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

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

Protocol Amendment Approval

07-Feb-2011

Investigator:	Dana Dabelea
Sponsor(s):	Centers for Disease Control and Prevention/DHHS~National Institutes of Health/DHHS~Juvenile Diabetes Foundation~
Subject:	COMIRB Protocol 01-934 Amendment
Effective Date:	04-Feb-2011
Title:	SEARCH FOR DIABETES IN YOUTH

Amendment Description:

PAM021-1:

Phase 1 of the SEARCH for Diabetes in Youth Study was conducted 2001-2005. The CDC extended the project as SEARCH Phase 2 in 2005-2010. In October 2010, the CDC awarded the project a grant to continue and expand the work as SEARCH Phase 3 for 2010–2015. This amendment summarizes the substantive changes in the SEARCH Phase 3 protocol.
Much of the protocol remains identical to Phase 2, however, the changes in study procedures and data collection will be summarized for each of the following 3 cohorts:
1) Incident cases in years 2010-2014;
2) Prevalent cases in 2009; and
3) Incident cases in years 2002-2006 and 2008.
The estimated completion date for data collection will be extended to September 29, 2015.

See file copy for the protocol changes breakdown.

Sincerely,
UCD Panel C

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

To: Ronny Bell, Ph.D.
PHS - Epidemiology

From: Chair, IRB # 2
Institutional Review Board

Date: 4/13/2011

Subject: Human Protocol: IRB00015926
SEARCH for Diabetes in Youth - Phase 3 - Coordinating Center

Study Documents:
Protocol Version: SEARCH 3 Protocol; Other Documents: CES-D form, Colorado IRB Approval Letter, Contact Information - Participant, Contact Information Form - Parent version, Diabetes Eating Problem Survey - age 10 and older, Diabetes Related Family Conflict Survey - Parent version, Diabetes Related Family Conflict Survey - Participant age 10 and older, Extended Core Information form, Family Medical History form, Food Frequency Questionnaire, Health Questionnaire - Parent version, Health Questionnaire - Participant version, Initial Participant Survey - Parent version, Initial Participant Survey - Participant version, Kaiser Permanente IRB Approval Letter, Low Blood Sugar Survey - Adult age 18 and over, Low Blood Sugar Survey - Child Teen age 10-17 version, Low Blood Sugar Survey - Parent, Medical Record Validation of Self-Report, Medication Inventory form, Neuropathy form, Pediatric Diabetes Quality of Life - Parent version, Pediatric Quality of Life - Participant version, PedsQL Child Report (ages 5-7), PedsQL Child Report (ages 5-7) Diabetes module, PedsQL Child Report (ages 8-12), PedsQL Child Report (ages 8-12) Diabetes module, PedsQL Parent Report for Children (ages 8-12), PedsQL Parent Report for Children (ages 8-12) Diabetes module, PedsQL Parent Report for Teens (ages 13-18), PedsQL Parent Report for Teens (ages 13-18) Diabetes module, PedsQL Parent Report for Toddlers (ages 2-4), PedsQL Parent Report for Toddlers (ages 2-4) Diabetes module, PedsQL Parent Report for Young Children (ages 5-7), PedsQL Parent Report for Young Children (ages 5-7) Diabetes module, PedsQL Teen Report (ages 13-18), PedsQL Teen Report (ages 13-18) Diabetes module, PedsQL Young Adult (ages 19 and over), PedsQL Young Adult (ages 19 and over) Diabetes module, Physical Examination form, Quality of Care - Parent version, Quality of Care - Participant version, Specimen Collection form, Supplemental Questionnaire for age 10 and older, Tanner Stage - Female, Tanner Stage - Male, Unanticipated Occurrence Condition Reporting form, Unregistration form

The Institutional Review Board (IRB) has approved the above-named protocol and study documents, after review at a convened meeting on 4/12/2011. A submission requesting renewal together with a summary progress report must be submitted to the Board at least one month prior to 4/12/2012.

This research meets the criteria for a waiver of consent entirely according to 45 CFR 46(d).

This research meets the criteria for a waiver of assent according to 45 CFR 46.116(d).

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.

Based on the information provided, the IRB has determined that HIPAA does not apply to this study.

This research, which involves children, meets the criteria at 45 CFR 46.404 (research involving no greater than minimal risk). Permission of one parent or guardian is sufficient.

Federal regulations and Board policy require that you promptly report to the Board for review/approval:

- Proposed changes in the research activity (e.g., protocol amendments; consent form revision; advertisements). Changes may not be initiated without IRB review and approval, unless necessary to eliminate an immediate hazard to subjects.

