DATA USE AGREEMENT FOR DISCLOSURES TO A LIMITED DATA SET RECIPIENT WHO IS NOT A KAISER PERMANENTE WORKFORCE MEMBER

This Data Use Agreement ("Agreement") with respect to a Limited Data Set is entered into by and between Southern California Permanente Medical Group (hereafter referred to as "Data Provider") and Wake Forest University Health Sciences (hereinafter referred to as "Data Recipient").

RECITALS

Data Provider and Data Recipient desire to set forth the terms and conditions under which Data Provider will disclose to Data Recipient certain Protected Health Information ("PHI") in the form of a limited data set described in this Agreement ("the Limited Data Set") for the research described in this Agreement.

In consideration of the mutual promises below, and Data Provider's disclosure of the Limited Data Set to Data Recipient under this Agreement, the parties agree as follows:

ARTICLE I
DEFINITIONS

1.1 **Limited Data Set,** as defined in the Privacy Rule at 45 CFR Section 164.514(e), is PHI that can include specific identifiers and must exclude others considered to be PHI. A limited data set may **include**: 1) dates (e.g., admission, discharge, and service dates, dates of birth and death); and 2) five-digit zip codes and state, county, city, and precinct, but not any other postal address information. A limited data set must **exclude** the following direct identifiers of an individual and his or her relatives, employer(s), and household members: name; postal address information (except town or city, state and zip code which are permitted); telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; license plate numbers and other vehicle identifiers and serial numbers; device identifiers and serial numbers; URLs; Internet Protocol (IP) address numbers; biometric identifiers including finger and voice prints; and full-face photographic and any comparable images. In the event of any conflict between this description and the definition in the Standards for Privacy of Individually Identifiable Health Information (45 CFR, Parts 160 and 164, Subparts A and E) ("the Privacy Rule"), the Privacy Rule definition will govern.

1.2 Security Rule means the Standards for Security for the Protection of Electronic Protected Health Information, codified at 45 CFR parts 160 and 164, Subpart C, effective April 20, 2005.

1.3 The following terms shall also have the meanings given to them in the Privacy Rule: Covered Entity, Individual, Protected Health Information, and Required by Law.

ARTICLE II
DATA PROVIDER'S OBLIGATIONS

2.1. Data Provider will disclose to Data Recipient the Limited Data Set for the purposes of the research study entitled "SEARCH for Diabetes in Youth, Phase 3: California Center (KPSC IRB #5836)" which study is more specifically described in Exhibit A ("the Study"). Exhibit A, which also describes the Limited Data Set, is attached to, and by this reference incorporated in, this Agreement.

2.2. Data Provider shall not request Data Recipient to use or disclose the Limited Data Set in any manner that would violate the Privacy Rule if done by a Covered Entity.

ARTICLE III
DATA RECIPIENT'S OBLIGATIONS

3.1. Unless specifically stated otherwise in this Agreement, Data Recipient's obligations with respect to the Limited Data Set apply to the whole and to any part of the Limited Data Set.

3.2. Data Recipient shall not use or disclose the Limited Data Set for any purpose other than the Study or as Required by Law. In addition, Data Recipient shall not use or disclose the Limited Data Set in any manner that would violate the Privacy Rule if done by a Covered Entity.

3.3. Exhibit A specifies who is permitted to use or receive the Limited Data Set for the purposes of the Study.

3.4. Data Recipient may not subcontract its performance obligations, or assign its rights, under this Agreement without the express written consent of Data Provider. Data Recipient shall ensure that any subcontractor agrees in writing to the same terms and conditions regarding a Limited Data Set that apply to Data Recipient under this Agreement.

3.5. Data Recipient must have appropriate safeguards to prevent the use or disclosure of the Limited Data Set in any manner not permitted by this Agreement.

3.6. Data Recipient must not identify or contact (or attempt to do so) either directly or through another person, any Individual in the Limited Data Set.

