MD (MUSC data collection site)
Christine Turley, MD (USC data collection site)

If you sign your name below, it means that you agree to take part in this research study.

_____ _____
Sign your name here if you want to be in the study Date

_____
Print your name here if you want to be in the study

_____ _____
Signature of Research Team Member Obtaining Assent Date

_____
Printed Name of Research Team Member Obtaining Assent

COMIRB
APPROVED
For Use
10-May-2016
09-May-2017

Principal Investigator: Dana Dabelea, MD, PhD
COMIRB No: Protocol 01-934
Version Date: 01/29/2016
Version No: 4.0

Study Title: SEARCH for Diabetes in Youth Registry Study

Assent Format for participants 8 - 13 years of age

What is this study about?
I am being asked to decide if I want to be in this research study. The goal of this study is to know more about diabetes in children and how it affects my life.

Why are you asking me?
I am being asked to be in the study because I have diabetes.

What do I have to do?
I know that to be in the study I will come to the clinic for one visit, for approximately 1 hour, which includes questionnaires, blood draw, urine collection and body measurements.

Will this hurt?
The blood draw might hurt but we can use a numbing cream so that you do not feel the pain.

Can I ask questions?
I asked any questions I have now about the study. All my questions were answered. I know that I can ask any questions about this study at any time. If I want to, I can call Dr. Dana Dabelea at (303) 724-4414.

Do I have to do this?
I know that I do not have to be in this study. No one will be mad at me if I say no.

I want to be in the study at this time. ☐ YES ☐ NO

I will get a copy of this form to keep.

Child's Printed Name: _____

Child's Signature: _____ Date: _____

Witness or Mediator: _____ Date: _____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of person obtaining assent: _____ Date: _____

COMIRB
APPROVED
For Use
10-May-2016
09-May-2017

Principal Investigator: Dana Dabelea, MD, PhD
COMIRB No: Protocol 01-934
Version Date: 04/15/2016
Version No: 4.0

Study Title: SEARCH for Diabetes in Youth Registry Study

You (in this form 'you' refers to you and/or your child) are being asked to participate in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?
You are being asked to take part in a research study called the SEARCH for Diabetes in Youth Registry Study because you have diabetes and were diagnosed under the age of 20. The study's aims are to count how many children have diabetes and determine whether diabetes is increasing in children and adolescents, to more accurately determine what type of diabetes you have, and to identify how diabetes affects the lives of youth with diabetes.

Diabetes is the third most common chronic disease in individuals under 20 years of age. The total number of cases of diabetes in this age group is increasing. Also, types of diabetes not seen previously in young people are now being seen. We do not know how many cases and types of diabetes in children and adolescents there are in the United States and whether diabetes is increasing. We also do not know the type of care young people with diabetes receive, or the effect of diabetes on their lives. Specifically, this project is interested in studying the following questions.

a. How many cases of diabetes are there in the United States in people under 20 years old?
b. How many new cases of diabetes develop every year?
c. What can we learn about each type of diabetes?
d. What medical care is given to youth with diabetes?
e. How does diabetes affect the lives of youth with diabetes?

What is the purpose of this study?
In this research study we want to learn more about diabetes in people less than 20 years of age. You are being asked to be in the study because you have diabetes and were under the age of 20 and living in Colorado when the diabetes started.

Are there any reasons you should not be in this study?
You should not complete a study visit if currently pregnant. You may take part in the study visit when it has been at least four months after the end of the pregnancy.

How long will your part in this study last?
The Registry Study visit will take about 60 minutes.

Other people in this study
Up to 10,500 youth less than 20 years old will be enrolled locally, and up to 30,000 youth less than 20 years old will be invited to participate nationally in this study. A total of approximately 832 people at five sites across the US will take part in the Registry Study visit, including approximately 220 people from the Colorado SEARCH site from 2016-2020.

What will happen if I take join the study?
A research team member will set up an appointment for you in the early morning. You will come to the appointment after not having anything to eat or drink other than water for 8-12 hours. You will not take your usual diabetes medicines until after you have been given breakfast during the appointment.

Before your child's scheduled appointment, you will be mailed a container with detailed instructions to collect the first morning urine the day of the study visit. You will be asked to bring this urine container with you to your visit. We may ask you to repeat the urine collection for research purposes; we will not know this until the sample is reviewed by the laboratory.

Laboratory Tests
When you arrive, blood will be taken from your arm to measure blood sugar, hemoglobin A1c (a measure of long-term blood sugar control), different types of cholesterol (fat), islet cell antibodies (markers in the blood for type 1 diabetes), c-peptide, and cystatin-C and serum creatinine (measures of kidney function). The total amount of blood drawn will be based on weight tables and will not exceed 3 tablespoons. The total amount of blood drawn will not exceed 3 tablespoons. The blood draw takes about 10 minutes. If you need numbing medicine for the blood draw, SEARCH staff can provide that.

If you agree, results commonly used in clinical practice (hemoglobin A1c, cholesterol, c-peptide, islet cell antibodies, and urine albumin/creatinine) will be shared with your doctor.

After the blood and urine samples are obtained, you can take your diabetes pills or insulin and will be given a snack.

Physical Exam and Questionnaires
After eating, we will ask you some questions about the medicines you uses. A physical examination will be done by trained study staff. The physical examination will include height, weight, waist measurement, blood pressure, and examination of the skin on the neck. Then you will fill out a brief form to update your contact information. We will also ask you about the type of providers you see for your diabetes care.

Medical Record Release
In the future, the SEARCH Study staff may ask you for permission to see your medical record. We are particularly interested in key medical events such as hospitalizations. If you give permission, you will be asked to sign a medical release form, which will specify which doctor's or health care professionals will be contacted.

What will happen to the specimens?
The blood, and urine will be sent to the study's central laboratory at the University of Washington, Northwest Lipid Research Laboratories, for storage and testing. These samples will be labeled with your unique study number. The laboratory will not be able to link the number to you. The list linking the number to you is kept at the SEARCH Colorado site in a password-protected file.

SEARCH may share your stored specimens with other investigators to be used for testing related to diabetes or associated complications. This would only be done after the investigators have submitted a proposal to use these specimens to the SEARCH Ancillary Studies Committee. The committee will review the proposal to ensure the proposed testing adequately relates to the goals of SEARCH.

Central Storage Facility at the National Institutes of Health

We are asking if you would agree that some of the remainingblood, urine and DNA samples and data that are collected for that study may be sent to the central storage facility at the National Institute of Diabetes, Digestive and Kidney Diseases or NIDDK once the study is complete. This is a research resource supported by the National Institutes of Health or NIH. The facility collects, stores, and distributes biological samples and associated data from people with many kinds of disorders and from healthy people.

The purpose of this collection is to make samples and data available for use in research of the study of diabetes, obesity, and heart disease and their complications after the current study is completed. Sending data and samples may give scientists valuable research material that can be used to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists who want to use the samples and study data have to go through a formal proposal process and all proposals are reviewed by an external panel of experts.

Your samples and data will be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know the name, date of birth, medical record number, social security number, etc., of the person who donated the sample. Your child's donation is voluntary, and if you/your child choose not to participate there will be no penalty or loss of benefits to which you are entitled. **I**f you/your child agree donate samples, you can change your mind up until the end of the SEARCH study. When study researchers receive written instructions from you/your child, they will destroy your sample and all information that identifies your child. However, after we send the samples to the NIDDK repository at the end of the study, we will be unable to destroy your samples or data because it will be unlinked and impossible for us to identify which samples or data belong to you.