- Serious adverse events and unanticipated problems involving risks must be reported to the Board, institutional officials, FDA, sponsor and other regulatory agencies as required by the protocol, local policy and state or federal regulation.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Gregory Hawkins, Ph.D.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

OMB No. 0990-0263
Approved for use through 11/30/2008

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [x] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [x] OTHER: subcontract	DHHS/CDC via Wake Forest Univ, WFU , U01 DP000250/WFUHS 11246
4. Title of Application or Activity Search for Diabetes – Central Laboratory (SEARCH II)		5. Name of Principal Investigator, Program Director, Fellow, or Other UW PI: Santica M. Marcovina Main award PI: Ronny A. Bell

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. **FWA 00006878**, the expiration date **11/17/2011** IRB Registration No. **IRB00006878-A**

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [X] **Expedited Review** on (date) : APR 08 2010
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments: **Approval only for procedures described in Human Subjects Application HSD No. 33949,"Northwest Lipid Research Laboratories" PI: Santica M. Marcovina, M.D. This IRB approval does not apply to any other research activity that may be described in the above grant proposal.**

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 206.543.2529 12. Fax No. *(with area code)* 206-543.9218 13. Email: katbuck@u.washington.edu	Human Subjects Division University of Washington Box 359470 Seattle, WA 98195
14. Name of Official: Kathy Buck	15. Title: Human Subjects Review Coordinator
16. Signature: Kathy Buck	17. Date: APR 08 2010

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UNIVERSITY OF WASHINGTON
SEATTLE, WASHINGTON 98195-9470

Human Subjects Division Box 359470
Office of Research

October 5, 2010

PI: Dr. Santica M. Marcovina, Research Professor
Medicine/Metabolism, Box 357333

Cc: Ms. Trisha Speer

Re: Modification Approvals; Human Subjects Application #HSD No. 33949; Mods #24-29;
"Northwest Lipid Research Laboratories"

Dear Dr. Marcovina and Ms. Trisha Speer,

The above referenced Modifications to Human Subjects application #HSD No. 33949; Mods #24-29 have all been reviewed and are **approved** by Human Subjects. Each modification involved the following changes: adding a new funding source (see below).

Mod. No. 24 (received 8/25/10), added: *Wake Forest University/CDC subcontract* – Approved 10/5/10.

Mod. No. 25 (received 9/9/10), added: *NIH/Univ. No. Carolina, Chapel Hill subcontract* – Approved 10/5/10.
Search for Diabetes in Youth (Search III)
Mod. No. 26 (received 9/10/10), added: *NIH/NIAID, U of CA N01AI15416 subcontract* – Approved 10/5/10.

Mod. No. 27 (received 9/29/10), added: *NIH/Thomas Jefferson Univ. subcontract* – Approved 10/5/10.

Mod. No. 28 (received 9/29/10), added: *NIH/Univ. So. Carolina subcontract* – Approved 10/5/10.

Mod. No. 29 (received 9/30/10) added: ***ARRA** funding: *NIH/NIDDK 3U01DK072493 subcontract via Cincinnati Childrens Hospital Research Foundation* – Approved 10/5/10.

I will forward the investigator copy of your approved Modifications via campus mail. Please also note that the **signed original 310 forms** are also provided in the front of each modification approval. I wish you the best of luck with your continued research, and if you have further questions, feel free to contact our office.

Regards,

Kathy Buck
Human Subjects Review Coordinator
Minimal Risk; UW Human Subjects
206-543-2529; katbuck@u.washington.edu

Trisha Speer

From: Kathy Buck [katbuck@u.washington.edu]
Sent: Tuesday, October 05, 2010 12:43 PM
To: 'smm@uw.edu'
Cc: 'tspeer@uw.edu'
Subject: RE: HSD No. 33949_Mods 24 to 29_Approved
Attachments: Marcovina _33949_Mods 24 to 29_approval ltr.doc

RE: HSD No. 33949; Mods #24-29

Dear Dr. Marcovina and Ms. Trisha Speer,

Attached, please find a letter of approval as it relates to your Human Subjects Application (HSD No. 33949; Modifications #24-29) . The investigator copy of the approved Modifications (and any related forms, or other materials, as applicable) are being returned to you via campus mail. Thank you, and we wish you and the study team success in all of your continued research efforts!

Regards,

Kathy

.....