3.7. Data Recipient agrees to mitigate, to the extent feasible and allowed by law, any harmful effect that is known or becomes known to Data Recipient that arises from a use or disclosure of the Limited Data Set by Data Recipient or its agents in violation of this Agreement or the Privacy Rule.

3.8. Data Recipient must notify Data Provider within twenty-four (24) hours by phone, and in writing within five (5) business days, after Data Recipient becomes aware of any use or disclosure not authorized by the Agreement and any actual or suspected breach of Data Recipient's security.

3.9. Data Recipient acknowledges that Data Recipient has no ownership rights in the Limited Data Set.

3.10 . Within ten (10) business days of a written request by Data Provider, Data Recipient shall allow Data Provider to conduct a reasonable inspection of Data Recipient's facilities, systems, books, records, agreements, and policies and procedures relating to the use or disclosure of the Limited Data Set for the purpose of determining Data Recipient's compliance with this Agreement. Any failure of Data Provider to inspect or to detect or notify Data Recipient of an unsatisfactory practice does not constitute acceptance of the practice by Data Provider or a waiver of any remedy or right Data Provider has under the Agreement or applicable law.

3.11 Standards for Electronic PHI. To the extent that Data Recipient creates, receives, maintains, or transmits electronic PHI, Data Recipient shall also have administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic Protected Information that may be transmitted in conformity with the requirements of the Security Rule.

3.12 Reporting of Security Incidents. If the Data Recipient creates, receives, maintains, or transmits electronic PHI, Data Recipient shall appropriately report any incident, as defined by the Security Rule.

3.13 Mitigation of Security Incidents. Data Recipient shall mitigate promptly, to the extent practicable, any harmful effect that is known to Data Recipient caused by a security incident regarding electronic Protected Information by Data Recipient in violation of this Agreement, the Security Rule, or other applicable federal or state law.

3.14. Data Recipient shall comply with state security and privacy laws to the extent that they are more protective of the Individual's privacy than the HIPAA Privacy Rule.

3.15 Data Recipient shall indemnify, hold harmless and defend Data Provider from and against any and all claims, losses, liabilities, costs and other expenses (including attorneys fees) that result from or arise directly or indirectly out of or in connection with any negligent act or omission or willful misconduct of Data Recipient, its officers, employees, agents or subcontractors relative to the Limited Data Set, including without limitation, any violation of Data Recipient's responsibilities under this Agreement with respect to the Limited Data Set.

ARTICLE IV
AMENDMENT AND TERMINATION

4.1 When Data Provider reasonably concludes that an amendment to the Agreement is necessary to comply with applicable law, Data Provider shall notify Data Recipient in writing of the proposed modification(s) ("Legally-Required Modifications"). Data Provider shall request Data Recipients written approval in the form of an amendment to this agreement at the time of notification. Data Recipient shall have thirty (30) days to sign the amendment and return it to Data Provider. Data Recipient's rejection of a Legally Required Modification is grounds for termination of the Agreement by Data Provider on thirty (30) days written notice.

4.2. A breach by Data Recipient of any provision of the Agreement, as determined by Data Provider, shall constitute a material breach and grounds for immediate termination of the Agreement by Data Provider. At its sole discretion, Data Provider may give Data Recipient 30 days to cure the breach.

4.3. On termination of the Agreement for any reason, Data Recipient shall return or destroy the Limited Data Set. If return or destruction is not feasible, Data Recipient shall explain to Data Provider why, in writing, to the address given in this Agreement.

4.3.1. If Required by Law, Data Recipient may retain documentation for the time specified as necessary to comply with the law.

4.3.2. Data Recipient's obligations under this Agreement shall continue until Data Recipient destroys the Limited Data Set or returns the information to Data Provider; provided however, that on termination of the Agreement, Data Recipient shall not further use or disclose the Limited Data Set except as Required by Law.

4.4 If Data Recipient elects to destroy the Limited Data Set, Data Recipient shall certify in writing to Data Provider that the Limited Data Set has been destroyed.