Full Gene Analysis (looking at all of your genes) and the National Storage Center (NIH/dbGaP)
As a part of the SEARCH study, your DNA may be analyzed to identify a complete picture of your genetic makeup. This is called Genome Wide Association (GWAS). This information would be sent to a national data bank to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies or diabetes or other conditions. No personal information would be included, such as name, date of birth, or address. Thus, researchers would not be able to link this information back to you.

_____ I agree to allow information about my DNA to be included in the NIH data bank.

_____ I do not agree to allow information about my DNA to be included in the NIH data bank.

Participation in this study is voluntary and you may choose to withdraw from the study at any time. You may request that your stored samples be permanently removed from the Central Laboratory if you choose to withdraw consent. To request that your sample be permanently removed from the central laboratory, contact:

Dr. Dana Dabelea
UCD Colorado School of Public Health
Dept. of Epidemiology
Bldg 500, Box B-119
Aurora, CO 80045
Ph. (303) 724-4414 FAX (303) 724-4491

We will send a request to the central laboratory and they will then destroy the samples and send us a letter certifying that the sample has been destroyed. We will send you a copy of this letter. However, please note that if you request for your samples or data to be destroyed after the conclusion of the study, we will be

unable to destroy samples and data that were sent to the NIDDK Repository and/or the dbGaP data bank. All samples held at the central laboratory at the University of Washington can be destroyed at any time.

Please read each sentence below and think about your choice. After reading each sentence, check "Yes" or "No" and write your initials. If you have questions, please talk to the SEARCH study staff, Dr. Dabelea or your healthcare provider. Remember, no matter what you decide to do about the storage and future use of your data, blood, DNA, and urine samples, you may still take part in the study.

1. I wish to have the results of my blood and urine tests given to my doctor or diabetes care provider.

☐ Yes ☐ No _____Initials

2. I give my permission for my blood and urine samples to be stored in a central laboratory at the University of Washington, Seattle for future use by study investigators in studies of diabetes and diabetes risk factors and complications.

☐ Yes ☐ No _____Initials

3. I give my permission for my DNA (genes) blood sample to be tested for inherited factors in the development of diabetes, diabetes risk factors and complications.

☐ Yes ☐ No _____Initials

4. I give my permission for my DNA (genes) blood sample to be stored by the SEARCH study laboratory at the University of Washington, Seattle for future use in diabetes and diabetes-related studies.

☐ Yes ☐ No _____Initials

5. I give my permission for the results of my DNA analysis and associated data to be sent to a national storage center for future study on how genes may affect the risk of diseases such as asthma, cancer, diabetes and heart disease.

☐ Yes ☐ No _____Initials

6. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

☐ Yes ☐ No _____Initials

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Youwill not benefit personally from being in this research study.

What are the possible risks or discomforts involved with being in this study?
The risks from drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the possibility of these risks, blood will be drawn by experienced staff and a local numbing medicine may be placed on the skin before the blood is drawn to decrease any

pain. The total amount of blood that will be obtained will be no more than 3 tablespoons (45cc) depending on your age and body size. When drawing your blood, our research staff will follow all necessary safety precautions.

The blood tests require that you not eat any food overnight. In order to limit low or high blood sugars, your blood sugar will be checked and your diabetes medication or a fast-acting carbohydrate will be given as needed.

Some of the tests will look for the presence or risk of developing of the complications of diabetes. If these tests identify complications of diabetes or risk of developing the complications, the results may make you anxious. If this happens, you will be referred to your diabetes care provider or a local mental health professional.

Other possible risks include loss of privacy or confidentiality. Making sure that information about you remains private is important to us. To protect your privacy in this research study, we will assign a special number to you. This number will be used instead of your name to identify the information and laboratory tests collected during the study. The list containing the special number assigned to you is kept in a password-protected database at the University of Colorado Denver.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

Are there alternative treatments?
There are no treatments proposed in this study, and the decision to participate in this study will not affect your treatment. Blood and urine test results will be available approximately 3 months after the samples are collected. Someone from the study will explain the results to you if you wish. Your diabetes provider will also receive the results, if you have given your permission.

Who is paying for this study?
This research is being paid for by the Centers for Disease Control and Prevention (CDC) (PA number DP-10-001).

Will I be paid for being in the study?

You will be given a gift card worth $10 for completing the Initial Participant Survey. You will be given a gift card worth $40 for having a blood draw and an additional $40 in gift cards for completing the questionnaires and physical measurements. It is important for you to know that payment for participation in the study is taxable income. If needed, we can offer assistance with transportation to the visit. We may be asked to repeat your urine sample. You will be paid an extra $20 for providing these urine samples. You may be paid $5 for providing updated contact information annually (for years you do not come for a SEARCH Study visit).

Will I have to pay for anything? It will not cost you anything to be in the study.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If you drop out of the research study, you can request that all blood or DNA samples that have been collected be destroyed before the end of the study. 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 health care professionals are providing. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them. Significant new findings that relate to your participation in this study will be discussed with you and/or your health care provider with your permission.

Can I be removed from this study?
You may be taken out of this study if the study doctor thinks it is not safe for you to be in the study. You can be taken out of the study even if you do not want to leave the study. The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?
If you are hurt by this research, you should call Dr. Dana Dabelea immediately at (303) 724-4414. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for the care that is needed. You should inform your health care providers if you decide to participate in this research study. If you have questions about injury related to the research, you may call Dr. Dabelea and/or your private physician.

Who do I call if I have questions?
If you have questions right now, you can ask the person who is talking to you about this consent form. The researcher carrying out this study is Dr. Dana Dabelea. If you have questions, concerns or complaints later, you may call Dr. Dana Dabelea at (303) 724-4414. You will be given a copy of this form to keep. If you have questions about your rights as a subject in this study, you can call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055.

Who will see my research information?
The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institution involved in this study is the University of Colorado Denver. We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Dana Dabelea
UCD Colorado School of Public Health
Dept. of Epidemiology
Bldg 500, Box B-119

Aurora, CO 80045
Ph. (303) 724-4414 FAX (303) 724-4491

Both the research records that identify you and the consent form signed by you may be looked at by the following people:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), who are the sponsors paying for this study
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research purpose outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

- Wake Forest University Biostatistics Center Northwest Lipid Metabolism and Diabetes Research Laboratory
- NIH Genome-Wide Association Studies (GWAS) Repository dbGaP
- The National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK)
- IMS

Information about you that will be seen, collected, used and disclosed in this study:

- Age, sex, race/ethnicity
- Date of birth
- Date of diabetes diagnosis
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnoses, History and Physical, or laboratory studies, procedure results
- Research visit and research test records including questionnaires and physical examinations
- Blood, DNA and urine samples
- Results of genetic analyses and the associated data

What happens to Data, Blood and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, blood, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, blood, or other specimens collected from you.
- If data, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.

- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

All information gathered during this study will be held in strict confidence. Once you decide to join the research study, a unique number, called a research study number, will be assigned to you. The unique identifying number will be used instead of your name. The list linking the number assigned to you to your name will be kept in a locked file at the clinic site in Denver, Colorado. Thus, no one other than Dr. Dana Dabelea and her research team will be able to connect any of the research study information to you.

All answers that you give will be kept private. This is so because this study has been given a certificate of confidentiality. This means that anything you tell us will not have to be given to anyone even if a court orders us to do so unless you give permission. However, under the law we must report to the state suspected cases of child abuse or if you tell us you are planning to cause serious damage to yourself or others.

HIPAA Authorization for Optional Additional Study Procedures –

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.
Some of these optional procedures may involve genetic testing or the use of your genetic information. Your genetic information will be released to the NIH Genome-Wide Association Studies Repository.
If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Contact in the Future
We may contact you every year to be sure we have your correct contact information.
The researchers will also call you as new studies are developed in the future to let you know about new studies and ask you/your child to take part in these studies. As with this study, taking part in any future study is voluntary. Taking part in the present study does not mean that you are agreeing to take part in any future study.

_____ I agree for you to contact me/my child in the future to tell me about other studies

_____ I do not agree for you to contact me/my child in the future to tell me about other studies

Agreement to be in this study
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I choose to be in this study. I will get a signed and dated copy of this consent form. (Please initial all previous pages of the consent form).

Signature: _____ Print Name: _____ Date: _____
Parent or guardian if subject ≤ 17 years

Signature: _____ Print Name _____Date: _____
Subject >18 years

Consent form explained by: _____Date:_____
Signature Print Name

Witnessed by: _____Date:_____
Signature Print Name

Investigator's Signature: _____ Date: _____
Investigator must sign with 30 days

For children ages 14-17 who can read this form:

_____ Date_____
Child's Name

PROTOCOL TITLE: SEARCH for Diabetes in Youth Phase 4 – Registry Component

Principal Investigator: Dana Dabelea, MD, PhD
University of Colorado Denver

SUBJECT CONSENT FORM

January 2016

Project Description and Purpose: You (in this form "you" refers to you and/or your child) are being asked to participate in a research study to determine how many children have diabetes and to better determine what type of diabetes you have. You are being asked to participate in this study because you have diabetes and were diagnosed under the age of 20. This form is to help you decide if you want to take part in this research study. First, we want you to know that taking part is up to you. You may stop taking part at any time, without penalty or loss of care or services to which you are otherwise entitled. There will be approximately 125 people enrolled locally and 6000 enrolled nationally.

Diabetes is the third most common chronic disease in individuals under 20 years of age. The total number of cases of diabetes in this age group is increasing. Also, types of diabetes not seen before in young people are now present. We do not know if diabetes is increasing among Navajo Nation youth. We also do not know the type of care young people with diabetes get and the effect that diabetes has on their lives. This research study will explore these questions.

The purpose of this study is to learn:

a. How many cases of diabetes there are in parts of the United States in people under 20 years old;
b. Whether diabetes is increasing among youth in the United States;
c. What medical care is given, and;
d. How diabetes affects the lives of youth with diabetes.

Procedures: If you agree, you will be asked to complete one survey and have your medical records reviewed to get more information about your diabetes. If you were diagnosed in 2016 you will also be asked to participate in an in-person visit. All aspects of this study are for research purposes only and are in addition to your regular health care. You may choose not to take part in any part of this study.

1) Initial Participant survey (IPS): The questionnaire will gather information about your diabetes type, current treatment including the medications you take and you or your family's income and education. You may choose not to answer any questions at any time. If you need help with the form, a staff member will help you. An interpreter will be provided if you need help from a Navajo-speaking staff member. The estimated time to complete this survey is 15 minutes.

2) Medical Record Review: Your medical records will be reviewed to get information about your diagnosis. We will record your date of birth, date of diagnosis, type of diabetes, as well as your weight and height at diagnosis, and whether you had complications.

OFFICIAL USE ONLY

APPROVED: 2-16-2016 EXPIRES: 2-16-2017

Benny Becenti-Cyn

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD DATE SIGNED: 3-15-2016

3) <u>In person Visit</u>:

a) <u>Lab tests and physical exam</u>: You will be scheduled for a morning appointment. Before your scheduled appointment, you will be mailed or given a container with detailed instructions to collect your first urine at home on the morning of the visit. You will be asked to bring the urine container with you on the day of your visit. Your urine will be tested for microalbumin (small particles of protein) to see how well your kidneys are working. You will come to the visit after not having anything to eat or drink other than water for 8 to 12 hours. You will not take your diabetes pills or shots until after you arrive, and you should bring your medication with you. When you arrive, blood will be drawn from your arm to measure blood sugar, hemoglobin A1c, c-peptide (a measure of your insulin production), different types of cholesterol (fat), and auto-antibodies (markers in the blood for type 1 diabetes). After these tests are completed, you may take your medication and you will be given a breakfast snack.

After the breakfast snack, you will have a personal and family medical history and a short examination done by trained study personnel. The physical examination will include height, weight, waist measurement, blood pressure, and examination of the skin of the neck. The time to complete this section of the visit is about 30 minutes.

The total time for the in-person visit is approximately one hour.

Please read the following sections and initial each activity that you would like to participate in:

1. **Disclosure of laboratory results** to your diabetes provider and to the Navajo Nation: The research team will inform you of your test results that may affect your health or health care. With your permission, this information will also be shared with the health care providers who are taking care of you and given to the Navajo Nation.

I wish to have the results of my tests given to my diabetes care provider.

_____ Yes initial

_____ No initial

If yes, please indicate which record you would like us to use:

_____ Indian Health Service Clinic or Hospital - specify location:_____

_____ Other doctor or facility:

name: _____

address: _____

2. **Storage of blood and urine**: You are being asked for permission to use your blood and urine in future non-genetic studies by having a sample of your blood and urine stored. If you agree, an additional sample of blood (1.5 tablespoons) will be taken, and the excess urine sample will be saved. Your samples will be used only for obtaining information related to diabetes and its complications. Whenever possible, blood for storage will be drawn at the same time the other blood samples are being collected. If it is not possible, an additional needle stick will be required.

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APPROVED: 2-16-2016 EXPIRES: 2-16-2017

Benjamin Begaye - Pigman

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD DATE SIGNED: 3-15-2016

The specific test(s) to be done on the samples have not been established at this time. We expect that our studies of factors involved in diabetes and related conditions (such as high cholesterol and heart disease) will take some years to complete. We may never identify the specific factors involved in these conditions.

Your stored samples will be kept until the end of the study. A code number identifies samples and the link between the code and your personal information is stored in a password protected secure location at the local site in Shiprock, New Mexico. Your samples will not be directly identified with your name. Your samples would be released to a SEARCH investigator only after the SEARCH Executive Committee has approved the proposed study.