Kathy Buck
Human Subjects Review Coordinator
Subcommittee EA, Minimal Risk, E-mail: katbuck@uw.edu
Direct Line/Voicemail: 206-543-2529

UW Human Subjects Division
UW Tower, NE 45th Street & Brooklyn Avenue NE Campus Box: 359470 Seattle, WA 98195-9470
Main Office Phone: 206-543-0098; Fax: 206-543-9218; Website:
http://www.washington.edu/research/hsd

OMB No. 0990-0263
Approved for use version: 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [x] OTHER: subcontract via Wake Forest University/CDC	CDC/Wake Forest University
4. Title Application or Activity Search for Diabetes in Youth – Central Laboratory		5. Name of Principal Investigator, Program Director, Fellow, or Other Main awardee offsite PI: Ronny Bell UW PI on subcontract: Santica Marcovina

6. Assurance Status of this Project *(Respond to one of the following)*

[x] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA 00006878 , the expiration date 11/17/2011 IRB Registration No. IRB00000241-A

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [X] **Expedited Review** on (date): 10/5/2010
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments: **Approval only for procedures described in Human Subjects Application HSD No. 33949 ,"Northwest Lipid Research Laboratories." PI: Santica M. Marcovina , M.D.**

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	206.543-2529	Human Subjects Division University of Washington Box 359470 Seattle, WA 98105-6613
12. Fax No. *(with area code)*	206.543.9218	
13. Email:	katbuck@u.washington.edu	
14. Name of Official Kathy Buck		15. Title Human Subjects Review Coordinator
16. Signature Kathy Buck		17. Date 10/5/2010

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Medical School Institutional Review Board (IRBMED) • 2800 Plymouth Rd., Building 200, Room 2086, Ann Arbor, MI 48109-2800 • phone (734) 763 4768 • fax (734) 763 9603 • irbmed@umich.edu

To: Rodica Pop-Busui

From:
There are no items to display

Cc:

Catherine	Martin
Mitali	Mehta
Eva	Feldman
Rodica	Pop-Busui

Subject: Notice of Exemption for [HUM00040643]

SUBMISSION INFORMATION:
Title: SEARCH - CAN READING CENTER
Full Study Title (if applicable): SEARCH for Diabetes in Youth Study
Study eResearch ID: HUM00040643
Date of this Notification from IRB: 8/23/2010
Date of IRB Exempt Determination: 8/23/2010
UM Federalwide Assurance: FWA00004969 expiring on 11/17/2011
OHRP IRB Registration Number(s):

IRB EXEMPTION STATUS:
The IRBMED has reviewed the study referenced above and determined that, as currently described, it is exempt from ongoing IRB review, per the following federal exemption category:

> **EXEMPTION #4 of the 45 CFR 46.101.(b):**
> Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

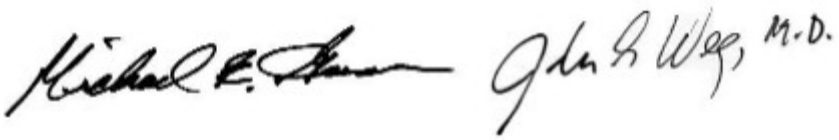
Note that the study is considered exempt as long as any changes to the use of human subjects (including their data) remain within the scope of the exemption category above. Any proposed changes that may exceed the scope of this category, or the approval conditions of any other non-IRB reviewing committees, must be submitted as an amendment through eResearch.

Although an exemption determination eliminates the need for ongoing IRB review and approval, you still have an obligation to understand and abide by generally accepted principles of responsible and ethical conduct of research. Examples of these principles can be found in the Belmont Report as well as in guidance from professional societies and scientific organizations.

SUBMITTING AMENDMENTS VIA eRESEARCH:
You can access the online forms for amendments in the eResearch workspace for this exempt study, referenced above.

ACCESSING EXEMPT STUDIES IN eRESEARCH:

Click the "Exempt and Not Regulated" tab in your eResearch home workspace to access this exempt study.