ARTICLE V
MISCELLANEOUS

5.1. Exhibit A may be modified by the parties at any time pursuant to a writing executed by both parties. No use or disclosure different from that permitted by the currently in force Exhibit A may be made until the new Exhibit A has been signed by both parties.

5.2. Any ambiguity in this Agreement relating to the use and disclosure of the Limited Data Set by Data Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information.

5.3 All notices required or permitted under the Agreement to be in writing may be delivered personally, by electronic facsimile (with a confirmation by registered or certified mail placed in the mail no later than the following day), or by registered or certified mail, postage prepaid, addressed to a party as indicated below:

If to Data Provider:	If to Data Recipient:
Sharon Figgins Research Financial Administrator 100 S. Los Robles, 2nd Floor Pasadena, CA 91101 Phone: (626) 564-3135 Email: Sharon.M.Figgins@kp.org	Attention: Wake Forest University Health Sciences ATTN: Ronny Bell Medical Center Boulvard, Winston-Salem, NC 27157-1063 Phone: 336-716-9736 Facsimile No.: 336-713-4300

Notice shall be deemed to have been given on receipt of communications personally delivered or transmitted by electronic facsimile (delivery confirmed) and, for communications made by United States mail, on the third (3rd) day after mailing. The above addresses may be changed by giving written notice as described in this section.

5.4. Data Recipient's obligations under Article IV of this Agreement shall survive the termination of the Agreement.

5.5 If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall continue in full force and effect.

5.6. This Agreement shall be governed by the laws of California, without regard to its choice of law rules.

5.7. The Agreement is entered into as of 4-4, 2011("Effective Date").
IN WITNESS WHEREOF, the parties agree as follows:

Data Provider	**Data Recipient**
By:	By:
Name: Marilyn Owsley	Name: Joseph Andrews, M.D.
Title: Business Administrator, SCPMG	Title: Chair, IRB – Wake Forest Health Sciences
Date: 5/13/11	Date: 4-4-11

EXHIBIT A
To the Data Use Agreement

1. **Description of the Study:**
SEARCH for Diabetes in Youth, phase 3 builds upon the past ten years of SEARCH Phases 1 and 2, which has been conducted since September of 2000. The study has two components: the Registry and Cohort sub-studies that combine into one protocol comprising of SEARCH 3. These substudies will address the following specific research aims, respectively:

Registry substudy:
Aim 1: Continue to ascertain newly diagnosed (2010-2014) incident diabetes cases in youth age < 20 years in order to assess temporal trends in diabetes incidence and temporal trends in presentation of diabetes for the period 2002-2014, by age, sex, race/ethnicity, and diabetes type.
Aim 2: Provide consultation and support to inform the development of low-cost sustainable public health surveillance systems of childhood diabetes in the U.S.
Aim 3: Assess total and cause-specific mortality among 2002-2008 incident cases for the period from the date of diabetes diagnosis through December 31, 2010.

Cohort substudy:
Aim 1: Assess the prevalence and incidence of, and risk factors for, chronic microvascular (retinopathy, nephropathy, and autonomic neuropathy) and selected markers of macrovascular complications (hypertension, arterial stiffness) of diabetes.
Aim 2: Assess the incidence of, and risk factors for, serious acute complications of diabetes including severe hypoglycemia and diabetic ketoacidosis.

Aim 3: Determine the degree to which barriers to care, quality of care, and the process of transition from pediatric to adult care impact disease factors, including dimensions of diabetes type (diabetes autoimmunity, insulin sensitivity), and diabetes-related outcomes (acute and chronic complications, quality of life, diabetes-related mortality).
Aim 4: Maintain and supplement the SEARCH repository for biological specimens, and promote access to SEARCH for conduct of scientifically and logistically appropriate ancillary studies.

Kaiser Permanente Southern California (KPSC) will send retinal images (per protocol) to The Ocular Epidemiology Reading Center (OERC) at the University of Wisconsin-Madison to grade these images for presence and severity of DR, macular edema, and retinal vessel caliber.