You may request that your sample be permanently removed at any time from the blood bank if you choose to withdraw your consent. To request that your sample be permanently removed from the blood bank, by completing and signing a "SEARCH-Navajo Study Withdrawal Form" that can be provided by the local SEARCH staff upon request, OR you may contact:

Dr. Dana Dabelea
University of Colorado Denver
CSPH Department of Epidemiology
13001 East 17th Place, Bldg 500, Box B119
Aurora, CO 80045
Ph. 303-724-4414 Toll free 1-866-484-3411 FAX 303-724-4491

I give permission for my **blood** to be stored in a central bank, at the University of Washington, for future use by the study investigators in studies of diabetes and diabetes risk factors and/or complications until study activities end in 2020:

_____ Yes initial
_____ No initial

I give permission for my **urine** to be stored in a central bank, at the University of Washington, for future use by the study investigators in studies of diabetes and diabetes risk factors and/or complications until study activities end in 2020:

_____ Yes initial
_____ No initial

3. **Future Contact:** If you agree to future contact, researchers can contact you, as new research studies are developed, to let you know about the studies and ask you to participate in these studies. As with the present study, participation in any future study is up to you. Taking part in the present study does not mean that you agree to take part in any future study.

_____ Yes initial
_____ No Initial

Risk: The blood tests require that you do not eat or drink anything overnight for 8 to 12 hours. You will need to check your blood sugar as you would at home and you may give yourself insulin or take sugar as needed to control your blood

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Benjamin Bennett-Pigman

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD DATE SIGNED: 3-5-2016

sugars. Approximately 3 tablespoons (45cc) of blood will be removed by putting a needle into your vein. This is the standard method used to obtain blood for tests. You will feel pain when the needle goes into the vein. To reduce the pain we can use a skin numbing cream (EMLA) before the blood is drawn. On rare occasions, EMLA cream may cause skin irritation. A bruise may form at the site.
Some of the tests will look for risk factors for complications of diabetes. If these tests identify complications of diabetes, the results may make you nervous or depressed about the complications. If this happens, you may be referred to a local mental health professional for evaluation and treatment.

Sample Storage Risks: You, your family, or your doctor will not receive results of these studies and the results will not become a part of your medical record because this research is not expected to affect your medical care. The study investigators will make every effort to maintain confidentiality by labeling your samples with a number rather than with your name or other personal information. However, in the unusual circumstance that your test results are unintentionally made known to a third party, or revealed to you because they are deemed to be important to your medical care, you will need to consider the risks associated with having this information. First, as with any medical study, there is a risk that the result may be in error. Next, having information that you are at risk for a condition related to that disease might be emotionally stressful. Knowing that you are at risk for a related condition might change your eligibility to obtain new health, disability, or life insurance.

There is a chance that this research project, like all research, may have other unforeseen risks, other than those listed above.

Benefits:

1. This study will allow collection of accurate data regarding diabetes in Navajo children and youth, like yourself.
2. Study results will help the understanding of diabetes in children and youth in the U.S. in different age and ethnic groups.
3. Information gained will aid in developing ways to tell what type of diabetes a child has, so there is less error in treating youth with diabetes.
4. You will benefit by having the most up to date blood testing done for antibodies (markers in the blood) and c-peptide (your body's response to the food you eat) levels to determine what type of diabetes you have. This may change your treatment of diabetes and make problems less likely.
5. Navajo Nation may benefit by having information on the types of diabetes found locally. Communities will also be able to determine if more youth are getting diabetes. This information will be important for improving care and focus on how to keep more kids from getting diabetes.

Alternative Treatments: There are no treatments proposed in this study, and the decision to participate in this study will not affect your medical care.

Source of Funding: This study is funded by the Centers for Disease Control and Prevention (CDC), grant no. U18DP006139-01.

Cost to Subject: There is no cost to you.

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Benny Bricarti - Chair

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD DATE SIGNED: 2-15-2016

Subject Payment: You or your parent/guardian will be given a gift card worth $10 for completion of the Initial Participant Survey. An additional $80 in gift cards will be given for completion of the blood draw and physical exam if eligible.

Study Withdrawal: You may choose not to enter the study or leave from the study at any time and your health care provider will continue to take care of you without you losing your medical care or services. Your doctor may also choose to take you out of the study at any time if he/she feels that it would be bad for your health to continue or risks are too severe. Important new findings that relate to your participation in this study will be discussed with you. As noted under the Storage of Blood and Urine section, you may ask to have any stored samples destroyed at any time.

Invitation for Questions: You will receive a copy of this consent form. Please ask questions about this research or consent either now or in the future. You may direct your questions to the Navajo Nation Human Research Review Board, whose toll free number is 1-877-873-4356, or to Dr. Dana Dabelea at 303-724-4414, Dr. Jeff Powell at 505-368-7450 or Beverly Becenti-Pigman at 928-871-6650. The SEARCH-Colorado toll free number is 1-866-484-3411. The SEARCH-Navajo toll free number is 1-800-549-5644 ext. 6322

If you have questions regarding your rights as a research subject, please call Beverly Becenti-Pigman at the Navajo Nation Human Research Review Board in Window Rock at 928-871-6650, toll free at 1-877-873-4356.

Confidentiality: Information about you will be confidential. Only study staff members employed by the Indian Health Service will be permitted access to your records and only for study purposes. Upon entry into the study, a unique number will be assigned to you. The number will be used to identify the information and laboratory tests that will be performed during this study. The unique identifying number and the information collected during this study will be sent to a central database at Wake Forest University in order to analyze the information. The list containing the number assigned to you will be kept in a locked file at the local site in Shiprock, New Mexico. Thus, no one other than the local research team will be able to link any of the information collected to you.

Your investigator, their research team and the CDC will treat your identity with professional standards of confidentiality. However, information form this study may be submitted to the sponsor. Medical records which identify you and the consent form signed by you may be inspected and/or copied by:

- The Centers for Disease Control and Prevention (CDC)
- The Department of Health and Human Services (DHHS) agencies
- COMIRB (Colorado Multiple Institutional Review Board)
- Navajo Nation Institutional Research Review Board

Safeguards will be used to protect your confidentiality, including rare situations where sharing your data with the above groups would be unavoidable for accomplishing the goals of the study. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

CDC Certification of Confidentiality: All answers that you give will be kept private. This is so because this study has been given a certificate of confidentiality. This means that anything you tell us will not have to be given 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 tell us you are planning to cause serious damage to yourself or others.

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Bev Becenti-Pigman

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD DATE SIGNED: 3-15-2016

Injury: If you are injured because of this study, your local Indian Health Service Medical Center or your tribal health care corporation will provide you with treatment in its usual manner. **If you have any questions about these issues, or believe that you have been treated carelessly in this study, please contact Beverly Becenti-Pigman at the Navajo Nation Human Research Review Board in Window Rock at 928-871-6650, toll free at 1-877-873-4356.** Any subject that feels they have been injured by this study will be referred to the local IHS or health care corporation facility study liaison for address of the complaints; and you may call: Dr. Dabelea at 303-724-4414, toll free at 1-866-484-3411; and/or Dr. Jeff Powell at 505-368-7450 toll free at 1-800-549-5644 ext. 6322.

AUTHORIZATION: I have read this paper about the study or it was read to me, I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be (or to have my child) in this study. I know I can stop being in the study at any time and I (my child) will still get the usual medical care. I will get a copy of this consent form (Initial all the previous pages of the consent form).