Michael Geisser
Co-chair, IRBMED

John Weg
Co-chair, IRBMED

THE UNIVERSITY of WISCONSIN MADISON

Minimal Risk IRB

NOTICE OF ACTION

Approval

Date of Correspondence: 11/16/2010

Principal Investigator:	Ronald Klein, M.D., MPH Ocular Epidemiology Reading Ctr. Rm. 460 WARF Bldg. 610 North Walnut St., Madison, WI 53726
Point of Contact:	Tiffany K Jan Ophthalmology + Visual Sciences, Rm. 426 WARF Bldg. 610 N. Walnut St., Madison, WI 53726
Protocol:	**M-2009-1377** "The "SEARCH for Diabetes in Youth" Study: A Proposal for Assessment of Diabetic Retinopathy among Youth with Type 1 and Type 2 Diabetes"
Review Period:	12 months
Approval Expires:	November 15, 2011
IRB Staff Contact:	Gretchen L Anding, 608-263-4170, gla@medicine.wisc.edu

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Your Continuing Review Protocol Progress Report was reviewed and approved by an IRB member on November 16, 2010 pursuant to 45 CFR 46.110(b)(1) and 21 CFR 56.110(b)(1), if applicable. This protocol qualified for expedited review because the research is not conducted under an investigational new drug application or investigational device exemption and categories 2-8 of the OHRP expedited review categories do not apply but the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. This action will be reported to the Minimal Risk Institutional Review Board. You may continue your research. The review period and expiration date of your approval are listed above.

Please be sure to do the following:

- Use your Minimal Risk IRB protocol number (listed above) on any documents or correspondence with us concerning your protocol.
- Keep a copy of this approval letter with your files.
- Comply with all requirements described in the **Investigator Responsibilities Related to the Protection of Human Subjects** attachment.

Sincerely,

Gretchen L Anding
Staff Reviewer, Health Sciences IRB Office

Enclosure(s):
Investigator Responsibilities Related to the Protection of Human Subjects

Seattle Children's
HOSPITAL • RESEARCH • FOUNDATION

INSTITUTIONAL REVIEW BOARD
FWA00002443

March 23, 2011

Catherine Pihoker, MD

Re: IRB Application Number 12074, entitled "SEARCH for Diabetes in Youth 3"

Dear Dr. Pihoker,

The Institutional Review Board (IRB) Chair reviewed the contingency response to the requested modification(s) on March 16, 2011. The IRB Chair determined that you sufficiently addressed the contingencies, and approved the modification(s) to begin SEARCH 3. The approval period for this modification is March 3, 2011 through February 2, 2012 (with the exception of the "Patient Instructions for Collecting Overnight Urines" document). Attached is a copy of the approved modification form for your records.

The Institutional Review Board (IRB) Subcommittee reviewed the "Patient Instructions for Collecting Overnight Urines" document on March 23, 2011, after it was discovered the document was accidentally omitted from review with the other SEARCH 3 documents. The Subcommittee determined this modification qualifies for expedited review as a minor change in previously approved research during the period for which approval is authorized. (*45 CFR 46.110(b)(2)*). The Subcommittee approved the "Patient Instructions for Collecting Overnight Urines" document. The approval period for this modification is March 23, 2011 through February 12, 2012.

IRB Findings and Determinations
Category of Research with Children: The IRB determined this research remains open under the following category of research involving children as subjects:

Research not involving greater than minimal risk (**45 CFR 46.404** and **21 CFR 50.51**).

(Note, now that the C-peptide portion of the study has been eliminated, the 45 CFR 46.405 risk category no longer applies.)

Alteration of Limited Elements of Informed Consent: The IRB understands that many participants were enrolled in the Initial Participant Survey (IPS) portion of the research under a waiver of documentation of consent (45 CFR 46.117(c)(2)). The IRB noted the cover letters to the surveys were to serve in lieu of a consent form or consent discussion. The letters did not contain all required elements of consent under 45 CFR 46.116(a). The missing elements include:

1. a statement regarding benefits,
2. risks,
3. alternatives, and
4. who to contact in the event of an injury

The IRB determined this research meets the criteria for an alteration of the above outlined elements of consent (45 CFR 46.116(d)) for subjects already enrolled with an IPS cover letter that did not contain all required elements of consent. This waiver is not intended to be retrospective in nature. It is, however, intended so that you do not have to obtain "re-consent" from all prior participants utilizing a method with all required elements of consent to use their data.

You will be required to use cover letters for the IPS portion of the research which contain all required elements under 45 CFR 46.116(a) going forward.

Alteration of HIPAA Authorization: The IRB determined the IPS portion of the research meets the criteria for an alteration of authorization under HIPAA (45 CFR 164.512(i)) for the signature requirement. This means that you are no longer required to obtain a signed authorization form for IPS participants. You are still required to provide an authorization form in the materials sent to potential IPS participants, which they may choose to return. This alteration means that for participants that forget to return the authorization form with the survey, or participants that take the survey online, you will not be required to attempt to contact participants to obtain a signed authorization.