2. **Limited Data Set 1**: All data elements stated in the Study Protocol and any additional data elements collected as part of a protocol under the umbrella SEARCH3 IRB approval (i.e., via IRB modification). This does not pertain to data collected as part of a protocol requiring a separate study-specific IRB approval.

Limited Data Set 2: N/A

3. **Permitted Uses:** Data Recipient may only use Protected Health Information solely for the purposes under the Study as described in the Study Protocol.

4. **Permitted Disclosures.** Data Recipient may only disclose the Limited Data Set for the Study as descried in the Study Protocol. Data Recipient may also disclose Limited Data Set to DHHS agencies, Federal Office of Human Research Protection, along with members agents or successors of the research team such as the other site PIs, Co-Is, and members of their research staff involved with this study at other medical centers, central laboratories or study related sites such as data monitoring committees. No other disclosures are permitted.

IN WITNESS WHEREOF, the parties agree as follows:

Data Provider	**Data Recipient**
By:	By:
Name: Marilyn Owsley	Name: Joseph Andrews, M.D.
Title: Business Administrator, SCPMG	Title: Chair, IRB – Wake Forest Health Sciences
Date: 5/13/11	Date: 4-4-11

Cincinnati Children's
Hospital Medical Center

Limited Data Use Agreement

This Limited Data Use Agreement ("Agreement") is made and entered as of the 31st day of March, 20 11, by and between Cincinnati Children's Hospital Medical Center ("CCHMC"), an Ohio not-for-profit corporation, and Wake Forest University Health Sciences ("Recipient").

1. Purpose: The purpose of this Agreement is to provide for the use and/or disclosure of a limited data set from CCHMC to the Recipient to comply with the Standards for Privacy of Individually Identifiable Health Information ("protected health information") promulgated by the Secretary of the U.S. Department of Health and Human Services ("HHS") as 45 C.F.R. Part 160 and Part 164 (the "Privacy Regulation") pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA").

2. The following protected health information (or "PHI") will be included in the limited data set used by and/or disclosed to the Recipient (NOTE: the type(s) of PHI to be included in the limited data set must **NOT** include any PHI described in the box below):

date of birth, gender, race, zip code, county, and date of diagnosis for diabetes

NOTE: A limited data set MUST *NOT* INCLUDE any one or more of the following patient information:

a. Names;
b. Postal address information, other than town or city, state, and zip code;
c. Telephone numbers;
d. Fax numbers;
e. Electronic mail addresses;
f. Social Security numbers;
g. Medical record numbers;
h. Health plan beneficiary numbers;
i. Account numbers
j. Certificate/license numbers;
k. Vehicle identifiers and serial numbers, including license plate numbers;
l. Device identifiers and serial numbers;
m. Web Universal Resource Locators (URLs);
n. Internet Protocol (IP) address numbers;
o. Biometric identifiers, including finger and voice prints; or
p. Full face photographic images and any comparable images.

3. The permitted uses and disclosures of the limited data set are as follows:

for aggregate analysis of data for the SEARCH for Diabetes in Youth study

The Recipient may not use or disclose information in a manner that would violate HIPAA regulations if done by CCHMC.

4. The following is a list of persons who are permitted to use or receive the limited data set:
Members, agents or successors of the research team such as the principle investigator, co-investigators, and members of their research staff; other researchers and their staff involved with this study at other medical centers, central laboratories or study-related sites such as data monitoring committees; the Department of Health and Human Services (DHHS) agencies; the Federal Office of Human Research protection; and Wake Forest University Health Sciences,

5. The purpose of this Limited Data Use Agreement is for (choose one):
   - ☒ Research
   - ☐ Health Care Operations
   - ☐ Public Health Purposes

6. CCHMC and the Recipient both must ensure the PRIVACY and SECURITY of PHI as provided for under all state and federal laws. In carrying out each party's responsibilities, each party agrees to follow all CCHMC policies and procedures related to PHI.