Signature: _____ Print Name: _____ Date: _____
Parent or Guardian if participant < 18 years

Thumb print (only if unable to sign):

Signature: _____ Print Name: _____ Date: _____
Participant > 18 years

Thumb print (only if unable to sign):

Consent form explained by:

Signature: _____ Print Name: _____ Date: _____

Investigator: _____ Date: _____

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This consent document is approved for use until:

Beverly Becenti-Pigman

Navajo Research Program Date

NAVAJO NATION HUMAN RESEARCH REVIEW BOARD DATE SIGNED: 3-15-2017

STUDY TITLE: SEARCH FOR DIABETES IN YOUTH
(STUDY VISIT: 2016 REGISTRY)

STUDY NUMBER: 2011-0407

FUNDING ORGANIZATION: Centers for Disease Control and Prevention; National Institutes of Health

Lawrence Dolan, MD
Name of Principal Investigator

513-636-2444
Telephone Number

INTRODUCTION

We are asking you to be in a research study so we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about diabetes in people less than 20 years of age.

We are asking you and others with diabetes to be in the research, because we want to count the number of children and teens with diabetes. We also want to learn more about all the types of diabetes that affect children and teens. There will be about 1,000 people invited to participate in this study.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Lawrence Dolan is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) who is in charge of this study.

CCHMC is being paid by the CDC (Centers for Disease Control and Prevention) and the NIH (National Institutes of Health) to do this study.

WHO SHOULD NOT BE IN THE STUDY

You cannot be in this study if you do not have diabetes.

- If you are pregnant, you will not be able to take part in the study visit until 4 months after delivery or end of the pregnancy.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain the visit to you. You will be able to ask questions to make sure you understand what will happen to you.

If you qualify and you decide you want to be in the study, you will come to CCHMC one time. This visit will last about one hour. You may be contacted once a year by mail to update any changes in your address or phone number. If your address/phone number has changed, we may attempt to update your contact information through a public database, such as LexisNexis.

These are the things that will happen to you while in the study:

- Fast for 8-10 hours before the visit (no food or drinks, except water)
- Bring in a urine sample to be tested for albumin and creatinine to see how well your kidneys are working
- Measure height, weight, waist, and blood pressure. Each will be done 2-3 times
- Look at skin on back of neck
- Blood will be taken from your arm or hand to measure blood sugar, hemoglobin A1c (measures average blood sugar over past 3 months), c-peptide (measures your own insulin production), creatinine and cystatin C (measure kidney function), different types of cholesterol (fat), and diabetes antibodies (markers in the blood for type 1 diabetes). The amount of blood needed for these tests is about 3 teaspoons

➢ If you agree, extra blood will be collected and saved for the duration of the study. This blood may be used in the future as new tests are developed to tell your type of diabetes and your risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and being overweight. The amount of blood needed is about 3¾ teaspoons.

☐ I agree to have my blood and urine stored. _____initials

☐ I do not agree to have my blood and urine stored. _____initials

- If you agree, extra blood will be collected for DNA. This blood sample may be tested to identify your genetic makeup. DNA testing may help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease. You will be notified of any significant results. Incidental results will not be reported to you. The amount of blood needed is about 1¾ teaspoons.

☐ I agree to have my blood stored and tested for DNA. _____initials

☐ I do not agree to have my blood stored and tested for DNA.

_____initials

- After the blood test is done, you will be given breakfast. You may take your diabetes medicine at that time.
- You will be asked questions about your diabetes, medical care, current medications, family history of diabetes, education, family income level, and health insurance.

Central Storage Facility at the National Institutes of Health

- If you agree, your blood, urine, DNA samples and data may be sent to the central storage facility at the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK). This is a research resource supported by the National Institutes of Health. This facility collects, stores, and distributes biological samples and associated data from healthy people and people with many kinds of disorders.

The purpose of this collection is to make samples and data available for use in research of the study of diabetes, obesity, and heart disease and their complications after the current study is completed. Sending data and samples may give scientists valuable research material that can be used to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists who want to use the samples and study data have to go through a formal proposal process and all proposals are reviewed by an external panel of experts.

Your samples and data will be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know your name, date of birth, medical record number, social security number, etc. Your donation is voluntary, and if you choose not to participate there will be no penalty or loss of benefits to which you are entitled. If you agree to donate samples, you can change your mind up until the end of the SEARCH study. When study researchers receive written instructions from you, they will destroy

your sample and all information that identifies you.

☐ I agree for my blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility.

_____initials

☐ I do not agree for my blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility.

_____initials

☐ I agree for my DNA to be donated to the NIDDK storage facility.

_____initials

☐ I do not agree for my DNA to be donated to the NIDDK storage facility.

_____initials

Full Gene Analysis and the National Data Storage Center

- If you agree, your DNA may be analyzed to identify a complete picture of your genetic makeup. This information would be sent to the National Institutes of Health (NIH) data storage center to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies of diabetes or other conditions. Your personal information, such as name, date of birth, etc. would not be included. Thus, researchers would not be able to link this information back to you.

☐ I agree to allow information about my DNA to be included in the NIH data storage center. _____initials

☐ I do not agree to allow information about my DNA to be included in the NIH data storage center. _____initials

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this research may not help you right now. When we finish the study, we hope that we will know more about diabetes. This may help others with diabetes later on.

As part of this research you will receive blood and urine test results at no

charge. At your request, we will send copies of your test results to your healthcare provider. This may allow the provider to change, if indicated, how they take care of your diabetes and to treat any complications that may be present.

- If you agree, your results will be shared with your provider(s).

☐ I agree to have my results shared with my healthcare provider. _____initials

☐ I do not agree to have my results shared with my healthcare provider. _____initials

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

The risks of drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the possibility of these risks, experienced medical staff will draw blood. A local numbing medicine may be placed on the skin before the blood is drawn to decrease any pain.

You will be fasting for 8-10 hours before your appointment. To help prevent and treat low or high blood sugars, your blood sugar will be checked; and you may take diabetes medicine or a fast-acting carbohydrate as needed to control the blood sugar level.

Some of the tests will look for the presence or risk of developing the complications of diabetes. If these tests identify complications of diabetes or risk of developing the complications, the results may make you anxious. If this happens, you will be referred to a local mental health professional for evaluation and treatment.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your privacy in this research study, we will assign a special number to you. This number will be used instead of your name to identify the information and laboratory tests collected during the study. The list containing the special

number assigned to you is kept in a password-protected database at CCHMC. Thus, no one other than Dr. Dolan and his research team will be able to link any of the information collected in the study to you.

WILL IT COST YOU ANYTHING EXTRA FOR YOU TO BE IN THE RESEARCH STUDY?

Your time is valuable and, therefore, would be the most costly part of your involvement in the study. The only other cost to you would be for transportation to and from the study site**.**

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be reimbursed for your time, effort and travel while you are in this research study.

You will be paid $60 for completing the study visit and an extra $20 for bringing in a 1st morning urine sample.

We may ask you to repeat your urine sample. You will be paid an extra $20 for providing this urine sample.

You will receive your payment in the form of a debit card (MasterCard); and you will be given a handout that will explain how to use the card.

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe you have been injured as a result of this research you should contact Dr. Dolan as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor, it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document. If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. We will use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the

laws that apply to them.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?
By signing this document you agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent — Date

_____ _____
Signature of Legally Authorized Representative* — Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent — Date

STUDY TITLE: SEARCH FOR DIABETES IN YOUTH
(STUDY VISIT: 2016 REGISTRY)

STUDY NUMBER: 2011-0407

FUNDING ORGANIZATION: Centers for Disease Control and Prevention; National Institutes of Health

Lawrence Dolan, MD
Name of Principal Investigator

513-636-2444
Telephone Number

INTRODUCTION

We are asking for your permission for your child to be in a research study so we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow your child to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about diabetes in people less than 20 years of age.