If you would like to further modify your study, please submit the Modification Request Form and relevant documents to the IRB at irb@seattlechildrens.org.

Sincerely,

Douglas S. Diekema, M.D., M.P.H., Chair
Institutional Review Board

Tori Lallemont, J.D., MPH, Human Subjects Protection Analyst
Human Subjects Protection Program

KAISER PERMANENTE®
Medical Care Program
Southern California Region

Institutional Review Board
Kaiser Permanente Southern California

Approval Notice

December 22, 2010

KPSC Principal Investigator

Jean M. Lawrence, ScD, MPH, MSSA
Research and Evaluation
100 S Los Robles Ave, 4th Floor
Pasadena, CA 91101

KPSC Approved Performance Site(s)

Kaiser Permanente Southern California
(Except San Diego)

KPSC Sub-Investigator(s)

Kristi Reynolds, PhD
Ann K. Kershnar, MD

Study Title: SEARCH for Diabetes in Youth, Phase 3: California Center (#5836)

Approved Materials:

Centers for Epidemiologic Study Depression Scale Protocol; SEARCH for Diabetes in Youth Phase 3 Protocol, Version 11/09/2010; Blood Test Results Letter for Registry and Cohort English/Spanish; Blood Test Results with Error Message Registry and Cohort 110510 English/Spanish; Centers for Epidemiologic Study Mental Health Referral Letter; Immediate Retinal Pathology Participant Letter; IPS Introductory Letter-Young Adults 110810; IPS Last Chance Letter- Parent; IPS Last Chance Letter-Young Adult; Physician Cover letter for Lab Results; Business Reply Envelope; Opt-out and Information Request Post Card Eng/Spanish; Basic Guidelines for Scheduling Study Visits by Telephone; Appointment Reminder Card Spanish/English; Birthday Card English/Spanish; Birthday Card Envelope; Behavioral Health Care Declined Referral Form; Cohort Visit Invitation Card Parents 110510; Cohort Visit Invitation Card Young Adults 110510; Contact Information -Parent Spanish/English 020106; Contact Information- Participant Spanish/English 020106; Documentation of Receipt of Gift Cards for Search Study Participation; Explanation of SEARCH Laboratory Test Results Spanish/English; Family Medical History Form Spanish/English; Lab Fresh Specimen Shipment Form; Lab Frozen Specimen Shipment Form; SEARCH physical examination form (3 and older); Case Validation Form; SEARCH IPS Thank You Card Registry Visit Parent; SEARCH IPS Thank You Card Registry Visit Young Adult; SEARCH Phase 3 List of Forms Submitted; Retinal Eye Photography Report; SEARCH 3 Extended Core Information Form; Medical Record Validation of Self Report; Specimen Collection Form; Unanticipated Occurrence Condition Reporting Form; Un-registration Form

Approved Questionnaires:

SEARCH CES-D Survey English/Spanish; Diabetes Eating Problem Survey (DEPS-R) for Age 10 and Older Eng/Span; Diabtes Related Family Conflict Survey -Parent Version Cohort Study (Spanish); Diabetes Related Family Conflict Survey-Participant Version (Age 10-17)Eng/Spanish; Food Frequency Questionnaire Spanish/Engl
Health Questionnaire Young Adult Cohort Study Spanish; Health Questionnaire-Parent Version Eng/Span
Health Questionnaie-Young Adult Version (Age 18 and Older) Eng/Span; Initial Patient Survey-Parent/Gurdian Version Eng/Span; Initial Patient Survey-Young Adult Version; Eng/Span; Low Blood Sugar Survey-Children/Teen Version (age 10-17) Eng/Span; Low Blood Sugar Survey-Adult Version (Age 18 and over) Eng/Span; Low Blood Sugar Survey-Parent Version; Medication Inventory Form Eng/Span; Pediatric Quality of Life Scale-Parent Version Eng/Span; Pediatric Quality of Life Scale- Young Child Report (ages 5-7) Eng/Span; Peds-QL-Pediatric Quality of Life Inventory- Young Child Report (ages 5-7) Eng/Span; Peds-QL- Diabetes Module, Version 3.0-Young Child Report (Ages 5-7) Eng/Span; Peds-QL Child Report (Ages 5-7) Eng/Span; Peds-QL Diabetes Module Young Child Report (Ages 5-7) Eng/Span; Peds-QL Child Report (Ages 8-12) Eng/Span; Peds-QL Diabetes Module Child Report (Ages 8-12)Eng/Span; Peds-QL Parent Report for Children (ages 8-12) Eng/Span; Peds-QL Diabetes Module Parent Report for Children (ages 8-12) Eng/Span; Peds-QL Parent Report for