7. Recipient's Responsibilities. The Recipient of the limited data set will:
   a. Not use or further disclose the information other than as permitted by this Agreement or as otherwise required by law;
   b. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement;
   c. Report to CCHMC any use or disclosure of the information not provided for by this Agreement of which the Recipient becomes aware;
   d. Ensure that any agents, including a subcontractor, to whom Recipient provides the limited data set agrees to the same restrictions and conditions that apply to the Recipient with respect to such information; and
   e. Not identify the information or contact the individuals whose PHI is included in the limited data set.

8. Term. The initial term of this Agreement shall continue in effect from the date first written above for ★. Either party may terminate this Agreement by providing written notice to the other party ninety (90) days prior to the proposed date of termination. On the termination date of this Agreement, Recipient must return all limited data set information obtained from CCHMC to CCHMC or provide proof of destruction of the limited data set. ★ until the completion of the SEARCH for Diabetes in Youth Study.

9. Situs. This Agreement shall be governed and construed under the laws of the state of Ohio.

10. Additional Instruments. Each of the parties shall, from time to time, at the request of the other party, execute, acknowledge or deliver to the other party any and all further instruments that may be reasonably required to give full force and effect to the provisions of this Agreement.

11. Entire Agreement. All parties hereto declare and represent that no promises, inducements or agreements not expressly stated in this Agreement have been made. This Agreement constitutes the entire understanding of the parties with respect to the subject matter hereof; there are no representations, warranties, covenants or undertakings other than those set forth herein; and any and all prior discussions, negotiations, commitments and understanding related hereto are superseded and merged herein.

12. Modification and Waiver. A modification, waiver, amendment, change or termination of this Agreement, in any respect whatsoever, shall be effective only if made in writing and executed by both parties with the same formality as this Agreement. A failure of either party to insist upon strict performance of any of the provisions of this Agreement shall not be construed as a waiver of any subsequent default of the same or similar nature.

13. Section Headings. All section headings are inserted for convenience. The headings shall not affect the construction or interpretation of this Agreement.

14. Successors. All obligations, conditions, terms, covenants, warranties, representations and provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors, assigns, subsidiaries, parent corporations, officers, directors, trustees, representatives, agents and employees unless otherwise provided in this Agreement.

15. Assignment. This Agreement and any obligations hereunder shall not be assigned by either party without first obtaining the prior written consent of the other party.

16. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall constitute a separate original Agreement and all of which, taken together, shall constitute one Agreement, binding all parties hereto, notwithstanding the fact that not all parties have signed the same counterpart.

17. Notice. Whenever, under this Agreement, notice is required to be given, it shall be in writing and shall be delivered by mailing the same by certified or registered mail, postage prepaid, to the party to receive the notice at:

If to CCHMC: Cincinnati Children's Hospital Medical Center
Privacy Officer
CCHMC Legal Department
ML 9010
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

If to Recipient: Wake Forest University Health Sciences
Office of Research
Medical Center Boulevard
Winston-Salem, North Carolina 27157

Or such other address either party may designate from time to time by notice hereunder.

IN WITNESS WHEREOF, the parties have hereunto set their hands as of the date first set forth above:

Cincinnati Children's Hospital Medical Center

By: _____

Date: 5/5/11

Recipient

By: _____

Date: 4-4-11

Seattle Children's
HOSPITAL · RESEARCH · FOUNDATION

DATA USE AGREEMENT

This Data Use Agreement ("Agreement"), effective as of April 14, 2011 ("Effective Date"), is entered into by and between Wake Forest University Health Sciences ("Recipient") located at Medical Center Boulevard, Winston-Salem, NC 27157 and Seattle Children's Hospital d/b/a Seattle Children's Research Institute ("Children's"), located at 4800 Sand Point Way NE, Seattle, WA 98105 (each a Party and collectively the Parties) to set forth the terms and conditions under which Children's agrees to provide Recipient with access to certain information for Recipient's use in research.

In consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined shall have the meaning established for purposes of the HIPAA Regulations.
2. Purpose. The purpose of this Agreement is to satisfy Children's obligations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulations promulgated thereunder, codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time ("HIPAA Regulations") and to ensure the integrity and confidentiality of certain Protected Health Information disclosed or made available to Recipient by Children's ("Limited Data Set"), which Recipient shall use, disclose, receive, transmit, and maintain only as set forth in this Agreement.
3. Children's Responsibilities. Children's shall prepare and furnish to Recipient the Limited Data Set in accord with the HIPAA Regulations.
   - 3.1. Inclusion in Limited Data Set. The Parties agree that the Limited Data Set shall include the following data fields:
     - 3.1.1. Date of Birth (M/D/Y)
     - 3.1.2. Sex
     - 3.1.3. Race
     - 3.1.4. Diagnosis date (M/D/Y)
     - 3.1.5. 5-digit zip code (only part of the inclusion criteria)
     - 3.1.6. City of residence
     - 3.1.7. Year of diagnosis
     - 3.1.8. Diabetes type
     - 3.1.9. Results from diabetes autoantibodies testing
     - 3.1.10. Results from C-peptide levels testing
     - 3.1.11. Height
     - 3.1.12. Weight
     - 3.1.13. Insulin use history
     - 3.1.14. Diabetic ketoacidosis (DKA) history
     - 3.1.15. Acanthosis nigricans history

3.2. Exclusion from Limited Data Set: The following identifiers may not be included in the Limited Data Set: 1. Names; 2. Postal address information, other than town or city, state, and ZIP Code; 3. Telephone numbers; 4. Fax numbers; 5. Electronic mail addresses; 6. Social security numbers; 7. Medical record numbers; 8. Health plan beneficiary numbers; 9. Account numbers; 10. Certificate/license numbers; 11. Vehicle identifiers and serial numbers, including license plate numbers; 12. Device identifiers and serial numbers; 13. Web universal resource locators (URLs); 14. Internet protocol (IP) address numbers; 15. Biometric identifiers, including fingerprints and voiceprints; and 16. Full-face photographic images and any comparable images.

4. Permitted Uses; Permitted Recipients. Except as otherwise specified herein, Recipient may make all uses and disclosures of the Limited Data Set as may be necessary to conduct the Institutional Review Board approved research related activities described in applications associated with the CDC award entitled "Characteristics of Diabetes in Youth of the Puget Sound (SEARCH)" grant number U58/CCU019235 (the Research).

5. Recipient's Responsibilities. Recipient agrees to:

5.1. Use or disclose the Limited Data Set only as permitted by Section 4 of this Agreement or as required by law;

5.2. Use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted by this Agreement or required by law;

5.3. Report in writing to Children's, within ten (10) days of its discovery, any use or disclosure of the Limited Data Set that is not permitted by this Agreement of which it becomes aware, including without limitation, any disclosure of Protected Health Information to an unauthorized person or entity;

5.4. Require any of its subcontractors or agents that receives or has access to the Limited Data Set to agree in writing to the same restrictions and conditions on the use and/or disclosure of the Limited Data Set that apply to Recipient under this Agreement;

5.5. Not to re-identify the information contained in the Limited Data Set or contact the individuals; and

5.6. Indemnify, defend and hold harmless Children's and any of Children's affiliates, and their respective trustees, officers, directors, employees and agents from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs through appeal) arising out of or in connection with any unauthorized or prohibited use or disclosure of the Limited Data Set or any other breach of this Agreement by Recipient or any of its employees, subcontractors, or agents.

6. Term and Termination.

6.1. Term. The term of this Agreement shall commence as of the Effective Date and shall terminate when all of the Limited Data Set provided by Children's to Recipient is destroyed or returned to Children's, unless terminated sooner as set forth in this Agreement.