We are asking your child and other children with diabetes to be in the research, because we want to count the number of children and teens with diabetes. We also want to learn more about all the types of diabetes that affect children and teens. There will be about 1,000 people invited to participate in this study.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Lawrence Dolan is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) who is in charge of this study.

CCHMC is being paid by the CDC (Centers for Disease Control and Prevention) and the NIH (National Institutes of Health) to do this study.

WHO SHOULD NOT BE IN THE STUDY

Your child cannot be in this study if your child does not have diabetes.

- If your child is pregnant, she will not be able to take part in the study visit until 4 months after delivery or end of the pregnancy.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain the visit to you. You will be able to ask questions to make sure you understand what will happen to your child.

If your child qualifies and you decide you want your child to be in the study, your child will come to CCHMC one time. This visit will last about one hour. You may be contacted once a year by mail to update any changes in your address or phone number. If your address/phone number has changed, we may attempt to update your contact information through a public database, such as LexisNexis.

These are the things that will happen to your child while in the study:

- Fast for 8-10 hours before the visit (no food or drinks, except water)
- Bring in a urine sample to be tested for albumin and creatinine to see how well your child's kidneys are working
- Measure height, weight, waist, and blood pressure. Each will be done 2-3 times
- Look at skin on back of neck
- Blood will be taken from your child's arm or hand to measure blood sugar, hemoglobin A1c (measures average blood sugar over past 3 months), c-peptide (measures your child's own insulin production), creatinine and cystatin C (measure kidney function), different types of cholesterol (fat), and diabetes antibodies (markers in the blood for type 1 diabetes). The amount of blood needed for these tests is between ½ and 2½ teaspoons. Smaller amounts will be used for very young children

➢ If you agree, extra blood will be collected and saved for the duration of the study. This blood may be used in the future as new tests are developed to tell your child's type of diabetes and your child's risk of developing the complications of diabetes, insulin resistance (insulin is not working as well as it should), and being overweight. The amount of blood needed is about 3¾ teaspoons.

☐ I agree to have my child's blood and urine stored. _____initials

☐ I do not agree to have my child's blood and urine

stored. _____initials

- If you agree, extra blood will be collected for DNA. This blood sample may be tested to identify your child's genetic makeup. DNA testing may help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease. You will be notified of any significant results. Incidental results will not be reported to you. The amount of blood needed is about 1¾ teaspoons.

☐ I agree to have my child's blood stored and tested for DNA. _____initials

☐ I do not agree to have my blood stored and tested for DNA. _____initials

- After the blood test is done, your child will be given breakfast. Your child may take his/her diabetes medicine at that time.
- You will be asked questions about your child's diabetes, medical care, current medications, family history of diabetes, education, family income level, and health insurance.

Central Storage Facility at the National Institutes of Health

- If you agree, your child's blood, urine, DNA samples and data may be sent to the central storage facility at the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK). This is a research resource supported by the National Institutes of Health. This facility collects, stores, and distributes biological samples and associated data from healthy people and people with many kinds of disorders.

  The purpose of this collection is to make samples and data available for use in research of the study of diabetes, obesity, and heart disease and their complications after the current study is completed. Sending data and samples may give scientists valuable research material that can be used to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists who want to use the samples and study data have to go through a formal proposal process and all proposals are reviewed by an external panel of experts.

  Your child's samples and data will be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know your child's name, date of birth, medical record number, social security number, etc. Your child's donation is voluntary, and if you choose not to participate there will be no penalty or loss of benefits to which you are entitled. If you agree to donate samples, you can change your mind up until the end of the SEARCH study. When study researchers receive written instructions from you, they will destroy your sample and all information that

identifies your child.

☐ I agree for my child's blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility.
_____initials

☐ I do not agree for my child's blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility.
_____initials

☐ I agree for my child's DNA to be donated to the NIDDK storage facility. _____initials

☐ I do not agree for my child's DNA to be donated to the NIDDK storage facility. _____initials

Full Gene Analysis and the National Data Storage Center

- If you agree, your child's DNA may be analyzed to identify a complete picture of his or her genetic makeup. This information would be sent to the National Institutes of Health (NIH) data storage center to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies of diabetes or other conditions. Your child's personal information, such as name, date of birth, etc. would not be included. Thus, researchers would not be able to link this information back to you or your child.

☐ I agree to allow information about my child's DNA to be included in the NIH data storage center. _____initials

☐ I do not agree to allow information about my child's DNA to be included in the NIH data storage center. _____initials

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this research may not help your child right now. When we finish the study, we hope that we will know more about diabetes. This may help other children with diabetes later on.

As part of this research you will receive blood and urine test results at no charge. At your request, we will send copies of your child's test results to your child's healthcare provider. This may allow the provider to change, if indicated,

how they take care of your child's diabetes and to treat any complications that may be present.

- If you agree, your child's results will be shared with your child's provider(s).

☐ I agree to have my child's results shared with my child's healthcare provider. _____initials

☐ I do not agree to have my child's results shared with my child's healthcare provider. _____initials

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

The risks of drawing blood from a vein in the lower arm include mild pain, bruising at the site of the blood draw, and occasionally fainting. To lower the possibility of these risks, experienced medical staff will draw blood. A local numbing medicine may be placed on the skin before the blood is drawn to decrease any pain.

Your child will be fasting for 8-10 hours before your appointment. To help prevent and treat low or high blood sugars, your child's blood sugar will be checked; and your child may take diabetes medicine or a fast-acting carbohydrate as needed to control the blood sugar level.

Some of the tests will look for the presence or risk of developing the complications of diabetes. If these tests identify complications of diabetes or risk of developing the complications, the results may make you or your child anxious. If this happens, you or your child will be referred to local mental health professionals for evaluation and treatment.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to have your child be in it.

HOW WILL INFORMATION ABOUT YOUR CHILD BE KEPT PRIVATE?

Making sure that information about your child remains private is important to us. To protect your child's privacy in this research study, we will assign a special number to your child. This number will be used instead of your child's name to identify the information and laboratory tests collected during the study. The list containing the special number assigned to your child is kept in a password-protected database at CCHMC. Thus, no one other than Dr. Dolan and his research team will be able to link any of the information collected in the

study to your child.

WILL IT COST YOU ANYTHING EXTRA FOR YOUR CHILD TO BE IN THE RESEARCH STUDY?

Your time is valuable and, therefore, would be the most costly part of your involvement in the study. The only other cost to you would be for transportation to and from the study site**.**

WILL YOU/YOUR CHILD BE PAID TO BE IN THIS RESEARCH STUDY?

You and your child will be reimbursed for your time, effort and travel while you are in this research study.

Your child will be paid $40 for completing the study visit and an extra $20 for bringing in a 1st morning urine sample.

You will receive $20 for completing the study visit.

We may ask your child to repeat the urine sample. Your child will be paid an extra $20 for providing this urine sample.

You will receive your payment in the form of a debit card (MasterCard); and you will be given a handout that will explain how to use the card.