Teens (ages 13-18) Eng/Spanish; Peds-QL Diabetes Parent Report for Teens (ages 13-18) Eng/Span; Peds-QL Parent Report for Toodlers (ages 2-4) Eng/Span; Peds-QL Diabetes Parent Report for Toodlers (ages 2-4) Eng/Span; Peds-QL Parent Report for Young Children (ages 5-7) Eng/Span; Peds-QL Diabetes Parent Report for Young Children (ages 5-7) Eng/Span; Peds-QL Teen Report (ages 13-18) Eng/Span; Peds-QL Diabetes Teen Report (ages 13-18) Eng/Span; Peds-QL Young Adult (ages 19+) Eng/Span; Peds-QL Diabetes Young Adult (ages 19+) Eng/Span; Quality of Care Survey Parent/Guardian Version Cohort Study Eng/Span; Quality of Care Survey Young Adult Version Eng/Spanish; Michigan Neuropathy Screening Instrument and 10-gram Filament Exam; Diabetes Related Family Conflict Survey-Parent Version for those who have a 10-17 year old child; SEARCH Medication Inventory; Supplemental Questionnaire for age 10 and older English/Spanish; SEARCH Tanner Stage Female for age 10-17 English/Spanish; SEARCH Tanner Stage Male for age 10-17 English/Spanish

Accepted Documents:
Award Letter and two CDC funding Applications included

Study Expiration Date: **11/25/2011**

On **December 21, 2010**, the convened Kaiser Permanente Southern California (KPSC) Institutional Review Board (IRB) reviewed and **approved** your new study for one year.

The IRB determined that this study satisfies the requirements of 45 CFR 46.404, research/clinical investigations not involving greater than minimal risk. The permission, including signed informed consent, of one parent is required. In accordance with 45 CFR 46.408 , the KPSC IRB has determined that assent of children age 7 and older is a necessary condition for proceeding with this research/clinical investigation.

The IRB granted a waiver of written HIPAA authorization to use of Protected Health Information for the eligibility screening component of the study.

The IRB also **approved** the informed consent form(s) as submitted.

The finalized informed consent form[s], which includes the HIPAA Authorization section, will be sent to you via e-mail in an Acrobat PDF file. If you have any questions or need any information regarding the consent form[s], please contact Daria Galindo at (626) 405-5972 (tie line 8/335-5972).

The KPSC Principal Investigator (PI) is required to:

- Review the document entitled HIPAA Privacy Rule Instructions for Researchers (attached).
- Submit a complete progress or final report of research activities.

And if applicable,

- Submit for IRB review modifications to the research and/or IRB approved research documents.
- Submit Adverse Event report(s) according to IRB policies and procedures and consistent with federal regulations.
- Submit Protocol Violation report(s) according to IRB policies and procedures and consistent with federal regulations.

Sincerely,

Armida Ayala, MHA, PhD
Director, KPSC Research Subjects Protections
Office/Institutional Review Board (IRB)

Cc
Sharon Figgins
Area Research Chairperson

Academic Affairs
Pharmacy Service Director

InterOffice Memorandum

December 22, 2010

KAISER PERMANENTE®
Medical Care Program
Southern California Region

Institutional Review Board
Kaiser Permanente Southern California

To
Distribution

Steven J. Jacobsen, MD, PhD
Director, Research & Evaluation

Eric Macy, M.D.
Chair, Institutional Review Board

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Disposition of Pharmaceutical Company Funds After Completion of Research Project

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Congratulations on the approval of your research project. We want to inform you at the beginning of your study that there is an SCPMG Board of Directors policy on the disposition of account balances at the conclusion of pharmaceutical/ manufacturing company funded research projects. If applicable, this policy calls for any remaining balance at the completion of a study to be transferred to a general research fund which is administered by the Regional Research Department.

Consistent with this SCPMG policy, we want you to be informed that any funds remaining at the completion of your project will revert to the general research account to supplement Community Service research funds allocated for studies approved by the Regional Research Committee and the Institutional Review Board.

We wish you success in your research endeavors. Please do not hesitate to call Dr. Jacobsen (8-338-3460) or Dr. Macy (8-291-5410) if you have any questions.

Cc
Sharon Figgins
Area Research Chairperson

Academic Affairs
Pharmacy Service Director