6.2. Termination by Recipient. Recipient may terminate this agreement at any time by notifying Children's and returning or destroying all of the Limited Data Set.

6.3. Termination by Children's. Children's may terminate this Agreement at any time by providing 30 days prior written notice to Recipient, in which event Recipient shall take steps to destroy or return all of the Limited Data Set to Children's no later than the effective date of the termination.

6.4. For Breach. Children's shall provide 10 days prior written notice to Recipient of its intent to terminate this Agreement on the basis of Recipient's material breach. Recipient's failure to cure such material breach within the 10 day notice period shall be grounds for immediate termination of this Agreement by Children's.

6.5. Effect of Termination. Section 5 of this Agreement shall survive any termination hereof.

7. Miscellaneous.

7.1. Change in Law. The Parties agree to negotiate in good faith to amend this Agreement to comport with changes in applicable law that materially alter either or both Parties' obligations under this Agreement; provided, however, that if the Parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law, either Party may terminate this Agreement as provided in Section 6.

7.2. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

7.3. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the Parties and their respective successors or assigns any rights, remedies, obligations, or liabilities whatsoever. Without in any way limiting the foregoing, it is the parties' specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose Protected Health Information is used or disclosed pursuant to this Agreement.

7.4. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

7.5. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing, or enforcing any of the provisions of this Agreement.

7.6. Waiver. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

7.7. Authority. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.

7.8. Conflict. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of Recipient to Children's shall apply to the breach of any covenant in this Agreement by Recipient. In the event of any inconsistency between the provisions of this Data Use Agreement and mandatory provisions of HIPAA, as amended, the HIPAA provisions and obligations shall control. Where provisions of this Data Use Agreement are different than those provided in HIPAA, but are permitted by HIPAA, the provisions of this Data Use Agreement shall control.

7.9. Enforcement. If any action is brought to enforce, or arises out of, this Agreement, the prevailing party shall be awarded its reasonable attorneys' fees together with expenses and costs incurred with such action, including necessary fees, costs, and expenses for services rendered, as well as subsequent to judgment in obtaining execution thereof and through appeal. This Agreement will be interpreted, construed, and enforced in all respects in accordance with the laws of the State of Washington, without reference to its conflict of law rules to the contrary.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

Seattle Children's Research Institute		Recipient	Wake Forest School of Medicine
By:		By:	
Print Name:	James B. Hendricks, Ph.D.	Print Name:	Joseph Andrews
Print Title:	President, Seattle Children's Research Institute	Print Title:	IRB Director
Date:	5.12.11	Date:	4-14-2011

Cynthia Bellas
Manager OSR & Pre-Award Compliance
Seattle Children's Research Institute

I have received a copy of this Agreement and will comply with its terms as they affect me:

By:
Date: 5/6/11
Name: Catherine Pinoker, MD
Title: Principal Investigator

On Behalf of
James B. Hendricks, PhD
Seattle Children's Research Institute

DATA USE AGREEMENT

This Agreement is entered into by and between the **Regents of the University of Colorado, a body corporate, for and on behalf of the University of Colorado Denver ("University")** and the Recipient **("Recipient")** named on Schedule 1 (attached hereto and by this reference incorporated herein) as of the Effective Date noted on **Schedule 1**.

A. University is providing certain Protected Health Information ("PHI") to Recipient in the form of a Limited Data Set for the purpose(s) identified in paragraphs 4 and 5 of **Schedule 1**.

B. In connection with the provision of that PHI, pursuant to the Health Insurance Portability and Accountability Act and regulations promulgated pursuant thereto (collectively "HIPAA"), University is required to obtain assurances from Recipient that Recipient will only use or disclose PHI as permitted herein.

C. The parties enter into this Agreement as a condition to University's furnishing the Limited Data Set to Recipient, and as a means of Recipient's providing assurances about use and disclosure. The provisions of this Agreement are intended to meet the Date Use Agreement requirements of HIPAA.