WHAT HAPPENS IF YOUR CHILD IS INJURED FROM BEING IN THIS STUDY?

If you believe that your child has been injured as a result of this research you should contact Dr. Dolan as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If your child goes to the Emergency Room or to another hospital or doctor, it is important that you tell them that your child is in a research study. If possible, you should give them a copy of this parental permission form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document. If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or

complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's CCHMC medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Because this research study involves payment for participation we are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. We will use your SSN to keep track of how much money we pay you and your SSN will not be used as part of this research.

Who will share, receive and/or use your child's protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your child's PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who

receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?
By signing this document you agree for your child to participate in this research study and give permission to CCHMC to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent — Date

_____ _____
Signature of Parent or Legally Authorized Representative* — Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent — Date

SEARCH for Diabetes in Youth

PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up
ASSENT FORM: Ages 13-17

SEARCH 4 REGISTRY VISIT (2016 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
Joyce Yi-Frazier, PhD	Co-Investigator	Endocrinology	206 987-5037
Daksha Ranade	Co-Investigator	Research Informatics	206 987-5037
Eric Tham, MD MS	Co-Investigator	Information Services	206 987-5037
Davene Wright, PhD	Co-Investigator	CHBD	206 987-5037
Carla Greenbaum, MD	Co-Investigator	Benaroya Research Institute	206 987-5037
Martin Goldsmith, MD	Co-Investigator	Peds Northwest	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
Helen Dichek, MD	Co-Investigator	Endocrinology	206 987-5037
Millie Nandi-Munshi, MD	Co-Investigator	Endocrinology	206 987-5037
Faisal Malik, MD	Co-Investigator	Endocrinology	206 987-5037

Name/Degree	Title	Department	Phone Number
Lina Merjaneh, MD	Co-Investigator	Endocrinology	206 987-5037
Sara DiVall, MD	Co-Investigator	Endocrinology	206 987-5037
Grace Kim, MD	Co-Investigator	Endocrinology	206 987-5037
Parisa Salehi, MD	Co-Investigator	Endocrinology	206 987-5037
Jason Mendoza, MD, MPH	Co-Investigator	CHBD	206 987-5037
Erin Alving, ARNP, CDE	Co-Investigator	Endocrinology	206 987-5037
Karen Aitken, ARNP, BC-ADM	Co-Investigator	Endocrinology	206 987-5037
Sara Benitez, PA-C	Co-Investigator	Endocrinology	206 987-5037
Gwyn Recupero, ARNP, CDE	Co-Investigator	Endocrinology	206 987-5037
Alfonzo Armstead, PA-C	Co-Investigator	Endocrinology	206 987-5037
Vanessa Waldrep, ARNP	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
Katherine Cochrane, BS	Clinical Research Associate	Endocrinology	206 987-2540
Michael Pascual, BA	Clinical Research Associate	Endocrinology	206 987-2540
Natalie Beauregard, BA	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.

Joining the study as a parent:
Parents also have the option to take part in this research study. There is a page at the end of this form explaining what it would mean to participate as a parent.

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 life-long disease in children and young adults. 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.

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

- How common is diabetes in the United States among youth?
- What are the characteristics of each type of diabetes in youth?
- 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 visit because you have any type of diabetes, were diagnosed under the age of 20 in 2016, and lived in King, Kitsap, Pierce, Snohomish, or Thurston County in 2016.

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

We think that about 2,765 people will take part in the SEARCH 4 registry study at the Seattle site. About 155 people at our site will complete a registry study visit.

A total of about 14,500 people will take part in the registry study studywide. About 830 people will do a registry study visit at hospitals and clinics around the country.

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

The registry study visit includes:

- Blood draw
- Urine collection
- Brief physical exam
- Questionnaires
- Medical record review
- Follow up contact

Blood Draw and Urine Collection

You 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 would mean that you could consume no food or fluids, other than water, for at least 8 hours before coming to your visit. You 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 on how to collect one urine sample at home the morning of your visit. We would 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. We may ask you to repeat the urine collection at a later date, if the study laboratory determines that the first sample was inadequate.

When you arrive at your appointment, we would review the consent/assent form(s). This would take about 20 – 30 minutes. If you 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 arm to measure blood sugar, hemoglobin A1c (a test measuring your average blood glucose level over the past 3 months), different types of cholesterol (fat), islet cell antibodies (markers in the blood for type 1 diabetes), and cystatin-C and serum creatinine (measures of kidney function). If you agree to this part of the research, we would take DNA samples and samples for storage and future research.

Based on age and size, the total amount of blood that would be taken would be between 1 teaspoon and 3 tablespoons. If possible, we would collect the blood sample at the same time that a routine blood draw would be done. If you were to take part in more than one research study at the same visit, we would try to combine tests and results when we could.

This part of the visit would take 10 – 20 minutes.

After the fasting blood samples are collected, a breakfast or meal voucher would be provided and you 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 on the neck. The time to complete this exam would be about 20 minutes.

Questionnaires

Prior to or at your visit, you would 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 life, your family's education and income level, and general medical care. During your visit, we would ask some questions about the medications that you take. If you are 10 years of age or older, you would be asked to answer questions about the food that is available to eat and how this makes you feel. If you are 18 years old or older, we would ask you about any food assistance that you may receive; and we would ask you about your employment and income. If it looks like it is difficult for you to access food, we may refer you to a social worker to help you find available resources. We would ask your parents similar questions. We would also ask you to update your contact information. These surveys would take about 25 minutes.

Medical Record Review

The study team may review your child's medical record now or in the future. We are particularly interested in key medical events such as hospitalizations. We may ask you to sign a release form to allow us to access those 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 would send you periodic requests to update your contact information. Part of this update may include a question about your social security number, which we would use to track mortality among SEARCH study participants. If this study is expanded, or if other diabetes studies are developed, we may contact you in the future to ask if you want to participate further. As with this study, taking part in any future study is voluntary.

What would happen to the data and specimens?

Your blood, DNA, and urine would be sent to the study's central laboratory at the University of Washington, Northwest Lipid Research Laboratories for storage. These samples would be linked with your unique study number. The laboratory would not be able to link the number to you.

The SEARCH study would 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 the tests, the storage sample would allow us to repeat the tests without needing to ask for a second blood draw from you. In addition, we would collect a 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.

SEARCH might share your stored specimens with other investigators to be used for testing related to diabetes or associated complications. This would only be done after the investigators have submitted a proposal to use these specimens to the SEARCH Ancillary Studies Committee. The committee would review the proposal to ensure the proposed testing adequately relates to the goals of SEARCH.

Central Storage Facility at the National Institutes of Health

We are asking if you and your child would agree that the blood, urine and DNA samples and data that are collected for that study may be sent to the central storage facility at the National Institute of Diabetes, Digestive and Kidney Diseases or NIDDK. This is a research resource supported by the National Institutes of Health or NIH. The facility collects, stores, and distributes

biological samples and associated data from people with many kinds of disorders and from healthy people.

The purpose of this collection is to make samples and data available for use in research of the study of diabetes, obesity, and heart disease and their complications after the current study is completed. Sending data and samples may give scientists valuable research material that can be used to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists who want to use the samples and study data have to go through a formal proposal process and all proposals are reviewed by an external panel of experts.