NOW THEREFORE, the parties agree as follows:

1. **Definitions.** Each capitalized term used in this Agreement and not otherwise defined, shall have the meaning given it in HIPAA.

2. **Term.** This Agreement shall commence on the Effective Date and continue until terminated in accordance with Section 4 below.

3. **Recipient's Obligations.** Recipient shall:

   a. Comply with all applicable federal and state laws and regulations relating to the maintenance of the PHI, the safeguarding of the confidentiality of the PHI, and the use and disclosure of the PHI.

   b. Use and disclose the PHI only for the purpose(s) identified in paragraph 4 and 5 of **Schedule 1**, as otherwise required by law, and for no other purpose.

   c. Use appropriate safeguards to prevent the use and disclosure of the PHI, other than for a use or disclosure expressly permitted by this Agreement.

   d. Immediately report to University any use or disclosure of the PHI other than as expressly allowed by this Agreement.

   e. Ensure that its employees and representatives comply with the terms and conditions of this Agreement, and ensure that its agents, Business Associates and subcontractors to whom Recipient provides the PHI agree to comply with the same restrictions and conditions that apply to Recipient hereunder.

   f. Not identify or attempt to identify the information contained in the Limited Data Set, nor contact any of the individuals whose information is contained in the Limited Data Set.

   g. Not request use, or disclose more PHI than the minimum amount necessary to allow Recipient to perform its functions pursuant to the purpose identified in **Schedule 1**.

   h. Indemnify, defend and hold University harmless from all costs and expenses (including attorney fees) that relate to a breach of Recipient's obligations.

4. **Termination.** University may terminate this Agreement and any disclosures of PHI pursuant hereto, upon 10 days notice to Recipient, if Recipient violates or breaches any material term or condition of this Agreement. University may terminate this Agreement without cause upon 30 days written notice. Upon termination, Recipient shall promptly return or destroy the Limited Data Set received from University in connection with the purpose identified on **Schedule 1**. If return or destruction of the Limited Data Set is not feasible, Recipient shall continue the protections required under this Agreement for the Limited Data Set consistent with the requirements of this Agreement and applicable HIPAA privacy standards. If Recipient ceases to do business

or otherwise terminates its relationship with University, Recipient agrees to promptly return or destroy all information contained in the Limited Data Set received from University in a timely manner.

5. **Governing Law and Venue.** This Agreement shall be governed by the laws of the State of Colorado. Venue for any claim, action or suit, whether state of federal, between Recipient and University shall be Denver County, Colorado.

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the Effective Date.

University of Colorado:

By: _____

Title: Alison Lakin, RN, LLB,LLM,PhD
Interim Director for Regulatory Compliance

Date: 6.22.11

Recipient:

By: _____

Title: Director, IRB + HRPP

Date: 7-13-11

Please Sign & Date

Schedule 1

1. Effective Date: _____June 1, 2011_____

2. Name of University Person/Department Releasing the Limited Data Set: __Colorado School of Public Health_____

3. Name of Recipient of the Limited Data Set: _Wake Forest University Biostatistics Center_____

4. Purpose of Limited Data Set Disclosure:

   X Research Study
   Title: __SEARCH for Diabetes in Youth Phase 3 - Colorado Center_____
   Principal Investigator: ____Dana Dabelea, MD, PhD_____
   IRB #: ____01-934_____
   Sponsor: ____CDC/NIDDK_____
   ❑ Public Health
   ❑ Health Care Operations (i.e., Quality improvement, teaching, accreditation, the development of clinical guidelines.)

5. The recipient of the LDS listed in #2 is permitted to use and disclose the LDS for the following purpose(s):

   This LDS is an extension of an executed agreement from 2005 and will be used to continue to allow the SEARCH data coordinating center located at Wake Forest University Biostatistics Center to continue to receive and conduct analyses of data collected in the SEARCH study. Data analyses will be conducted specific to the University of Colorado site and aggregated for the five SEARCH study centers. The analyses will be conducted under the direction of Dr. Ronny Bell, Director.