Your samples and data would be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know the name, date of birth, medical record number, social security number, etc., of the person who donated the sample. Your donation is voluntary, and if you choose not to participate there will be no penalty or loss of benefits to which you are entitled. If you agree to donate samples, you could change your mind up until the end of the SEARCH study. When study researchers receive written instructions from you, they would destroy your sample and all information that identifies you.

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

As a part of the SEARCH study, your child's DNA may be analyzed to identify a complete picture of his or her genetic makeup. This is called Genome Wide Association (GWAS). This information would be sent to a national data bank to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies or diabetes or other conditions. No personal information would be included, such as name, date of birth, or address. Thus, researchers would not be able to link this information back to you or your child.

7. How long would I be in the study?

The study is currently funded through September 2020. The time to complete the registry visit would be about 1 hour.

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 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.

Some of the questions we ask may be sensitive in nature and may make you feel embarrassed or upset. You are free to not answer any questions you don't want to answer, and you may stop taking any survey at any time. If you decide not to answer any of the questions, you can still take part in the rest of the research study.

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 not have any food or fluids overnight, other than water. In order to prevent low or high blood sugars, your blood sugar would be checked by finger-stick and your diabetes medication would be given as needed to control your 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 some anxiety or concern. If this happens, you 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.
- Someone could 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. However, they do 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 may not directly benefit from participating in this research study. However, this study may more clearly tell us about your type of diabetes and whether you have complication of diabetes.

You and your doctor would receive results commonly used in clinical practice (hemoglobin A1C, lipid profile (cholesterol, c-peptide, islet cell antibodies, and/or urine albumin/creatinine. You and your 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 may choose not to take part in this study or in parts of the study.

11. What about confidentiality and privacy?

If you join the study, we will keep your information confidential as provided by law.

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history,
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
- If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).

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 information may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

There is no time limit for the use or sharing of your information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about you, but information that has already been collected may still be used and shared with others.

We will also put information from this study in your medical records, including this form, because this study involves your care. Medical records have different rules than research records. They are permanent and may be seen by others involved in your care, such as doctors, insurers, and others as required by law.

The use or sharing of your information will follow privacy laws, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as

part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you would not be used.

Your permission is documented by signing this form below. If you decide that we cannot use or share your information, you cannot participate in this study.

Teen Participants
You may agree to the use or sharing of certain kinds of information on your own. Please consider whether we may use or share the information listed below for this research. If you agree, please mark your permission with your initials.

____ Behavioral or mental health/illness, including psychotherapy notes (13 and above)
____ Drug or alcohol abuse, diagnosis, or treatment (13 and above)

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.

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 a $10 gift card for completion of the Initial Participant Survey, and an $80 gift card for completion of the registry visit. If you are fasting for the visit, we would provide a $6 breakfast voucher, or breakfast, after you complete the blood draw.

We may ask you to repeat your urine sample if the central laboratory says that a second sample is needed. You would be given an extra $20 gift card for providing this extra urine sample. In the rare circumstance that a blood redraw is necessary, you would receive an additional $20 gift card.

You may also be given a $5 gift card for providing updated contact information annually (for the years you do not come for a SEARCH study visit).

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 data and/or 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 contact if I have problems, questions, or want more information?

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

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	Diabetes Research Team	Phone: 206-987-2540
• Your rights as a research participant • Study questions, concerns or complaints • Contacting someone outside of study team	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

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. If you decide to stop participation in the study, the data collected until the time you withdraw will remain part of the study database and may not be removed. In addition, we will ask you if you want to provide further data collection from routine medical care.

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.
- You permit the creation, use, and sharing of your health information for the purposes of this research study as described in Section 11 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.

_____
Printed Name of Research Participant

_____
Signature of Research Participant (required if 13 years or older)

_____ _____
Date *Time*

_____
Printed Name of Parent or Legally Authorized Representative

_____
Signature of Parent or Legally Authorized Representative

_____ _____
Date *Time*

For study team use only:

If signature of second parent not obtained, indicate why: (select one)

- ☐ The IRB determined that the permission of one parent is sufficient.
- ☐ Second parent is deceased, unknown, incompetent or not reasonably available
- ☐ Only one parent has legal responsibility for the care and custody of the child

For study team use only (fill out for any enrolled minors and any enrolled adult participants incapable of providing consent):

Assent

- ☐ Obtained
- ☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Permissions:

Storage of Blood and Urine Samples

Do you give permission to have your 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 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 diabetes provider?

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

Central Storage Facility at the National Institutes of Health

Do you agree for your blood and urine samples and SEARCH study data to be donated to the NIDDK storage facility?

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

Do you agree for your DNA to be donated to the NIDDK storage facility?

- ☐ 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 DNA included in the NIH data bank? Your DNA would be analyzed to identify a complete picture of your genetic makeup. This is called Genome Wide

Association (GWAS). This information would be sent to a national data bank to help researchers better understand how genes affect the risk of developing diseases. The data may be included in larger studies on diabetes or other conditions. 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 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 in the future, to ask if you 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 are automatically volunteering to take part in any future studies. You would be asked to sign a consent form for any future research studies in which you 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*

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

PARENT PARTICIPANT ADDENDUM

Parent Participants

Why do parents have the option of taking part?
As a part of this research study, we would like to ask you to complete a brief survey on the amount of food that is available in your household and any assistance you may receive to provide enough food for your family. If it looks like it is hard for you to access food, we may refer you to a social worker to help you find available resources. This study will look at how difficult it is for families of youth with diabetes to access food and how that may affect youth with diabetes. Completing this questionnaire should take about 5 minutes.

Do parents have to take part?
Taking part in research is optional. If you decide not to join you will not be penalized or lose any benefits that you are otherwise entitled to.

What are the possible risks?
The main risk of participating as a parent participating in this study would be breach of confidentiality. Some of the questions may be sensitive in nature and may make you feel embarrassed or upset. You are free not to answer any questions you don't want to answer, and you may stop taking the survey at any time. If you decide not to answer any of the questions, you can still take part in the rest of the research study.

What are the possible benefits?
We do not expect you to benefit directly from participating in this research study. We hope that the information learned in this research study will benefit young people with diabetes in the future.

How will you protect my information and privacy?
The same general rules and procedures as discussed above about your child's information will apply to the use and sharing of your information. The information will relate to you and your

health, it may be used by or shared with others involved in these research or in future research studies, and its use or sharing will be consistent with the purpose for which it was collected.

You can find the rules and procedures in the form under the section "What about confidentiality and privacy?

Can I change my mind?
You can decide to take part and change your mind at anytime. Taking part in research is voluntary.

If you have questions about the study, your rights, or feel you have been harmed by the study, please contact the study team members listed on the front of this form.

What would my signature mean?
- You agree to take part in the research study.
- You permit the creation, use, and sharing of your health information for the purposes of this research study
- You keep all your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.

_____
Printed Name of Parent or Legally Authorized Representative

_____
Signature of Parent or Legally Authorized Representative

_____ _____
Date *Time*

_____
Printed Name of Parent or Legally Authorized Representative

_____
Signature of Parent or Legally Authorized Representative

_____ _____
Date *Time*

Original form to:
Research Team File
Copies to:
Participant
Parents/Guardians (if applicable)
Medical Records (if applicable)